Customer for the Ethics Advisory Group
The customer for the July 23 meeting was Rick Weisblatt, PhD, Vice President and Medical Director for Medical Management. Other HPHC staff involved with the management of advanced imaging were also present.

Background
In 2001, 225 leading general internists were asked to rank 30 medical innovations in terms of their importance for patient care.1 By a considerable margin the group judged magnetic resonance imaging (MRI) and computed tomography (CT) scanning to be the most important. For physicians who entered medicine before the new imaging techniques were developed, the information MRI and CT provide is little short of miraculous.

Not surprisingly, the use of “advanced imaging” technologies – MRI and MR angiography (“MRA” uses magnetic resonance to visualize blood vessels), CT, and nuclear cardiology (in which low-level radioactive materials that emit gamma rays are injected, allowing a nuclear scanner to visualize the heart and its functioning) – is growing 15-17% per year. The benefits from advanced imaging can be tremendous, but the costs are substantial. For Harvard Pilgrim Health Care, outpatient radiology accounts for approximately 9% of medical costs, with advanced imaging technologies being the primary cost driver. The US spends approximately $75 billion annually on diagnostic imaging services.

As background for this case I interviewed a number of colleagues in primary care and orthopedics. They reported that discussions with patients as to whether advanced imaging should be done come up virtually every day, especially in orthopedics. Here is a summary of the comments I received:

- One of the commonest circumstances is back pain and sciatica. When physical examination has no findings suggesting that a disc is pressing on nerves, the results of imaging are not likely to alter the treatment plan. Most back pain and sciatica improves with time, and disc abnormalities are common in people who have no back problems or sciatica. Therefore, finding an abnormality when no physical signs suggest impingement on a nerve will not alter the recommendation of what in olden days was called “tincture of time” with some combination of rest and pain medication.

- A primary care clinician cited headaches as a challenging problem. The clinician may be 99% or even 99.9% confident that the headaches are not coming from a tumor, aneurysm or other problem that might call for intervention. This clinician stated, however – “If an MRI cost no more than a simple blood test, I would get one when I was not 100% certain about a headache – that is what I would want for myself or a member of my family.”

- Another clinician commented about “false positives.” “I just saw a patient for whom the GI specialist got a scan because it wasn’t clear what was causing the abdominal pain. All of the

---
other tests were negative, but the scan showed ‘abnormalities’ of other organs. Now I have to follow up on these, even though I’m sure they are just coincidental findings.”

One piece of evidence about the public’s enthusiasm about advanced imaging and the intense marketing of advanced imaging services is the growth of commercial “whole body scanning centers.” (Insurers, including HPHC, do not cover whole body scanning as a screening procedure for otherwise healthy people.) A Google search for “whole body scan” led me to “Vital Imaging” at http://www.vitalimaging.com/full-body-scan.html. There I read the following advertising pitch:

One out of four Americans will die from heart disease. Wouldn't you take 10 minutes - the amount of time needed to have a full body scan - to ensure that you don't become a part of this statistic?

The electron beam CT full body scan has become the No. 1 tool in the fight against the No. 1 killer of both men and women in the U.S. - coronary artery disease (CAD). The technology has recently been featured on Oprah, Good Morning America, The Today Show, NBC Nightly News, and the front page of USA TODAY. Make an appointment for a full body scan today! - Price Information

I also went to the “Early Warning” site at http://www.earlywarninghealth.net/index.html. Like “Vital Imaging,” “Early Warning” promises a longer, healthier life through advanced imaging:

The **EARLY WARNING™** Healthcare Institute is dedicated to the non-invasive pre-clinical diagnosis of disease—many years before disease is symptomatic or evident by the common methods of diagnosis. No one should fear an **EARLY WARNING™** diagnosis because it allows for earlier therapeutic intervention when treatment options are the greatest and most likely to be both non-invasive and highly effective in eliminating the need for hospitalizations and intensive care. A pre-clinical or **EARLY WARNING™** diagnosis enables physicians to utilize simple treatment methods such as lifestyle changes or minimal medications that can arrest or prevent the progression of disease averting catastrophic events such as heart attacks, strokes and incurable cancers.

