REVIEW ARTICLE

New Technology Review Process: The Laparoscopic Adjustable Gastric Band

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Abstract

The Interregional New Technologies Committee (INTC) is one evaluation route for new medical technologies or technologies with expanded indications within Kaiser Permanente (KP). The primary focus of the INTC is to consider all available published evidence on a particular technology, surgical technique, or implantable device for a specific clinical indication and provide a recommendation on the sufficiency of the evidence for determining net medical benefit to Permanente Medical Group leaders and Kaiser Foundation Health Plan management throughout KP Regions. This iterative process provides an objective, evidence-based assessment to inform decision making by physicians and support the most appropriate care for KP members. This overview illustrates the INTC process and how it supports clinical decision making using implantation of laparoscopic adjustable gastric bands (LAGBs) as an example. In February 2011, the US Food and Drug Administration (FDA) approved lowering the acceptable body mass index for the Lap-Band from 35 to 30 kg/m^2 for patients with at least one comorbid condition. It is difficult to find published studies on medical technologies that have been recently approved by the FDA. The manufacturer often submits clinical data to the FDA, but details are frequently not publicly available at the time of approval. The LAGB example demonstrates the complex issues addressed by the INTC, particularly when there is some evidence of short-term improvement in outcomes with a medical device but little if any confirmation of long-term safety or effectiveness.

The laparoscopic adjustable gastric band (LAGB), a device surgically implanted around the upper stomach to restrict food intake, has been the focus of recent news. Two LAGB devices are currently approved by the US Food and Drug Administration (FDA): the Lap-Band from Allergan (Irvine, CA) and the Realize Solution from Ethicon Endo-Surgery (Cincinnati, OH). In February 2011, the FDA approved lowering the acceptable body mass index (BMI) for the Lap-Band from 35 kg/m^2 to 30 kg/m^2 for patients with at least one comorbid condition.[1] News reports indicate that the new approval greatly increased the number of eligible US patients from 13 million under the prior recommendation to approximately 32 million.[2] Within Kaiser Permanente (KP), the Interregional New Technologies Committee (INTC) is one evaluation route for new medical technologies or technologies with expanded indications. This article provides an overview of the INTC process and how it supports clinical decision making about whether to expand the use of LAGB on the basis of the FDA's recent ruling.

Background on the Interregional New Technologies Committee

The INTC, chaired by a surgeon, represents a broad stakeholder group. Primarily composed of physicians from various specialties from all 8 KP Regions, the INTC also includes subject-matter experts from technology assessment, ethics, benefits, research, and legal departments. Its primary focus is to consider all available published evidence on a particular technology, surgical technique, or implantable device for a specific clinical indication and provide a recommendation on the suf-

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ficiency of the evidence to Permanente Medical Group leaders and Kaiser Foundation Health Plan management throughout KP Regions. The INTC reviews 30 to 40 different technologies each year.

The INTC review encompasses a broader scope than an FDA review. The FDA is interested in safety and short-term efficacy data, whereas the INTC is also looking at effectiveness, longer-term safety, and durability. *Efficacy* refers to how a treatment performs in a specific patient population under optimally controlled conditions, and *effectiveness* refers to how a treatment performs in a broader patient population and under general conditions in a community-based setting. The INTC review focuses on the quality, quantity, and consistency of the evidence and may also include data from alternative technologies or interventions.

The INTC discussion provides an objective starting point for complex topics when it is time to consider potential patient use. The INTC does not determine coverage, make operational decisions, or consider cost. Each Region is responsible for evaluating the impact and implications of INTC recommendations with respect to the Region's benefit structure, regulatory issues, and delivery system, as well as for communicating any changes in that structure to appropriate clinicians in the Region. Table 1 provides an overview of the INTC review process.

