

Serving on the MAP of the Blue Cross and Blue Shield Association's TEC

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The Technology Evaluation Center (TEC) was founded as a joint effort between the Kaiser Permanente Foundation and the Blue Cross and Blue Shield Association. The purpose of the medical advisory panel (MAP), which is a part of the TEC, is very simple: as new technology, treatments, and operations evolve, the MAP examines whether they are effective and, hence, should be recommended for use. This function will become even more important as biological agents, which cost as much as \$40,000 per dose, or new technology, costing \$20,000 to \$50,000 per instrument, increasingly make their appearance. This year, in a significant departure from the past, the panel voted that in addition to considering efficacy it would examine cost-effectiveness.

The MAP has been active for more than 18 years, with many members serving six years or so. The panel, composed of 17 physicians and one ethicist, meets every four months.

At the heart of the MAP is a highly professional staff consisting of physicians, PharmDs, and PhDs who evaluate the question that is currently before the panel. The gold standard applied to determining the effectiveness of the therapy, technology, or procedure under consideration is properly done randomized clinical trials (RCTs). However, in the case of diagnostic tests, observational data from prospective studies (rather than RCTs) are the norm, and equally rigorous approaches are undertaken for their review.

Evaluation process

The individual reviewer starts each process by going to the *Index Medicus* and other sources and retrieving all papers (often more than 1,000) relevant to the subject under review. These are rapidly whittled down to prospective studies. Other studies, including case studies and retrospective studies, are included in the evidence considered, but the weight given to their conclusions is so low as to make their impact virtually negligible on our conclusions. The prospective trials are subjected to rigid criteria for the design, the statistical analysis, and whether they answer specific questions. One must remember that it is difficult to use an RCT as evidence when the problem in question differs considerably from the initial intent of the clinical trial.

At the end of this process, the question that is being studied is reviewed on the basis of five criteria. They are:

1. The technology must have approval from the appropriate governmental bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on *health outcomes*.
3. The technology must *improve* the net health outcome.
4. The technology must be as beneficial as any *established* alternatives.
5. The improvement must be obtainable outside of the investigational setting.

The staff reviews the data from RCTs and other prospective studies (particularly those involving diagnostic tests) and provides the MAP with a fairly long report on all of the studies that have been reviewed, their various characteristics, their strengths and weaknesses, and whether the treatment being considered meets the five criteria.

The panel then reviews not only the report, but also the original source material used during the review. Both are provided well in advance of the meeting so the panel may review them. The panelists then decide whether they agree with the conclusions of the reviewer or want to change it. It is not unusual for the MAP to disagree with the staff's analysis and/or to send it back for revision.

Once the studies are completed, all analyses are placed on the TEC Web site, <http://www.bcbs.com/tec/index.html> Initially, the products were available to Kaiser Permanente, the national Blue Cross

and Blue Shield Association, and its affiliated plans. Now, individual health plans may use the panel's findings or those of local groups to decide whether to cover a drug or device. Medicare also uses the TEC's resources, either when considering already completed work on topics it is interested in or when commissioning original work.

My role

Some members of the surgical community seem to misunderstand my role on the panel. First and foremost, my role as a surgeon is to help the panel to understand issues from the surgical perspective and to correct misapprehensions concerning the surgical procedures we review. Other than that, I use the same criteria to judge the efficacy of certain procedures and medications as the other MAP members, following established criteria and tracking the data closely. My role, therefore, is not to seek approval for new surgical procedures, but to point out how they solve certain medical problems.

When I joined the panel, I was impressed by the quality of the reviews and asked Allen Korn, MD, chairman of the MAP, whether it would be possible to publish those of surgical interest in the *Journal of the American College of Surgeons*. He agreed, and several have been published^{1,2} and others are in the pipeline.

Examples

Perhaps the easiest way for me to explain my role is to take four recent examples of some of the topics of surgical interest that the panel has studied, some of which have been published.

1. Radiofrequency ablation of carcinoma of the liver and/or metastases of colon cancer.^{1,2}

The panel considered whether radiofrequency ablation (RFA) alone improved the health outcomes of patients with unresectable tumors as compared to percutaneous ethanol injection. The MAP concluded that RFA was suitable for small, unresectable, primary hepatic neoplasms but not for unresectable liver metastases. I recently asked Dr. Korn and the panel to reexamine radiofrequency ablation with longer follow-up and more careful evaluation in light of a number of recent developments. This request is especially important given the MAP's suspicion that RFA is being used *instead* of resection in many patients who could

safely undergo operative procedures.