Whole body scanning is being promoted directly to the public despite authoritative professional opposition, as reflected in this statement from the American College of Radiology (http://www.acr.org/departments/pub_rel/press_releases/total-bodyCT.html):

The ACR, at this time, does not believe there is sufficient evidence to justify recommending total body CT screening for patients with no symptoms or a family history suggesting disease. To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life. In addition, the ACR is concerned that this procedure will lead to the discovery of numerous findings that will not ultimately affect patients' health but will result in unnecessary follow-up examinations and treatments and significant wasted expense.

The fact that whole body scanning for non-symptomatic persons is growing despite the a) lack of evidence that it produces benefits, b) significant risk of false positives, c) the absence of insurance coverage and d) substantial out-of-pocket-cost ($500 - $2,000) suggests just how much value the public places on advanced imaging.

**Questions for the Ethics Advisory Group**
Advanced imaging technologies pose a complex set of ethical challenges for health care insurers. MRI, MRA, CT and nuclear cardiology make tremendous contributions to diagnosis, treatment
and clinical outcomes. The quality and range of uses of the technologies continue to improve. Advanced imaging, however, along with pharmaceuticals, is a major driver of health care cost inflation, and as such must be looked at closely.

Studies of utilization by specialty companies that manage imaging utilization show that most advanced imaging requests meet clinical standards of “medical necessity.” One large national company reports that 65 – 70% are approved at the time of the initial call, with a substantial number of the other 30 – 35% being approved after further clinical review. But experience at HPHC mirrors that of other systems – there is a great deal of variation across the network. Academic studies suggest that both over- and under-utilization occur.

Here are some of the values held by different stakeholders with regard to advanced imaging:

- Advanced imaging technologies can make tremendous contributions to improved care and clinical outcomes for HPHC members.
- Patients find negative studies reassuring and a source of peace of mind. Even if an imaging study has no effect on the treatment recommendations, hearing that “the MRI shows nothing abnormal” can be a source of comfort.
- Physicians (like the PCP quoted above re headaches) value certainty.
- Physicians often feel reassured that using advanced imaging reduces their liability exposure.
- The public has a strong belief in the importance of advanced imaging studies and may feel that without such studies patients are receiving substandard care.
- The direct side effects of advanced imaging studies are minimal, and for many patients the possibility of false positives and the cascade of follow up activities that false positives engender do not seem like a significant risk.
- From the perspective of payers, false positive findings generate significant costs in terms of the testing that is often done to “rule out” a problem that wasn’t being looked for in the first place.
- Advanced imaging is a booming industry. There is a great deal of money to be made by imaging centers, hospitals and provider groups with imaging capacity.
- Requiring that physicians get prior approval for advanced imagining studies can reduce costs and decrease the risks posed by unneeded studies, but physicians dislike prior approval programs, and the managed care industry has been moving away from prior authorization utilization management strategies.

In light of the multiple values at stake with regard to advanced imaging technologies, the Ethics Advisory Group was asked to suggest a framework of values HPHC could use in its managerial approach to this clinical area.

Relevant precedents
On June 24, 1999, the Ethics Advisory Group discussed the new three-tier pharmacy benefit HPHC was about to introduce. Like advanced imaging, pharmaceuticals provide tremendous benefit, are associated with very substantial and rapidly escalating costs, involve many gray zone decisions about whether a particular medication is “indicated,” and are highly influenced by patient demand and marketing. The EAG emphasized the importance of engaging patients and the public in deliberation about the importance of considering the degree of value associated with choices among pharmaceuticals. It saw as a positive that the proposed three-tier program could align patients and physicians in discussing the pros and cons of alternatives without posing significant barriers to needed care.
On September 21, 2000 the Ethics Advisory Group discussed the broad question of “What Level of Quality is ‘Appropriate’ for a Member’s Care,” arising from the request from a member to go to Baltimore for prostate surgery, where the member believed the “best” surgery was available. The member, however, had purchased a managed care insurance product and the EAG endorsed as a value that a managed care program should consider the cost of marginal benefits in its coverage policies. In indemnity insurance patients pay more to be able to make choices that are less constrained. With reference to the case for July 23, 2003, this precedent implies that it would be correct for a managed care insurer to consider cost and marginal benefit in its approach to advanced imaging.