Technology Assessment: Internal and External Resources

In addition to the INTC's review of technologies, there are resources within KP that provide information on medical technologies. One example is the Technology Assessment and Guidelines (TAG) Unit based in the Department of Clinical Analysis in the Southern California Permanente Medical Group. Composed of analysts with graduate degrees in epidemiology, biostatistics, and/or public health, the TAG Unit provides technology-assessment assistance to KP physicians throughout the program. In the Northern California Region, The Permanente Medical Group's (TPMG) New Medical Technology provides support to the Northern California and Mid-Atlantic Regions. Both the Southern California and Northern California technology-assessment groups work closely with the INTC. The INTC also often uses credible, external technology assessments to efficiently manage KP resources.

Topic Selection

Topics are routed to the INTC from a variety of sources. These may include published studies, physician requests, FDA approvals, ongoing internal and external technology-assessment topics, Interregional Chiefs' Groups and other interregional groups and meetings, INTC members, and news reports. Member inquiries may also prompt reviews when routed through Member Services or treating physicians. Topics are investigated and compiled for polling committee members, and then they are selected on the basis of the level of interest from multiple Regions. Topics not reviewed by the INTC may be routed to internal or external technology-assessment groups to provide evidence reviews for topic originators.

Topics may be suggested at any time, but if the focus of the review is device-related, the topic is typically brought to the INTC after FDA approval. Figure 1 illustrates a possible timeline for FDA approval and introduction of new medical technology. Little is known about devices when they are initially approved by the

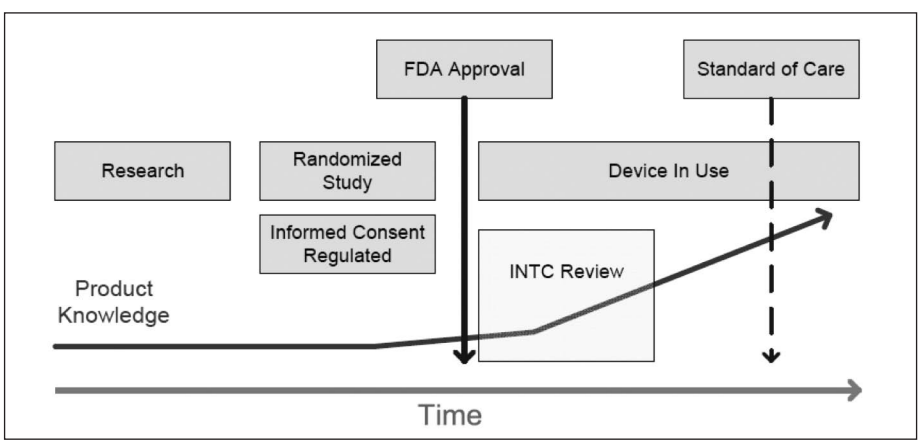

Figure 1. Possible timeline for Food and Drug Administration (FDA) approval and introduction of new medical technology. Initially little is known about the approved device. Although the actual time frame is different for each technology, the review by the Interregional New Technologies Committee (INTC) typically takes place after FDA approval and before the device is widely distributed.

