--CONSULTATION REPORT--
HARVARD PILGRIM HEALTH CARE ETHICS ADVISORY GROUP
July 18, 2007

Medical Tourism

Customer: Bill Corwin, Medical Director, Medical Management and Policy.

Background
An article in the June 24th Providence Journal starts as follows:

> *When Anne Grant needed surgery on a painful arthritic hip, she didn't go to a hospital in Rhode Island. She didn't even go to Boston.*
>
> *Instead, she packed her bags for India.*

Medical tourism – traveling to foreign countries for medical treatment – is a growing trend. The US has long been familiar with wealthy visitors from the Middle East and elsewhere who come to the US for advanced medical treatments. But in recent years the flow of medical tourists has gone in the other direction as well. It has been estimated that 150,000 Americans went abroad for treatment in 2006. A good portion of these journeys – perhaps half – were for cosmetic and dental procedures that would not have been covered by insurance. But an increasing number are for "medically necessary" medical and surgical treatment like the treatment Anne Grant was seeking.

There are four main reasons why Americans travel abroad for non-cosmetic treatment. First, individuals who are uninsured or whose insurance has substantial deductions or coinsurance may seek treatment in Thailand, India or elsewhere to save money – the treatment may cost 10 – 20 % of what they would pay in the US. Second, individuals may seek treatments that are unavailable in the US, such as cancer treatments or surgical devices that have not received FDA approval. Third, as good as medical care can be in the US, individuals may believe that a higher quality of care is available elsewhere, as for surgical procedures where surgeons in other countries may have significantly more experience. Finally, individuals on transplant waiting lists may seek transplantation in countries where the wait may be shorter.

The Joint Commission on Accreditation of Health Care Organizations (JCAHO), which accredits most U.S. hospitals for participation in the Medicare program, has created an affiliate entity – the Joint Commission International (JCI). JCI has accredited 125 overseas hospitals, and the numbers applying for accreditation is growing rapidly. Hospitals like Bumrungrad in Bangkok, Apollo in Chennai (where Anne Grant went) and others provide a high level of care and amenities and are working hard to attract an international clientele. Many of the physicians at Bumrungrad, Apollo and elsewhere have been trained in the US and are board certified, and administrative leadership is often brought in from the US and Europe.

A visit to the Bumrungrad website (http://www.bumrungrad.com/Overseas-Medical-Care/Bumrungrad-International.aspx) gives a sense of just how sophisticated the process of developing and marketing services to medical tourists is becoming. The 554 bed hospital has more than 200 physicians with US board certification on staff and sees 400,000 international patients each year. It was first accredited by JCI in 2002 and reaccredited in 2005. An international medical coordination office has 7 physicians and 12 nurses on staff to schedule procedures, assist with logistics and plan for follow up care. There are 17 referral offices in countries outside Thailand.

US health insurers are beginning to pay attention to medical tourism. In early 2007 Blue Cross Blue Shield of South Carolina created a new company – Companion Global Healthcare, to facilitate treatment at Bumrungrad Hospital for American patients whose insurance allows overseas treatment and for self-paying patients seeking less costly treatment. As of May no patients had made use of the new opportunity but other vendors are lining up to provide similar services. Here is what Companion Global Healthcare (http://www.companionglobalhealthcare.com/home.html) says to prospective patients and to brokers/agents:

> **(To patients)** *In need of a hip replacement? Knee replacement? Coronary artery bypass? Other procedures? You can now enjoy quality medicare care at a fraction of the cost.*
>
> *By traveling abroad, members can save money on most surgical procedures.*
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> **(To brokers/agents)** *Do your clients have high deductible health plans? More and more, they need to take a greater role in managing their health benefits through these plans. Companion Global Healthcare offers them greater choices and cost savings.*

Questions for the Ethics Advisory Group

HPHC is just beginning to receive requests for treatment abroad. In the last 16 months there have been four appeals re out of country treatment – (a) to Belgium for a hip resurfacing surgical procedure that was not (at the time) FDA approved, (b) to Germany for a laparoscopic procedure for abdominal adhesions that was not FDA approved, (c) to the Philippines for a chemotherapy in a breast cancer trial for an agent that was not FDA approved or yet in trial in the US and (d) to Austria for an experimental treatment for glioblastoma multiforme (a malignant brain tumor) that was not FDA approved. Since FDA approval is typically a necessary condition for coverage all four appeals were denied.