I have asked for the reexamination for the following reasons:

- RFA may be less efficacious in killing tumors than once thought. In several series in which livers had previously undergone RFA before transplantation, the explant contained a substantial amount of tumor at the previous sites of what was thought to be completed RFA. Indeed, in up to 58 percent of cases, RFA failed to eradicate the intended lesion.³ In another 28 percent, other lesions went undetected because hepatocellular carcinoma appears to be multicentric, as Cha and his colleagues have noted, and thus a singular isolated attempt to eradicate it in closed fashion is ineffective.⁴ In addition to the published articles dealing with this subject, Beth Israel Deaconess Medical Center's transplant experience shows that seven out of nine patients who underwent transplantation had persistent lesions in the explant that presumably had been eradicated by RFA.

- The mortality of this procedure, previously seen as innocuous, appeared to be as high as 10 percent and may be higher in patients with compromised hepatic function with hepatocellular carcinoma complicating cirrhosis as a result of hepatitis B and C. This appears to have been the result of inadequate follow-up in the radiological literature.

2. *The use of chondrocytes to restore articular surfaces.*

This is a promising form of therapy, and if chondrocytes could coat worn articular surfaces, it might help patients avoid joint replacements. Here, however, the studies were quite poor, and as many as three other therapeutic maneuvers may have been carried out simultaneously with chondrocyte injection. No RCTs had been done at that time, although one study is currently under way in Norway.

3. *Bariatric surgery.*

The panel was interested in whether there is any long-term benefit in the comorbidities (including hypertension, diabetes, and hypercholesterolemia) and in late mortality following bariatric surgery. With those criteria, the picture of bariatric surgery is far less promising than its advocates would have us believe.

The difficulty is that insufficient attention was paid to the panel's third criterion—that the technology must improve the net health outcome. Yes, patients lose weight following bariatric surgery, but the initial period of weight loss following any restrictive procedure takes place over the first 12 to 18 months; thereafter, patients often gain it back, sometimes needing a second procedure, if they are not followed rigorously in a program with long-term nutritional counseling. Moreover, there was a bewildering variability in results following some of the operations. Third, the so-called RCTs are actually not what they appear to be in many instances, but a report of results in two different groups without proper design.

The MAP also attempted to evaluate different operative techniques. While open gastric bypass seemed to yield reasonable outcomes that were nearly identical or reproducible among different centers and countries, laparoscopic gastric bypass and the laparoscopic band procedure did not result in the same outcomes. The panel was attracted to the laparoscopic band procedure because it is easily performed, it is minimally invasive, it seems to have very low morbidity and mortality when done properly, and the size of the stomach could be adjusted over the years to make certain that the efficacy of the procedure would continue.

Outcomes among a number of series reported in the literature showed tremendous variation. The panel noted with great satisfaction Paul O'Brien's data with his very careful follow-up and continual adjustment of the laparoscopic band with patients having up to 54 percent loss of excessive body mass. This, however, was far in excess of the average decrease of excess weight of 34 percent in most American series.^{5,6} Whether this relatively poor result was due to inadequate follow-up, the lack of continual adjustment, unavailability of nutritional counseling, or a myriad of other factors was unclear, but the panel was disappointed that Mr. O'Brien's excellent results could not, up to now, be duplicated in the U.S.

As a result, the panel elected to approve open gastric bypass based on a Swedish study in which good results and improvements in net health outcome was the result.⁷ No American study met the criteria, and, likewise, laparoscopic gastric bypass's results seemed to be extremely variable, perhaps

because of the difficulty of the procedure and lack of adequate follow-up programs.

This outcome ignited a firestorm within the bariatric community, which argued that the panel had not considered a number of specific papers. However, the evaluator did include those papers in the initial evaluation, but they did not meet the MAP's criteria.

4. Lung-volume reduction surgery

The history of lung volume reduction surgery (LVRS) is replete with numerous false starts and, interestingly, probably would not be studied yet if the Medicare program had not insisted that the National Emphysema Treatment Trial (NETT) be conducted. NETT was a clinical trial in which patients were randomly assigned either to medical treatment or to LVRS. NETT participants assigned to the surgical arm of the study had to engage in pulmonary rehabilitation for a period of time prior to having the surgery. Medicare patients in the surgical arm of the trial received coverage for LVRS.

After the initial rage following the introduction of the procedure by Cooper and his colleagues,⁸ a number of other factors appeared to have entered the supposedly good results:

- Pulmonary rehabilitation had a substantially positive effect on lung function, causing some patients to improve to the point of not requiring the operation.
- There appeared to be a certain heterogeneity of the patient population in which some achieved excellent results and some achieved minimal results.

- Above all, there was a specter of a significant morbidity and mortality in patients who were referred for this procedure. These patients were those who were extremely limited in lung function as well as poor operative risks in general, resulting in significant mortality.⁹


I had long believed that the surgical community that performed the lung-reduction operation had not been rigorous about selecting patients for the procedure. The panel believed that patients with homogenous disease not limited to the upper lobes were not candidates for the operative procedure. Therefore, in that particular group, the operation was not efficacious, nor should it be judged as such. However, from a

surgeon's clinical perspective, one could argue that the patients with heterogenous, primarily upper lobe disease were good candidates for the operation and that the mortality was not excessive. The MAP seemed to have accepted this argument on a split vote. Thus, the procedure was adopted.