Table 1. Overview of the INTC review process

INTC process	Process details	Details for consideration of LAGB implantation
Identification of topics	Topics come from patient or clinicians request, news reports, published studies, FDA approval, ongoing internal and external technology-assessment topics, Interregional Chiefs' groups or other interregional groups and meetings, and INTC members.	An INTC member requested an update after hearing news of the FDA panel review for the expanded indications for the LAGB. INTC staff confered with the CMI Bariatric Peer Group and with other KP Regions and committee members to confirm interest in the update.
Compilation of technology assessments	INTC staff confer with internal and external groups to locate existing resources and updates.	The TAG Unit provided prior bariatric surgery assessments and agreed to provide an update.
Literature review	An analyst searches the medical literature for published studies. Additional information is gathered, including data submitted to the FDA, adverse-event data posted on the FDA Web site, updated guidelines, and position statements from specialty organizations and government agencies.	A TAG Unit analyst updated existing assessments for bariatric surgery. The Bariatric Peer Group provided input for the PICO model and clinical questions.
Regional clinical input	INTC members and regional representatives request clinical input on the topic by e-mail or phone.	Clinical input was collected from the Interregional Bariatric Peer Group. In general, KP bariatric surgeons prefer gastric bypass over LAGB because it produces greater weight loss and better resolution of comorbidities, and because some patients entering the KP system with the LAGB in place have had complications, requiring its removal.
Determination of presenter	The INTC is composed of physicians from various specialties, and one of them agrees to review and present the topic. At times, a clinical expert will be invited to present, or the analyst will present.	The TAG Unit analyst agreed to present the topic.
Presentation of internal data	Internal data, if available, are requested and prepared for presentation.	A representative of the Southern California Bariatric Registry attended the INTC meeting and presented bariatric surgery data. A member of the Interregional Bariatric Peer Group also attended the INTC meeting and provided additional input.
Distribution of materials	Members download meeting material three weeks in advance of the meeting, review all assessments, and have access to associated literature.	Members arrived at the meeting ready to discuss the evidence and other issues surrounding the topic.
INTC meeting	Before the meeting, the clinical input collected from all Regions is distributed to the members. At the meeting, the evidence is presented, and various issues are discussed.	The current evidence base for the LAGB and other bariatric surgery procedures for patient populations with a lower BMI consisted primarily of retrospective reviews or small case series studies with short-term follow-up. Concerns regarding the LAGB remain, including erosion, reoperation, and LAGB removal. The committee agreed that comparative data and complete follow-up of long-term outcomes are needed to fully assess bariatric procedures.
Determination of recommendation	A draft recommendation is proposed, and the members vote on a recommendation that is based on the sufficiency or insufficiency of the evidence (quality, quantity, consistency).	Approved recommendation: There is insufficient evidence to determine whether the LAGB is a medically appropriate treatment option for adult patients with diabetes with a BMI of ≥30 and ≤35 kg/m^2. The existing evidence is of insufficient quantity and quality.
Circulation of findings	INTC staff provide detailed meeting minutes and recommendations. After the INTC approves the minutes, they are posted on an internal Web site and distributed to all KP Regions by e-mail.	Those who were asked to submit clinical input for the meeting were provided with the collected clinical input, the meeting minutes, and the recommendations.
Regional decision on actions	The regional KP Medical Groups, Kaiser Foundation Health Plans and Hospitals, and the interregional KP groups decide how to apply the findings and/or to implement the recommendation.	Findings and actions are discussed at an Interregional Bariatric Peer Group meeting. In this case, the INTC project manager attended the meeting and provided details.

BMI = body mass index; CMI = Care Management Institute; FDA = Food and Drug Administration; INTC = Interregional New Technologies Committee; KP = Kaiser Permanente; LABG = laparoscopic adjustable gastric band; PICO = Patient, Intervention, Comparison, and Outcome; TAG = Technology Assessment and Guidelines.

FDA, so the topic may be brought back to the INTC when significant published literature becomes available. Technologies expected to have a high rate of distribution may be reviewed before FDA approval, and in some cases, technologies that have become widely distributed may also be reviewed by the INTC.

The Laparoscopic Adjustable Gastric Band

The LAGB is an inflatable silicone ring, typically implanted laparoscopically during a hospital stay of less than one day. Weeks after the initial surgery, the patient returns and the subcutaneous reservoir is accessed and injected with saline to expand the LAGB to limit the amount of food consumed. Current guidelines suggest that patients treated with an LAGB should be seen by a physician three to eight times the first year, one to four times the second year, and one to two times per year thereafter.[3] As with any bariatric surgery, a multidisciplinary approach and good patient compliance improve outcomes.

