Alberta Health Technologies Decision Process

Consultation Report 05-01C-1

Review of Laparoscopic Adjustable Gastric Banding: Consultation Report

Review #1
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Alberta
HEALTH AND WELLNESS

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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

Alberta Health and Wellness undertook a review of laparoscopic adjustable gastric banding (LAGB) in late 2004 and early 2005, in response to requests from Albertans for access to this surgery to treat clinically severe obesity. The review served as a pilot test of the new Alberta Health Technology Decision Process.

The synthesis report, "*Review of Laparoscopic Adjustable Gastric Banding*," was forwarded to selected stakeholders on June 28, 2005, accompanied by a request from the Assistant Deputy Minister, Program Services Division to respond to seven questions.

In addition to Expert Advisory Group members and internal departmental stakeholders, the request for consultation was forwarded to Chief Executive Officers of Regional Health Authorities, the College of Physicians and Surgeons of Alberta, and the Alberta Medical Association.

There was considerable support expressed among stakeholders for offering the LAGB device as a medically insured good (option #2 in the synthesis report).

Participants genuinely appreciated the opportunity for a thorough consultation of the synthesis report, and particularly to learn from experiences of health regions in other parts of the province. In many respects, the most important outcome of this phase of the initiative was to heighten the profile of health technology assessment with health regions, as a prelude to future consultations.

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Background and Context

Alberta Health and Wellness undertook a review of laparoscopic adjustable gastric banding (LAGB) for clinically severe obesity in late 2004 and early 2005. LAGB 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 review served as a pilot test of the new Alberta Health Technology Decision Process, which involves three main steps:

1. Selection of health services for provincial review.
2. Conducting reviews of selected health services, and applying a screening assessment.
3. Consulting on findings, formulating advice and implementing the decision regarding the funding of the health service.

An Expert Advisory Group, chaired by Alberta Health and Wellness and composed of representatives from the University of Alberta, Alberta Medical Association, Calgary Health Region, Capital Health, and a bariatric surgeon in Edmonton reviewed LAGB from the perspective of five components:

1. Technological effectiveness (study conducted by Health Technology Assessment, Alberta Heritage Foundation for Medical Research).
2. Population health (study conducted by the Surveillance Branch, Alberta Health and Wellness).
3. Implementation issues (study conducted by Capital Health).
4. Cost and utilization (study conducted by the Institute for Health Economics).
5. Government policy (study conducted by the Institute for Health Economics).

Four surgeons in Alberta are currently performing bariatric surgery: two in Edmonton, one in Red Deer and one in Medicine Hat. Cardston's (Chinook Health Region) bariatric surgeon retired last year. There are approximately a dozen practicing bariatric surgeons in Canada.

Introduction and Methodology

The synthesis report, "*Review of Laparoscopic Adjustable Gastric Banding*," was forwarded to selected stakeholders on June 28, 2005, accompanied by a request from the Assistant Deputy Minister, Program Services Division, to respond to seven questions (Appendix I). Some challenges were encountered in contacting stakeholders during the summer months, which resulted in an elongated consultation period.

The contents of this document include relevant comments from stakeholders on the contents of the synthesis report. These comments are intended to provide accurate information to departmental staff in making a recommendation to the Minister of Health and Wellness on the potential for public funding of LAGB as a medically insured service.

Relevant Stakeholders and their Response to the Consultation

In addition to Expert Advisory Group members and internal Departmental stakeholders, the request for consultation was forwarded to Chief Executive Officers of Regional Health Authorities, the College of Physicians and Surgeons of Alberta, and the Alberta Medical Association. Given the highly technical and relatively narrowly focused nature of the review and questions, contact with the RHAs occurred through their respective Regional Medical Directors.

(i) **College of Physicians and Surgeons**

The Assistant Registrar noted:

"In that LAGB has established its place among the options for bariatric surgery, the only decision for the College will be its suitability for the non-hospital surgical environment.