The Ethics Advisory Group has never tried to draw a sharp line as to exactly how much likelihood of benefit should be required for coverage of a health intervention. However, in its discussion of liver transplantation for HIV-positive patients on November 15, 2001 the group “supported using a high standard of evidence in making coverage policy.” The discussion emphasized, however, “that the key issue is for all stakeholders to agree to and understand the rationale for the standards [of evidence] that a program uses and the trade offs involved in choosing a standard.”

**EAG DISCUSSION/RECOMMENDATIONS**

Jim Sabin opened the meeting with the announcement that this would be Collin Wild’s last EAG meeting. Collin was an early member of the EAG. Collin initially represented a purchaser – Sun Life. After leaving the company she continued as a consumer member. Jim thanked Collin for her wise, warm and witty participation over the years.

Jim welcomed Kerry Stefano as a new member of the EAG. Kerry is with PRW, a financial services company, and brings the distinctive window on health care and health insurance that comes from her work as a broker with numerous organizations with regard to the benefits they provide for their employees.

Rick Weisblatt, the customer for today’s meeting, told the EAG that the basic question for HPHC with regard to advanced imaging is “how do we as a health plan add value in this area?” Rick identified four values as especially pertinent for HPHC in its approach to advanced imaging:

- Support positive physician-patient relationships
- Cultivate collaborative relationships with network providers
- Sustain and enhance trust in HPHC
- Reduce variation in utilization that is not driven by clinical need/appropriate practice standards

Several EAG members emphasized that the area of advanced imaging “must be managed.” A member cited a recent Boston Globe article about the increasing number of personal bankruptcies. 50% of the bankruptcies were the result of health care expenditures! Without containment of costs the financial strain on individuals, employers and government will become progressively more severe. The EAG defined responsible cost management of advanced imaging technologies as an ethical responsibility.

The EAG noted that although as of 2003 the utilization (nationally) of advanced imaging is escalating with few brakes being applied, over the years providers, patients and the public have come to understand and accept new ways of managing resource use in other areas of medical
practice. Conditions that were routinely worked up or treated in the hospital 20 years ago are now just as routinely handled on an outpatient basis. Generic medications are routinely substituted for branded forms. There is every reason to believe that the health system is on a learning curve with regard to managing the use of advanced imaging technologies. The challenge is to move along the learning curve in accord with past experience and pertinent values.

Multiple EAG members stressed that their view, the ideal site for management of advanced imaging is within the physician-patient relationship. The model for the desirable relationship is one of collaborative decision-making guided by evidence and explicit clinical rationales. Here are two examples that were given to illustrate the kind of relationship the EAG wanted to encourage:

- An EAG member appropriately concerned about a recent injury saw a trusted orthopedic specialist. The orthopedist assessed the injury as not serious and not requiring an MRI. He said – “I think it is just a sprain. If it is not better within two weeks please let me know.” The member trusted the specialist and was comfortable with his recommendation. The injury improved as predicted. An MRI was not “contraindicated” but was indeed not necessary.

- Another EAG member reported that a relative had been determined to get a whole body scan. After an extended conversation with a trusted primary care physician the relative was convinced that the high risk of false positives, uncertainty about how best to deal with these “abnormalities,” and the absence of documented benefits made it a bad idea.

In both vignettes physician and patient collaborated in the clinical planning process. The physicians cited relevant evidence and provided clear rationales for their recommendations.

The EAG considered at length the question of what factors promote the kinds of conversations about advanced imaging the group envisioned as an ideal.

- For providers, professional ethics is the most important driver. Professional codes and medical education present collaborative decision-making, evidence based practice and patient education as the ethical ideal. Cultivating the role of trusted advisor to their patients, however, takes time. A payment system that recognizes and rewards this ideal would encourage the desired kinds of physician-patient conversations.

- For patients the question of what drives these conversations is currently more complex. Patients with established trusting relationships with their physicians will seek their physician’s advice. But at present, however, advanced imaging techniques have an almost magical aura. There is little public understanding of the risks created by false positive findings and an exaggerated sense of the benefits the imaging studies can yield. When these elements are combined with total insulation from the cost of the technologies there may be little interest in conversation about the pluses and minuses of doing the procedure. Insofar as insurance products like Best Buy encourage patients to act as discerning consumers, physicians can serve as “financial advisor” as well as the familiar role of clinical advisor.