The FDA initially approved LAGB for patients with a BMI of ≥35 kg/m^2 with multiple comorbidities (such as type 2 diabetes mellitus) and in patients with a BMI of ≥40 kg/m^2 without comorbidities. Recently expanded indications include patients with a BMI of 30 kg/m^2 and at least 1 comorbidity. When the INTC was examining this topic for the recently approved indications, its primary task was to evaluate the evidence for patients with a lower BMI who received the LAGB, and also to compare outcomes for alternative treatments for these patient populations. Although an alternative treatment, such as gastric bypass, may not fall directly within the FDA's purview, it does so in laparoscopic banding because there is an associated device involved. Guidelines for weight thresholds for bariatric surgery are set by the National Institutes of Health, but the FDA's expanded approval for the LAGB goes beyond these and other existing guidelines.[4]

The Review Process

Before an INTC meeting, an analyst prepares an assessment—a report detailing the available medical literature; position statements from specialty organizations, medical societies, and government agencies; and any other relevant information. Committee members and their staff also monitor and interact with external technology-assessment groups, using their resources when available. For the meeting on the LAGB, a TAG Unit analyst provided the assessment summarizing the published evidence on the use of LAGBs in patients who met the recent FDA-approved indications. TAG Unit analysts start with a standardized template to maintain a consistent search and report structure.

The scope of the assessment is guided by clinician and expert input in the area of interest. Clinical questions are formulated, and the PICO model (Patient, Intervention, Comparison, and Outcome) is used to clarify the scope of the report. A different scope can lead to the selection of different studies, so this step is critical for obtaining information that is useful for and relevant to the discussion. For this case, the INTC considered patients with a BMI between 30 and 35 kg/m^2 with type 2 diabetes. Interest in other comorbidities such as hypertension would also define specific patient populations, and each would be investigated separately. The intervention in this example is the use of the LAGB, and the comparison selected was laparoscopic Roux-en-Y gastric bypass (RYGBP). RYGBP is a surgical procedure producing malabsorption and is commonly used in the US and within KP, so it was the most relevant comparator. Lifestyle modification, other surgical treatments, and medical therapies are also alternative treatments and were described in the assessment.

When reviewing a topic, the committee frequently discusses which treatment or therapy would be considered the best comparator, as trials may use a comparator that is outdated or not as effective. In analyzing the use of LAGB, the committee might also have questioned why RYGBP would be selected as a comparator, because typically, those in the new BMI range would not be offered surgery under existing guidelines. Would medical management be a better comparator? The benefits and harms may be examined for each treatment considered.

For the outcome portion of the PICO model, the parameters might be percentage of excess weight loss, of resolution of type 2 diabetes, and of adverse events. When analyzing multiple studies, it is important to understand the measure used. For example, some studies might use elimination of diabetes medication as the outcome measure, and other studies might use an intermediate outcome measure, such as a threshold for laboratory results: a fasting glucose level of <7 mmol/L or a glycated hemoglobin level of <6%. The existence of multiple types of measures and different definitions of diabetes resolution make it difficult to analyze and summarize results, as resolution rates will vary depending on how they are defined and reported.

The analyst determines the search criteria on the basis of the clinical questions and information from the PICO model, performs a search, and selects relevant

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literature. Data are extracted from selected publications. This is a detailed process done by hand; however, the TAG Unit is evaluating software options to aid in the process. The analyst performs a critical appraisal, a process of systematically assessing and interpreting research studies to evaluate validity, results, and relevance. This involves evaluating the risk of bias that may affect studies' validity and conclusions about the intervention effect.

Absent high-quality, low-attrition, and long-term follow-up studies, it is difficult to predict benefits and harms for this new patient population.

Determining Clinical Effectiveness

An essential tool used to review the literature is the evidence hierarchy or pyramid. The INTC is most interested in evidence from studies that have directly compared the intervention of interest to usual care or placebo and report health outcomes. Duration of follow-up is of particular interest because it determines the durability of effectiveness and any identification of potential late adverse events. This level of evidence and adequate duration of follow-up are typically not available for many new technologies. In these situations, lower-level evidence such as case series studies are reviewed.