A previous request for LAGB to be approved in a non-hospital surgical facility was turned down. That refusal was partly due to: (i) uncertainty over the advanced skill set required of the surgeon, (ii) the requirement for an experienced surgical team, (iii) uncertainty over the selection of patients, and (iv) a lack of standards around the program necessary to support bariatric surgical patients, pre- and post-operatively.

However, had the College been provided with reassuring information on those points, I believe that the LAGB procedure would still fail to meet the test for approval in a non-hospital facility because: (1) it is an intra-abdominal procedure with significant risk of requiring conversion to an open procedure, and (2) these patients pose an unacceptable anesthesia risk for the non-hospital setting.

Although the College will not be commenting further on the questions posed, I would applaud this evolving technology decision review process."

(ii) **Council of Medical Directors**

The Council of Medical Directors (CMD) reports directly to the Council of Chief Executive Officers of all health authorities. When contacted following release of the consultation documents, the Chair of the CMD commented that, given the narrowly framed policy issues, it would not be appropriate to consult with Council members (Regional Medical Directors) at their next meeting in the fall. Instead, he suggested that contact be made with individual Regional Medical Directors.

(iii) **Peace Country, David Thompson, East Central and Aspen RHAs**

The sentiments of Regional Medical Directors in Peace Country, David Thompson, East Central and Aspen were consistent with the following representative comment:

"... this surgery should be restricted to regional and tertiary level centers where there are adequate post-operative support and facilities for pre-operative preparation and counseling."

At the David Thompson Health Region's Medical Director's request, a copy of the consultation package was provided to a Red Deer physician practicing bariatric surgery.

(iv) **Capital Health**

Concurrent with their involvement in the overall provincial review, Capital Health performed the first LAGB surgery in Alberta in late January 2005. Capital Health will continue to offer limited LAGB surgical services, within the context of their regional obesity prevention and management program ("WeightWise").

Capital Health's multi-disciplinary clinic at the Royal Alexandra Hospital provides counseling, education, nutritional advice, follow up, and support for these complex patients.

Capital Health's "WeightWise" strategy, which commenced on April 1, 2005, promotes healthy weight by:

- Establishing a single point of contact for the public for advice and referral to weight management services.
- Developing specialty weight management clinics for children and adults.
- Expanding the Bariatric Surgery Program at the Royal Alexandra Hospital to increase access to surgical options for obese adult patients.
- Incorporating weight management into a coordinated approach for treating patients with chronic diseases such as diabetes, heart disease and arthritis.
- Working with academic institutions to support research.
- Improving links with community providers, agencies and organizations.

Capital Health informally supports the provision of the LAGB device as a medically insured good.

(v) **Calgary Health Region**

The Calgary Health Region (CHR) and its tertiary care facilities, programs and services draw patients from southern Alberta, eastern British Columbia, western Saskatchewan and elsewhere. CHR performs no laparoscopic or open bariatric surgery, and does not yet offer a comprehensive regional weight management program. Their Regional Clinical Nutrition Program is faced with significant patient demand.

In a meeting with program managers, surgeons, dietitians, social workers, operating room managers and others on August 2, 2005, the CHR staff attending the meeting informally supported provision of the LAGB device as a medically insured good. They keenly recognize that the cost of the LAGB surgical device is but one small component of providing laparoscopic bariatric surgery, in the context of a regional weight management program.

The CHR staff attending the meeting expressed interest in proceeding with a regional weight management program, which might include bariatric surgery. The CHR staff were advised of the various components of the business case that would be required to consider the merits of a comprehensive program.

It is likely that a formal program proposal for proceeding with LAGB and other bariatric surgeries will be presented to the CHRs senior management committee in the next several months. Within the context of a comprehensive weight management program, LAGB might offer CHR a reasonable "return on investment" for treating morbidly obese patients.

It was noted by the CHR managers that there would be significant patient interest in this procedure, once widely available. (Capital Health reports in the "Royal Alexandra Hospital - Site Specifics - April/May 2005 edition that "50,000 people are waiting for bariatric surgery in the region.")

