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Good transplant candidate? Yes or no depends on who's doing the evaluating

Transplant teams face tough choices

A 50-year-old man with end-stage heart failure is referred to your medical center for evaluation to receive a heart transplant. He is in reasonably good health, considering his condition, but has only entered a smoking cessation program two months ago. His previous attempts to quit smoking all have been unsuccessful.

A 17-year-old female patient on dialysis also has been referred as a possible candidate for kidney transplant. She has been on dialysis for almost a year, but has had difficulty complying with her physician's instructions on diet and medication and also has a coexisting medical condition.

Is either patient an appropriate candidate for organ transplantation?

The answer depends largely on which transplant center evaluates the patient. Once referred by their primary physician, patients in end-stage organ failure must undergo a rigorous and lengthy evaluation process that seeks to determine how well each patient will function if transplanted with donor organs.

Factors such as coexisting chronic medical conditions or an inability to understand or comply with strict treatment protocols often will prevent a patient from receiving a transplant. But these decisions vary from center to center — at one center a patient might be considered an inappropriate candidate, but might be cleared for the surgery at another.

"There is tremendous variability in a number of respects," says **Mark D. Fox, MD**, a medical ethicist at the University of Oklahoma in Tulsa and chair of the ethics committee of the United Network for Organ Sharing, the nonprofit organization that administers the nation's donor organ network. "Each transplant center is free to sort of establish their own criteria for acceptance on the list."

An example of the spectrum of differences is thresholds that centers establish for smoking cessation in heart transplant candidates, Fox explains.

Transplant center A may say a candidate has to have quit smoking for six months to even be considered for transplant, while transplant

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center B will work with a patient on smoking cessation during the months he or she is on the list awaiting a suitable donor heart.

"Transplant center C may say something in the middle because we don't have good data that say, 'If you've quit for six months, that's more predictive that you will stay quit than anything else than if you've only quit for two months,'" he explains.

The centers are not trying to pass judgment on lifestyle choices or problems and determine a

candidate worthy for donor organs, Fox says, but they have a duty to try to ascertain which patients will have a good outcome after facing difficult transplant surgery and strict medical protocols following surgery to maintain the donor organ.

If a patient receives a donor heart but is unable to stop smoking, the chances are high that that organ will also be damaged and fail or that the patient will be susceptible to serious complications or other diseases that will prevent a good outcome.

Compliance issues are the most difficult for transplant teams to handle, agrees **Jennifer Braun**, RN, BSN, CCTC, a kidney transplant coordinator at Penn State-Milton S. Hershey Medical Center in Hershey, PA.

Patients receiving kidney transplants have to follow a strict medication and care regimen. It's questionable whether people who have demonstrated an inability or unwillingness to comply with dialysis protocols or other treatment protocols will do well with a transplant.

"If they've missed dialysis appointments or they've left dialysis early, then it's questionable whether they'd be able to undergo surgery and comply with the follow-up," she says.

It seems to be a particular issue with younger patients, she notes. When teen-agers go off to college, they often try to hide their disease, skipping appointments to have their labs checked and not adhering to dietary requirements.

But dialysis is a difficult, grueling, and often discouraging process that is ongoing, while a transplant offers the hope that the patient will lead a normal life.

"We've had some patients who didn't do well on dialysis but once they received a transplant, they did everything right, they made every appointment, followed every instruction," she says. "It's very difficult to make that call."

Medical comorbidities

Some centers have different standards for transplanting patients with coexisting conditions, which means some patients may be better off shopping around for transplant centers.

"For example, in the heart transplant community some centers are more comfortable accepting patients with diabetes and some other centers are very reluctant," Fox explains. "Patients with diabetes are at risk of small-vessel disease in their heart, so they are not candidates for bypass surgery, yet they are at very high risk of experiencing

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Editorial Questions

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complications [from a transplant].”

Again, says Braun, transplant centers do rigorous medical examinations of potential transplant candidates to determine whether the patient can withstand the operation and whether the organ will be able to function.

Some coexisting conditions, such as cancer or severe heart disease, will almost certainly rule out candidates at all facilities. But different centers and different surgeons will have different comfort levels about managing patients with other medical problems.