The search for studies for patients receiving an LAGB who have a BMI between 30 and 35 kg/m^2 and type 2 diabetes revealed a meta-analysis that included a total of 27 patients treated with an LAGB from 3 separate studies and one additional recent retrospective review comparing results for 109 patients treated with the LAGB with results for 109 patients treated with gastric bypass.[5,6] The retrospective study reported that gastric bypass provided superior weight loss and diabetes remission (28% vs 55% at 6 to 12 months). A diabetes remission rate of 28% in the LAGB group appears to be lower than the remission rate reported by other studies of patients with a higher BMI who were treated with the LAGB (48%).[7]

It is difficult to find reports of studies on medical technologies that have been recently approved by the FDA. The manufacturer often submits clinical data to the FDA, but details are frequently not publicly available at the time of approval. In fact, the data may never be published in a peer-reviewed medical journal. Thus the INTC may also consider data for patients falling outside this new BMI group and then discuss whether the outcomes can be extrapolated to other populations.

Because the evidence in the lower-BMI group is limited, the committee can examine data available for originally approved indications for LAGBs. Two meta-analyses have compared the use of LAGBs with RYGBP for patients who meet current National Institutes of Health guidelines for BMI and comorbidities and have found that RYGBP produces weight loss superior to that produced by LAGB (62% vs 48% for the study by Demaria et al and 63% vs 49% for the study by Garb et al).[6,8] Buchwald et al also found RYGBP to be superior to LAGBs for resolution of type 2 diabetes (72% vs 48%).[7] Some studies have suggested RYGBP has immediate effects on insulin secretion in type 2 diabetes, and patients may be discharged after bypass surgery without the need for diabetes medication.[9] The entry of a technology when an existing treatment has superior outcomes creates additional discussion for INTC members. Trade-offs in morbidity of the procedure such as recovery time, patient acceptance, delivery-system advantages, or other factors, may warrant consideration.

Although these meta-analyses indicate that gastric bypass is superior to LAGB as far as effectiveness, the committee also looks closely at the limitations of the studies reviewed in the meta-analysis and the validity of the meta-analysis itself. The meta-analysis by Garb et al[8] reported on >7000 patients; however, >70% of the studies analyzed were retrospective in nature, and patient attrition at 3 years was 83% for LAGBs and 89% for RYGBP. Studies have demonstrated that patient compliance is a critical factor in outcomes[10]; thus, INTC discussions frequently include the issue of patient compliance. Clinical experts provide comments and recommend methods of improving compliance.

The importance of long-term follow-up is highlighted in a recent report by DiGiorgi et al showing that 24% of 42 patients who underwent gastric bypass had a reemergence of diabetes after 3 years.[11] Interestingly, the study also reported that the reemergence of diabetes occurred in patients who had a lower preoperative BMI. Absent high-quality, low-attrition, and long-term follow-up studies, it is difficult to predict benefits and harms for this new patient population.

Determining Safety

Safety is a top concern of the committee. As with any implanted device, adverse events may occur at any time after LAGB placement. Infection and port-related complications can occur, which may require port removal, possibly followed by replacement concurrently or at a later date. Other potential problems include LAGB slippage and pouch dilation, which may require LAGB repositioning, replacement, or deflation, followed by reinflation after a few months. The adjustable gastric band is composed of silicone. It surrounds and constricts the upper portion of the stomach, which may lead to ischemia and erosion. Erosion, a potentially life-threatening event, can occur when the LAGB

harms the tissue and starts to penetrate the stomach wall. Removal of an LAGB and repair of any damage are often technically very challenging.

Long-term follow-up is needed, particularly because an LAGB may remain in the patient for many years. The INTC will examine the data for the expected rate of each type of adverse event over time. In many cases this is difficult because studies report events poorly, have different detection and reporting mechanisms, and are small with wide confidence intervals.

Another resource for information on adverse events is the FDA Manufacturer and User Facility Device Experience database.[12] Data are limited because submission by physicians, other clinicians, and patients is voluntary. Less than 1% of the adverse events in this database are reported by physicians.[13] Nevertheless, the database can provide some information on the types of adverse events occurring in the community setting. A search revealed >8000 adverse-event reports for LAGBs, including 80 deaths, which raised concern among INTC members.