Although outside the scope of this project, a portion of the meeting was spent discussing the potential for viewing LAGB as an elective procedure, potentially considered for private health care paid by patients. This could include patients with the financial means to pay for the necessary pre-operative care, surgery and post operative counseling, support and monitoring. This might offer the CHR some modest revenue generating opportunities.

The CHR surgeons requested information on billing for gastric partitioning surgery under the Schedule of Medical Benefits, including post-operative office visits that might involve adjustments of the gastric band.

The Calgary Health Region will be sending a large, multi-disciplinary contingent of health professionals to meet with Capital Health in the coming months.

(vi) **Palliser Health Region**

Palliser's Medical Director informally supports the LAGB device being designated as a medically insured good. He commented upon the two year waiting list for bariatric surgery in Medicine Hat, performed several times per week. The Medicine Hat - based surgeon sees patients in his private office, and provides all necessary pre- and post-operative services, without any regional involvement.

The Medical Director commented that Palliser is interested in becoming involved in a regional weight management program, possibly in some form of collaborative arrangement with the Calgary Health Region. He commented that physicians in the region would certainly appreciate the opportunity to refer selected patients for bariatric surgery and related services in Calgary.

(vii) **Chinook Health Region**

Chinook's Medical Director noted that a surgeon at the Cardston Hospital completed approximately three bariatric surgeries per week for many years, until he retired approximately a year ago. Cardston was able to attract and retain an entire bariatric surgical team, including an anesthesiologist, internist and specialized registered nursing staff.

The team carefully investigated bariatric surgery services throughout North America, and then adopted "best practices." Working closely with carefully selected patients, the surgical team produced excellent long-term results.

Chinook's Medical Director informally supports public funding for the LAGB device. The region may consider commencing a bariatric surgery program at the Lethbridge Regional Hospital in the future.

(viii) **Alberta Medical Association**

Given that this consultation occurred over the summer months, the Assistant Executive Director, Professional Affairs, respectfully advised that the AMA's formal response would be delayed. The AMA's response, received on October 3, 2005, supported the content of the synthesis report.

The AMA suggests that the report could be strengthened with a greater focus on access to the entire obesity/weight management team, as part of a comprehensive regional service.

Patient safety literature suggests that safety increases as the volume of a specific procedure by each surgeon increases. The AMA believes that, given the average of 175 LAGB procedures per year, consideration should be given to one provincial centre of excellence.

Should Alberta Health and Wellness decide to provide LAGB, it would be important to establish an appropriate fee code in the Schedule of Medical Benefits, through the Physician Services Committee of the Trilateral Master Agreement.

Discussion

Participants genuinely appreciated the opportunity for a thorough consultation on the synthesis report, and particularly an opportunity to learn from experiences of health regions in other parts of the province. In many respects, the most important outcome of this phase of the initiative was to heighten the profile of health technology assessment with health regions, as a prelude to future consultations.

There was general support expressed among stakeholders for offering the LAGB device as a medically insured good. Regions certainly are mindful of the importance of the appropriate clinical management of obesity. Some health authorities are considering the potential to offer bariatric surgery for morbidly obese patients in selected facilities.

The Chair of the Council of Medical Directors and selected Regional Medical Directors noted that the relatively narrowly framed issues in this consultation were not of sufficient profile to merit a formal response from health authorities. Selected Regional Medical Directors' informal support for LAGB being a medically insured good may, however, be taken as reasonably equivalent to a formal letter from health authority CEOs.

One in six Canadians is reportedly obese, and health status declines with obesity. As was commented upon in the majority of interviews, obesity is highly correlated with chronic disease. As is noted in the Spring 2005 Capital Health Quarterly, "*Today 60% of health care spending in Canada can be attributed to six chronic diseases: diabetes, high blood pressure, kidney disease, heart failure, lung disease and mental health*." LAGB offers one option to attempt to reduce the co-morbidities found with morbid obesity.

Stakeholders supported the contents of the synthesis report. In several instances, they requested further information on the clinical/technological aspects of LAGB, and were provided with copies of the Alberta Heritage Foundation for Medical Research report.