Sometimes, it is a matter of geography. In Pennsylvania, there seem to be a higher proportion of people with blood clotting disorders, says Braun. A transplant surgeon who moved into the area from California said he had no experience even considering whether to do a transplant, she says.

“Here, it is something we see all the time, so we are used to dealing with it,” she notes.

If transplant teams are aware, however, that another center might be willing to perform the surgery, they have a duty also to inform the patient, Fox says.

For example, he used to live in a city with two large transplant centers, but both had very different views about smoking cessation in heart transplant candidates. A patient that one center would not list because he had not quit smoking could probably get on the list at the other.

“If we have to say no, the patients ought to know that there are other places that might have a difference of opinion that might be willing to list them,” Fox says. “I think that piece of information may not be readily available to patients, and I think there needs to be that level of transparency there.”

Although Fox says he believes that it is appropriate for centers to set their own thresholds for listing candidates, he worries that potential candidates are not aware that the criteria are not set in stone nationwide.

Psychosocial concerns

One of the most difficult ethical areas involves dealing with patients who have personality disorders or other psychological problems that make it difficult for transplant professionals to feel comfortable the patient can understand and appreciate the risks of the surgery itself and be able to comply with the follow-up care, notes Fox.

“Around the psychosocial issues arise the biggest divisions in transplant teams,” Fox says.

“Answering the questions of, ‘Does this person have adequate psychosocial support?’”

That may also present problems when the patient goes to another transplant center, he adds.

“If we decide, for whatever reason, that you are not an appropriate candidate at our center — that we just can’t feel comfortable that you will do well — and we tell you, and you say, ‘I want to be referred to another center,’ then we will. But then the other center may want to know why we didn’t accept you as a candidate,” Fox explains. “If I then say, well I think these are the issues, then that is going to color their perception of you as a candidate. The other center is not going to be too eager to do the transplant if I express those concerns, and they may have been comfortable doing it if they had done the initial evaluation.”

Who makes the decision?

Different transplant teams also have different dynamics when it comes to the final decision. Most transplant centers have a team of professionals evaluate a potential candidate — giving examinations that evaluate the person physically, mentally, and emotionally. But when it comes to the final decision, it may either be a team decision or left up to the surgeon.

At Hershey Medical Center, it is usually the transplant surgeon who ultimately makes the call, says Braun.

“There is usually not a lot of disagreement, but the final decision is up to the surgeon,” she notes. “If he or she feels someone is not an appropriate candidate, then they aren’t. And if he or she feels someone is, then that is also the case.”

However, not all centers and surgeons operate that way, Fox notes.

“There are really not that many cases where there is a strong difference of opinion,” he says. “But I have known surgeons who always want to have a consensus. If they think someone is an appropriate candidate and others on the team feel strong the person is not, then he or she is not an appropriate candidate. On the other hand, some surgeons feel that since they have the ultimate responsibility [for the patient’s outcome] then they should make the final decision.”

Aside from the issue of who should be listed, a more compelling question for transplant teams is when to admit that patients who are already listed are no longer appropriate candidates, Fox says.

Patients with end-stage organ failure of any kind are seriously ill with a condition that will

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prove fatal if they don't receive a transplant. In many cases, the longer they wait on the list, the more serious their problems become and the more secondary medical conditions they develop.

In some cases, it becomes highly unlikely that these candidates will be able to undergo a transplant and do well and recover, he adds. And transplant teams need to begin considering when palliative measures and not transplant are indeed the better option.

Transplant teams are in a unique situation as medical professionals because they must contend with the scarcity of available donor organs and the large number of patients that these organs could help in some way, he explains.

"I think we do much better on the front end of deciding who to list in the first place and not on the back end, because these are patients that we've gotten to know, we've taken care of them, and transplantation may be a better option for them than no transplant, but it is not a better option for them than for someone down the street or someone at another center," says Fox. "There is no good consensus about when a patient is too sick to be transplanted. Once they are listed, they don't get off the list, that's it."

In some cases, this means that donor organs go to a very sick patient who is only able to live a few more months without truly recovering, he says, and another patient who might be able to go on to live a normal life loses that chance.

Transplant teams need to do a better job of considering palliative care as an appropriate option for people who have end-stage organ failure, both in patients who have been listed but have not been matched and for patients who never make it on to the list, for whatever reason, he says.