Conclusion

I have tried to outline the functions of this little-known and even less understood panel. I hope that my respect for those individuals who constitute the professional staff of the organization, Dr. Korn, and my fellow panelists is apparent in this report. They continue to surprise me with the points they make. I very much enjoy participating in the MAP and believe that perhaps I am doing some good by bringing the surgical voice to its deliberations.

I would reiterate that my principal role in this venture has been to interpret surgical procedures, including their limitations and outcomes, and what we wish to accomplish in a given patient.

I would hope that the American College of Surgeons Oncology Group and other ACS clinical trials programs will help surgeons really understand how to conduct rigorous randomized prospective trials. I think RCTs will make life a lot easier for us and our patients. One of the difficulties surgeons have is that we are so certain that what we do is correct that we have not bothered to justify our actions through the cold light of randomized prospective trials; these are the tests that others are using to evaluate the efficacy and, soon, the cost-effectiveness of our work. 

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- during residency. *N Eng J Med*, 314(7):418-423, 1986.
10. Web site: http://www.amwa-doc.org/publications/Position_Papers/maternityleave2.htm.
 11. Finch SJ: Pregnancy during residency: A literature review. *Acad Med*; 78(4):418-428, 2003.
 12. Web site: www.womensurgeons.org/womenin_surgery2003c.PDF.
 13. Web site: <http://home.absurgery.org/default.asp?aboutbooklet2003>.
 14. Web site: <http://www.gsres.wustl.edu/Compensation/LeavePolicy.asp>.
 15. Web site: <http://www.siumed.edu/resaffairs/Documents/parental-approved-6-12-98.doc>.

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to be a surgeon that he decided to get the surgical clerkship out of the way first. But then he was struck by the speed with which he could change a patient's situation. He also was more comfortable with the surgical personality—the matter-of-fact efficiency: “This person needs this and this and this, so we'll do this, and it'll be done,” he says.

Commitment

Each physician is on his or her own track for the future. Dr. Williams plans on an academic career in general surgery with an emphasis on trauma and critical care. Dr. Lewis will be a general surgeon in military practice for the next four years and then enter private surgical practice. Dr.

Kibbe will be pursuing her research on nitric oxide. Dr. Winslow is debating whether she will concentrate on minimally invasive surgery or colon and rectal surgery, and Dr. Rose is deciding on a subspecialty fellowship.

The residents all agree that surgical training is demanding. The hours are long—but they were longer before—and the skills are difficult to hone. But they all say that the surgical residency isn't nearly as bad as people had said it would be, mostly because of the challenge and the excitement, and, yes, the fun of operating. As Dr. Winslow puts it, “Even if you work a lot, you enjoy what you're doing and keep on learning.” □

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References

1. Seidenfeld J, Korn A, Aronson N: Radiofrequency ablation of unresectable primary liver cancer. *J Am Coll Surg*, 194:813-828, 2002.
2. Seidenfeld J, Korn A, Aronson N: Radiofrequency ablation of unresectable liver metastases. *J Am Coll Surg*, 195:378-386, 2002.
3. Harrison LE, Koneru B, Baramipour P, et al: Locoregional recurrences are frequent after radiofrequency ablation for hepatocellular carcinoma. *J Am Coll Surg*, 197:759-764, 2003.
4. Cha C, Fong Y, Jarnagin WR, et al: Predictors and patterns of recurrence after resection of hepatocellular carcinoma. *J Am Coll Surg*, 197:753-758, 2003.
5. O'Brien PE, Dixon JB, Brown W: The laparoscopic adjustable gastric band (Lap-Band®): A prospective study of medium-term effects on weight, health and quality of life. *Obes Surg*, 10:269-271, 2002.
6. U.S. Food and Drug Administration, Center for Devices and Radiological Health: Lap-Band® Adjustable Gastric Banding (LAGB®) summary of safety and effectiveness, 2002. Available at: <http://www.fda.gov/cdrh/pdf/P000008b.pdf>.
7. Hell E, Miller KA, Moorehead MMK, et al: Evaluation of health status and quality of life after bariatric surgery: Comparison of standard Roux-en-Y gastric bypass, vertical banded gastroplasty and laparoscopic adjustable silicone gastric banding. *Obes Surg*, 10:214-219, 2000.
8. Cooper JD, Patterson GA, Sundaresan SR, et al: Results of 150 consecutive bilateral lung volume reduction procedures in patients with severe emphysema. *J Thorac Cardiovasc Surg*, 112:1319-1330, 1996.
9. Fishman A, Martinez F, Naunheim K, et al: A randomized trial comparing lung-volume-reduction surgery with medical therapy for severe emphysema. *N Engl J Med*, 348:2059-2073, 2003.