Over the last few years, there has been an increase in advertisements promoting easy weight loss with minimally invasive surgery. Some community medical centers have started to promote LAGBs to individuals in this lower BMI range, and patient requests are increasing. Few, if any, harms are discussed, and patients' expectations of easy weight loss does not prepare them for the change in lifestyle that accompanies LAGB implantation. Despite inadequate long-term safety data for LAGBs, patients may be unaware of the importance of continued follow-up and may neglect to schedule appointments with physicians. This may lead to patients delaying treatment for complications that would have been easier to treat if seen sooner. The INTC review process provides physicians with current safety evidence that they can use to better inform patients.

Committee Discussion

Topics dealt with by the INTC are frequently complex. The INTC must navigate the issues of appropriate medical use, considering the innovation horizon. Many devices are continuously evolving to improve outcomes. New versions of a device may be introduced into the market with little or no clinical data, and studies frequently include multiple versions of a particular device. Although there is an expectation that device changes will lead to improved outcomes, this is not always the case and cannot be assumed. The INTC must also be aware of surgical techniques and other factors that change over time that also may affect outcomes.

Many INTC members have served for several years and keep the discussion consistent and reduce bias. Members also bring to the table perspectives from the various stakeholder groups. For example, those with an ethics background may discuss disease burden, access to care, and conflicts of interest such as manufacturer sponsorship of studies or study authors' financial benefits.

INTC members are responsible for communication with their Region by gathering clinical input and recommending new topics. Members also connect with interregional specialty groups and Chiefs' groups. In the case of LAGBs, the Interregional Bariatric Peer Group, which suggested topics, advised regarding timing and formulated the assessment questions. The KP Department of Research and other internal research groups may also supply data on various topics. For the LAGB topic, a representative of the Southern California Bariatric Registry attended the INTC meeting and presented bariatric surgery data.

During the committee meeting, there was concern about LAGB removal rates, reoperation, and adverse events such as erosion. In summary, the evidence base for implantation of the LAGB and for other bariatric

Interregional New Technologies Committee Recommendation Language

Interregional New Technologies Committee recommendations will take one of the following forms:

1. There is sufficient evidence to determine that the technology is medically appropriate (or is a medically appropriate treatment/diagnostic option) for select patients.
2. There is insufficient evidence to determine whether the technology is medically appropriate for any patient; *or* there is insufficient evidence to determine whether the technology is a medically appropriate treatment/diagnostic option for any patient.
   a. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is of insufficient quantity and/or quality.
   b. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is conflicting or inconsistent.
   c. There is no evidence on the use of this technology in the prevention or diagnosis or treatment or management of this health condition.
3. There is sufficient evidence to determine that the technology is generally not medically appropriate (or is not a medically appropriate treatment/diagnostic option) for any patients.

surgery procedures for lower-BMI patient populations consisted primarily of retrospective reviews or small case series studies with only short-term follow-up. The INTC debated longer-term patient issues such as consequences of LAGB removal and weight regain or recurrence of comorbidities. Loss of access to follow-up data, particularly if a member leaves KP, was also a concern. The committee members agreed that comparative data and complete follow-up of long-term outcomes are needed to fully assess bariatric procedures for the lower-BMI patient population.

INTC members reached the following recommendation (See sidebar: Interregional New Technologies Committee Recommendation Language). There is insufficient evidence to determine whether implantation of the LAGB is a medically appropriate treatment option for adult patients with diabetes and a BMI of 30 to 35 kg/m^2. The existing evidence is of insufficient quantity and quality.

Conclusion

The INTC considers many complex issues, as discussed here using LAGB implantation as an example. For many new technologies that are reviewed, the committee determines that there is insufficient evidence; however, the evidence review is invaluable for understanding the present and future implications of technology and health care delivery models. With so many unanswered questions and concerns, it is likely that KP will proceed cautiously with the use of LAGBs in this new patient population. Aggregation of internal patient outcomes may facilitate clinical decisions in the future. After INTC meeting details are distributed to the Regions, staff will continue to monitor future trials and other information and bring the topic back to the INTC as appropriate. This complex, multidisciplinary, and iterative process provides an objective, evidence-based assessment to inform decision making by physicians and support the most appropriate care for KP members. ❖

Disclosure Statement

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