Clinicians at the meeting reported that the majority of advanced imaging procedures that are done are done for good reasons. But as Dr. Thomas Lee, a medical director for Partners Health Care, is quoted as saying in the Boston Globe article circulated with these minutes, in all likelihood 10 – 30 percent do not need to be done. The EAG agreed with Dr. Lee’s statement that “good medicine means eliminating low-value tests and treatments so we can preserve resources and provide good care for everyone.”
But who should decide when an advanced imaging procedure is “low-value” and should not be done? And what should the decision be based on?

Steve Pearson identified four approaches to managing variation in practice and deciding about marginal value in situations of the kind the EAG was discussing:

1) Providers can be given incentives. EAG members commented that in the 1990s this was done by placing providers at financial risk. Providers and the public, however, have pushed back against incentives of that kind, and managed care 2003-style is moving away from them. It would be possible, however, to develop incentives for providers that reward attentive clinical management of the kind described in the Boston Globe article or in the clinical vignettes presented by EAG members.

2) Consumers can be given incentives. EAG members commented that financial risk is a “blunt instrument.” At best, when consumers have what is often referred to as “skin in the game,” they will become discerning assessors of value, and will a) reject imaging studies that are not likely to alter treatment and b) seek low cost/high quality vendors. But at worst, financial risk will deter consumers from having interventions with a major bearing on their health.

3) Guidelines and education can be offered for voluntary adoption. The EAG recognized that education and optional guidelines, while having the advantage of respecting of provider and patient autonomy, are unlikely to achieve significant results. The EAG felt, nevertheless, that education is a crucial component of a long-term management strategy. Several EAG participants suggested that HPHC could use its database to educate members about the costs of their care on a regular basis, in a format like the one many credit card companies use in their regular summary reports. HPHC can use other modes of communication, like its newsletter and annual report, to present relevant education. Employers suggested that they could educate their employees with regard to the annual cost of their health premiums, the reasons for the continuing increases, and what employees can do to help bend the cost trend.

4) Guidelines and education can be mandated. The target for mandatory approaches like “prior authorization” is not simply to eliminate unnecessary studies, but also to ensure that the right study is being ordered. Programs of this kind can reduce costs and improve quality. Prior authorization, however, is part of the managed care approach circa 1990s, satirized by comments like “1-800-Nurse-May-I-Please?” and “1-800-Just-Say-No!” Nationally, health plans are moving away from taking this role.

EAG members commented that from the perspective of values, prior authorization programs can be justifiable if used in an evidence based manner. With regard to advanced imaging studies, if 10 – 30 percent do not need to be done, does this represent 10 –30 percent of each provider’s ordering or does the unneeded ordering clump with a small number of outlier individuals and groups? If the latter is the case, applying a prior authorization program to all providers would impose an unnecessary, unwelcome and costly methodology on the non-outliers. Physicians with clinically excellent referral patterns should ideally be exempted from prior authorization requirements. Education and, perhaps, mandatory review, targeted to the outliers, would be a more evidence based approach. Several EAG members emphasized that if a prior authorization program were used, review criteria should be public and available for use in provider and member education.

Summary

1. The EAG recognized the tremendous value advanced imaging techniques provide and the fact that the technologies are rapidly improving and extending in scope. The group, however, felt that an active managerial approach to unintended variation and high costs is an ethical imperative. Experience in other areas of health care – such as use of the hospital – suggest that
over time providers, patients and the public can learn to use the technologies in a more constrained and evidence based manner.

2. Collaborative, evidence based, educative conversation between patients and physicians is the ideal setting for decision making about the use of advanced imaging technologies.

3. HPHC can add value in the area of advanced imaging by encouraging this kind of conversation between provider and patient. This could be done with a range of incentives targeted to both providers and consumers and through a multi-pronged educational approach.

4. Financial risk for consumers, however, is a blunt instrument, and carries the risk of reducing needed use of advanced imaging as well as less needed, marginally valuable use.

5. Prior authorization is an acceptable approach if it is based on evidence and targeted to recipients for whom there is good reason to believe it will be beneficial. The EAG endorsed “transparency” as a value with regard to prior authorization, as by making review criteria public and using the criteria for education.

6. The group thanked Rick Weisblatt and his colleagues for inviting it to contribute to HPHC’s planning for this important area!

Jim Sabin