"It should be seen as part of a continuum of care that we provide to patients with end-stage organ failure," he says. "Then, it is not a stretch to say, 'You are too sick to benefit from transplantation, but we are going to help take care of you in the final phase of your illness.' It's not saying we have

nothing more to offer you. It is just saying that transplant might not be the most appropriate option."

End-of-life issues should be discussed with patients in end-stage organ failure and their families regardless of the patient's prospects for transplant, he adds.

Any person with a condition serious enough to warrant transplant should also be asked to consider what treatments they do and do not want in the event that a transplant is not possible, or, if performed, not successful, he notes.

"Transplant candidates are put in a really unique limbo where it is sort of prepare for the worst and hope for the best," Fox explains. "There is this carrot dangling out there that you hope an organ becomes available, and at the same time you have to be realistic that you are sick enough that your mortality risk is substantial and you need to make end-of-life decisions." ■

Study shows women not happy with cardiac care

Physician attitudes impact patient progress

The first national survey of women with heart disease has found that more than half of them are dissatisfied with their health care and face significant obstacles to recovery.

Of the women who reported dissatisfaction with some aspect of their health care, 58% pointed directly to physician attitudes and communication styles as their main complaint, specifically citing physician insensitivity, rudeness, abruptness, and ignorance about heart disease in women.

In addition, more than half of the survey respondents said they suffered mental illness as a result of their heart disease, with ailments ranging from anxiety (17%) to clinical depression (38%), or both (21%).

"This survey is a wake-up call for health care professionals who need to understand how much their attitudes and communication styles influence their female patients' willingness to ask questions, participate in medical decisions, and adhere to recommended treatment and lifestyle modification," says **Sharonne Hayes, MD**, director of the Mayo Clinic Women's Heart Clinic in Rochester, MN, and a co-author of the survey report, published in the January/February edition of *Women's Health Issues*.

Although the researchers only surveyed 204 people, the responses are significant in that so many women were saying the same thing, Hayes tells *Medical Ethics Advisor*.

"I would look at this as sort of a preliminary study. We received no funding and it wasn't a random digit-dialing survey with a high level of scientific scrutiny, so we need to be careful about generalizing," she notes. "But the thing we noticed is that they singled out the physician experience as their most problematic."

The survey was sponsored by Washington, DC-based WomenHeart: The National Coalition for Women with Heart Disease and was conducted by surveying women who had joined the organization or who had requested information from the coalition in some way.

Hayes and colleagues decided to do a formal survey after WomenHeart staffers were inundated with callers reporting bad experiences and asking for better resources to cope with their heart conditions.

"They just started hearing from so many women who told their stories about the good, the bad, the horrible, there was a sense that we really didn't know what the experience of being a woman with heart disease was like," Hayes reports. "So they decided to formalize it with a survey."

Missed diagnoses

A significant number of respondents reported that their primary physician initially misdiagnosed their condition as something nonclinical. Only 66 women (35%) who reported symptoms and 68% of their physicians correctly recognized their symptoms as potentially related to the heart. Eleven percent of patients reported their physician misdiagnosed their conditions as panic disorder, stress- or menopause-related conditions, or hypochondria.

The findings are consistent with other research showing that physicians still have a blind spot when it comes to recognizing that women are at risk for heart disease, says Hayes.

While physicians are likely to consider a cardiac diagnosis in a 45-year-old man with shortness of breath and chest pain, they are less likely to consider the same diagnosis for a woman with the same characteristics, she says.

"Most physicians are misled into thinking that a younger woman who is thin and looks healthy does not have heart disease, even when she is having classic symptoms," she continues. "Obviously,

if she is diabetic and smokes and she is 65, a good doctor is going to think heart. But if she is 45 and thin and doesn't look like she has health problems, they might not."

The fact is, heart disease is the No. 1 killer for both men and women, something physicians as well as the rest of the population seem not to realize, says **Nancy Loving**, WomenHeart's director and herself a heart attack survivor.

"I don't know how this came to be considered a 'man's disease,' but it has, even though it kills just as many women," she notes. "When you talk to most women, they are afraid of getting breast cancer or cervical cancer, but things like heart screenings and cholesterol counts aren't even on their radar."