As (a) the standard of care at overseas sites continues to improve, (b) US cost escalation continues its inexorable trend, (c) marketing to potential medical tourists becomes more sophisticated and aggressive and (d) media and the web report on positive experiences with overseas treatment it is (e) inevitable that questions about medical tourism will arise with more frequency for HPHC. On July 18th the EAG was asked to offer consultation to

HPHC leadership as it develops principles for future coverage policy. Questions included:

1. **For enrollees with PPO products that cover out of network services and do not limit their care to a contracted network, what values considerations are relevant to defining the geographical boundaries of the PPO coverage? From the perspective of values what is the rationale for saying "yes" or "no" to overseas treatment?**
2. **HMO enrollees receive their care from a defined network of providers. Treatment outside of the network is ordinarily approved only if it is not available within the HMO network. What, if anything, should HPHC cover as part of its benefit structure when HMO members request outside-of-US services? What values considerations are relevant to answering this question?**
3. **How should HPHC think about the impact of medical tourism on the host country? Suppose it appears that medical tourism is siphoning human and financial capital away from the host country system or organs for transplantation away from host country citizens on transplant waiting lists? Suppose there is suspicion that donors are being paid to provide organs?**
4. **It is inevitable that some HPHC members will go abroad for treatment in circumstances in which HPHC approval has been requested and denied. What values are relevant to deciding who is responsible for the cost of follow up treatment if complications occur?**

Relevant precedents

On September 21, 2000 the EAG discussed "What Level of Quality is 'Appropriate' for a Member's Care?" The case focused on a request from an HMO member for prostate cancer treatment at Johns Hopkins, based on his contention that an "appropriate" level of quality was not available within the HMO network. The report includes this paragraph:

> *With regard to the question of whether the relevant elements of quality have been demonstrated in an adequately **objective** manner the EAG made a distinction. The EAG believed that the nerve sparing technique itself had been demonstrated to be superior to non nerve sparing surgery. It questioned, however, whether a meaningful difference between nerve sparing surgery by Dr. Walsh at Johns Hopkins and nerve sparing surgery available within the HPHC network had been objectively demonstrated. There was no doubt that Dr. Walsh is highly competent and that Mr. A strongly preferred having the surgery at Johns Hopkins with Dr. Walsh. The EAG felt, however, that it is important to distinguish between claims of superiority and objectively demonstrated superiority.*

In a meeting devoted to "Developing a Framework of Values for Determining when Interventions are 'Experimental' and 'Unproven'" (November 9, 2005) the EAG reaffirmed its commitment to a high standard of evidence for coverage decisions:

The EAG emphasized that making decisions about coverage for new technologies requires a prior decision about the standards for "good enough evidence"… the EAG again strongly endorsed the high standard put forward in the Benefit Handbook[1] as consistent with the mission of "improv[ing] the health of the people we serve" and the historical medical ethics teaching – "first, do no harm."

The EAG had not deliberated about out-of-the-US treatment heretofore – July 18th involved new territory!

EAG DISCUSSION/RECOMMENDATIONS

At the outset of the discussion the EAG put the topic of medical tourism into the broad context of globalization. US healthcare occurs in a market environment and markets extend beyond national boundaries. We should expect overseas providers to compete for a share of the US health care market and US consumers to "shop" for health services abroad as well as at home. Likewise, we should expect to see outsourcing to occur in health care as it does in other industries. Already some radiologists in the HPHC network are using "nighthawk" programs in India in which US trained radiologists read scans taken at night in US facilities. And, HPHC's Perot partner has moved selected backroom functions to India. These globalizing trends will accelerate, probably quite rapidly.

The EAG recognized the many practical problems associated with treatment outside of the United States. Before HPHC considered covering overseas treatment it would need to be able to assess quality of care. The Joint Commission International certification program provides a start, and it will not be long before entrepreneurial enterprises begin to offer new quality monitoring reports. If HPHC sponsored treatment abroad it would have to ensure continuity of care for when patients returned to the US. Legal issues

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[1] The section on exclusions in the Harvard Pilgrim Schedule of Benefits states "Drugs, devices, treatments or procedures which are Experimental or Unproven [are excluded from coverage]." Here is how the HPHC Benefit Handbook defines the key terms:

> A service, procedure, device or drug will be deemed Experimental or Unproven by HPHC under this Member Agreement for use in the diagnosis or treatment of a particular medical condition if any of the following is true:
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> a. The service, device or drug is not recognized in accordance with generally accepted medical standards as being safe and effective for the use in the evaluation or treatment of the condition in question. In determining whether a service has been recognized as safe or effective in accordance with generally accepted medical standards, primary reliance will be placed upon data from published reports in authoritative medical or scientific publications that are subject to peer review by qualified medical or scientific experts prior to publication. In the absence of any such reports, it will generally be determined that a service, procedure, device or drug is not safe and effective for the use in question.
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> b. In the case of a drug, the drug has not been approved by the United States Food and Drug Administration (FDA) (This does not include off-label use of FDA approved drugs).

would have to be addressed, such as what sort of liability protections patients would have if something went wrong at a foreign hospital and whether HPHC would have any special liability in such circumstances. But the EAG conducted its deliberations on the assumption that these practical problems could be solved.