Many stakeholders expressed particular interest in the contents of the technical/clinical report. There is a good understanding among the medical and nursing profession about the risks inherent in the provision of anesthesia and surgery for morbidly obese patients. This includes administering anesthetic to patients with a significant amount of weight pressing on their diaphragms, as well as dealing with the significant co-morbidities often found with morbidly obese patients. Additionally, these patients often require extensive multi-disciplinary resources (physicians, nurses, social workers, psychologists, dietitians, etc.) pre- and post-operatively.

Key Messages

The Alberta Health Technology Decision Process includes eight steps to review existing and potential health technologies:

(i) Identify services and technologies for review.

(ii) Await approval of priorities by the Minister.

(iii) Plan and approve the review.

(iv) Conduct the review process.

(v) Consult and formulate advice.

(vi) Await ministerial decision.

(vii) Implement technology.

The contents of this document are intended to assist the Department to "*consult and formulate advice*."

In response to the questions posed:

(1) The contents of the synthesis report were positively received by stakeholders. Several requested copies of the more technical/clinical report prepared by the Alberta Heritage Foundation for Medical Research, and will likely conduct further research.

(2) There was widespread support for the second option, providing LAGB as a standard medical good, and encouraging regions to offer it as part of a comprehensive obesity management program. Regions are attempting to address the profound resource implications of obesity, and see laparoscopic bariatric surgery as one option for a carefully selected cohort of patients.

(3) Stakeholders' overall sentiments were that the provincial health technology assessment was a meaningful initiative. Most suggested that rather than an overall provincial review, health authorities were in a position to make the required decisions at a regional level.

The "test case" of LAGB was comprehensive and detailed, yet this form of surgery appears to be as safe and effective as other bariatric surgeries. Despite the threshold being set very high for LAGB, the process and particularly the consultation reinforced the importance of evidence-based clinical practices, within the context of health technology assessment.

(4) There was little support among most stakeholders for a provincial "Centre of Excellence" for LAGB. Most health authorities believe that the initiation of LAGB and other bariatric surgeries, as part of a regional weight management program, would require considerable expertise and resources. However, with the appropriate resources in place, this surgery could possibly be introduced at the Calgary Health Region, as well as at "regional" RHAs such as David Thompson, Chinook and Palliser.

(5) There are considerable operational and implementation considerations to offering LAGB as a standard medical good, and encouraging regions to provide it as part of a comprehensive obesity management program.

Regions are mindful of the multi-faceted aspects of staffing, infrastructure, financial resources, involvement of various health professional disciplines, outcome measurement and other areas. There are also considerations in terms of significant patient demand, once programs become operational.

(6) Regions considering LAGB have a clear appreciation of the importance of evaluating post-implementation effectiveness and efficiency. They have considerable experience with evaluating the introduction of new programs and services consistent with performance measures and other accountability requirements of Alberta Health and Wellness.

Appendix I: Consultation Questions

(1) Do the contents of the synthesis report, summarizing the five components of the review, respond to your need for information upon which to base an informed opinion? Is there any other information that you believe is necessary to consider? (The five analyses are available upon request from the consultant, on behalf of Alberta Health and Wellness).

(2) The "Policy Options" section of the paper presents two options: (i) Do not provide LAGB, and (ii) Provide LAGB as a standard medical good, and encourage regions to offer it as part of a comprehensive obesity management program. What are the advantages and disadvantages of each option? Does the procedure offer a long term "return on investment" for the treatment of clinically severe obesity?

(3) Although selected for provincial review, would the introduction of LAGB be more beneficial to be considered at the regional level?

(4) Should a provincial "Centre of Excellence" be established or should the LABG program be decentralized? If the program is decentralized, what should be Alberta Health and Wellness' expectations of Regional Health Authorities?

(5) What are the operational and implementation considerations of proceeding with the second option ("*Provide LAGB as a standard medical good, and encourage regions to offer it as part of a comprehensive obesity management program.*")?

(6) If the second policy option is chosen, what are your recommendations with respect to evaluating its effectiveness and efficiency after it is implemented?

(7) Please provide any further comments that you believe might assist in decision making.