The EAG reached a strong consensus that if (a) high quality care at a favorable price was available overseas and (b) issues of continuity of care, legal liabilities, etc could be successfully addressed, then (c) covering overseas care would support many important HPHC values:

- Insofar as high quality care at a lower cost was available overseas covering it would advance the HPHC mission to "improve the health of the people we serve."
- As HPHC serves more large national accounts through its alliance with United Health it will deal increasingly with companies that have employees outside of the US and require solutions for these employees' needs. Skill in addressing overseas treatment would allow HPHC to serve its large corporate customers better.
- Self-insured companies are likely to see high quality/low cost overseas treatment for selected conditions as a benefit for themselves and their employees. In this way too, skill in addressing overseas treatment would allow HPHC to serve this segment of its corporate customers better.
- In the context of high deductible health insurance the EAG imagined that in the future health plans might wave the deductible for patients who had selected procedures done overseas. This would benefit the patients and the health plan.
- One EAG participant commented that "the US health system is clearly broken and costs are out of control…from a competitive perspective, endorsing overseas treatment would send a strong message to US providers that costs must be controlled better!" Another participant commented that covering treatment abroad is a form of "outsourcing cost containment, an area managed care has largely given up on in the US!"

The EAG briefly discussed the issue of members who want to go abroad for treatment that is not FDA approved or otherwise available within the United States. The group felt that its previous recommendations with regard to a framework of values for coverage of new technologies apply to this area as well. The same standards for judging whether to cover treatment in the US (FDA approval, etc) should be applied to requests for treatment overseas. Requests are likely to be more common in the future as it is easier for drug companies to do initial Phase I studies in developing countries than in the US.

With regard to the question of who should be financially responsible if members choose to go abroad for treatments for which HPHC approval has been denied the group was divided. Some felt that "health insurance covers injuries from doing dumb things like bungee jumping, so why shouldn't it cover injuries from other dumb choices, like going abroad for unapproved treatment?" Others felt that if members (a) know that their insurer

does not see the requested treatment as appropriate for coverage and (b) choose to go ahead on their own then (c) they should be financially responsible for the full treatment, including (d) treatment of complications arising from the unapproved treatment.

The EAG spent the final half hour of the meeting discussing the impact of medical tourism on the host country. It recognized the possibility that high quality/good value treatment for Americans could have negative effects on the host country:

- There could be an internal "brain drain" in the host country if the most qualified physicians gravitated towards facilities serving foreigners.
- In poor countries persons living in dire poverty may sell organs for transplant in hope of providing better for their families. The EAG debated whether individuals should be allowed to make "informed choices" about sale of organs. The consensus of the group was that even if the host country accepted voluntary sale of body parts a US health plan should govern its practices by its own values and the values reflected in the US prohibition on selling body parts.
- One participant reported having been at a presentation describing allegations that in several countries prisoners were used as a source of organs and that involuntary tissue typing was done on admission to the prison as a way of "inventorying" available organs.

The EAG recognized that HPHC cannot solve the problems of poverty in countries that host medical tourism or ensure optimal distribution of the host country's medical resources. But the group felt that the last five words of the HPHC mission – "to improve the health of the people we serve **and the health of society** (emphasis added)" – should be interpreted to refer to the host country's society as well as US society. Especially for extreme examples like sale of body parts or "harvesting" transplant organs from prisoners HPHC should not serve its members by means that produce significant harms to the host country.

The EAG emphasized the importance of transparency in any developments with regard to medical tourism. Endorsing transparency means that if getting high quality treatment at a lower price is the rationale for offering coverage that should be made explicit to stakeholders. Similarly, transparency means that issues like the potential impact of medical tourism on the host country should be addressed openly and proactively. HPHC aspires to being a thought leader with regard to health care policy, and medical tourism offers an opportunity to speak out in an educational manner.

Summary

1. *On the assumption that a host of important practical problems could be solved, the EAG felt that offering high quality/low cost treatment abroad could provide a win/win opportunity. If incentives were designed properly members, purchasers and HPHC could all save money while providing high quality care.*

2. *The EAG felt that the same values framework HPHC uses for deciding about coverage for treatments in the US (FDA approval, evidence base, etc) should be applied to requests for treatments abroad.*

3. *The issue of how medical tourism impacts host countries is complex, but the EAG felt that these impacts should be considered if and when HPHC considers coverage of overseas treatments. The EAG felt that fundamental HPHC and US values – such as the view that body parts should not be sold (or, in the case of prisoners, taken) – should be adhered to, even if the host country accepts these practices.*

4. *The EAG strongly supported the active way in which Bill Corwin and his colleagues were addressing medical tourism – beginning to plan for the area in a proactive manner, not simply responding to trends as they emerged. The group thanked Bill and his colleagues for allowing it to undertake this anticipatory ethical analysis of the area before any problems hit the fan!*

Jim Sabin