If the women themselves are less likely to consider themselves at risk for a heart attack, they may not think to report appropriate symptoms to their doctor or seek medical attention, she adds.

Symptoms not that different

It's a mistake to attribute the discrepancy in diagnosing to differences in symptoms experienced and expressed by women and men, says Hayes.

Although some research indicates women may experience atypical symptoms of heart disease, the data are very limited.

"What data we do have on differences in symptoms is pretty weak," Hayes says. "There are more similarities than differences. So focusing on the differences isn't going to be very fruitful. If you look at symptoms of acute heart attack, the No. 1 symptom in both women and men is chest pain or some type of chest symptom. But maybe female patients aren't even asked if they are having symptoms."

All the data obtained have been in retrospective studies — reviews of medical records of patients found to have heart disease, she explains. If the physician never asked the patient about chest pain, it's not likely to be in the medical record.

The low numbers of respondents reporting referrals to cardiac rehabilitation was also a disturbing finding, Hayes adds.

"This is not the first study to discover this," she notes. "In fact, if you look at the nationwide average, both men and women are under-referred to cardiac rehab. But women are half as likely, in some studies a third as likely, to be referred than men."

Since participation in a program is a strong

SOURCES

- **Nancy Loving**, WomenHeart, 818 18th St. N.W., Suite 730, Washington, DC 20006. Web: www.womenheart.org.
- **Sharonne Hayes**, MD, Mayo Clinic Rochester, 200 First St. S.W., Rochester, MN 55905.

predictor of a positive outcome, it is particularly concerning that such low numbers of women report attending.

Depression, social isolation

Another key finding of the survey is that a large percentage of women report suffering from an undiagnosed mental condition in addition to their cardiac illness, say both women.

Women in general have a higher incidence of depression, and depression and other mental illnesses have been shown to have an adverse effect on overall health and on heart function, says Hayes.

"If you talk to female heart patients, you will find many have been depressed and many were not diagnosed with it," she relates. "It wasn't until they came out of their fog six or eight months later and realized it."

Since women are two to three times more likely to suffer from depression, it would make sense for physicians to screen for this in women with as serious a health complication as heart disease, she adds.

The different ways society responds to male and female heart patients may have something to do with the phenomenon, also, says Loving. Because heart disease is not seen as a women's disease, many women feel extremely socially isolated after their diagnosis.

"When it happened to me, the social isolation was more devastating than the heart attack itself," she recalls.

At WomenHeart, women have reported that their families became upset and resentful of the woman after she became ill and her condition affected her ability to perform traditional caretaker roles.

"One woman reported that her husband wasn't able to deal with her illness and so resorted to blaming her and yelling at her when she was unable to do things she once had done," Loving says.

As a result, many women don't comply with recommended alterations in diet and lifestyle recommended by their physicians. And many try to return to normal work and household duties too

soon and harm their recovery, Loving adds.

WomenHeart has sponsored support groups for women with heart disease that offer some opportunities for information and encouragement. But hospitals and health care providers must do more to address family and social issues with female heart patients in order to improve rates of compliance with treatment recommendations and improve outcomes, she says. ■

Providers aren't keeping up with genetic medicine

Resources being developed to bridge knowledge gap

As controversies over fetal tissue research, cloning, and stem cells grab the headlines, other applications of genetic research are quietly making their way into clinical practice. But many health care providers aren't ready for them.

"What we hear most often when we go to talk to health care professionals about genetics is, 'OK, we know it's coming, we know it's important, but stop telling me what it's going to be doing for me five years from now. Tell me what I need to know now,'" says **Joseph McNerney**, director of the National Coalition for Health Professional Education in Genetics (NCHPEG) in Luthersville, MD.

According to McNerney, they need to know a lot but most haven't been able to wade through the massive amounts of confusing and conflicting information to glean portions relevant to their practice.

NCHPEG, which is made up of 125 separate medical professional organizations and societies, is hoping to change that by offering resources for physicians and other health care professionals to guide them in becoming more gene literate.

Two years ago, they developed a set of core competencies in genetics that health care professionals should be able to meet. Now, they are offering guidance on taking an appropriate family history and establishing a clearinghouse of web sites that provide comprehensive, correct information on genetics and medicine.

"Most health care professionals are not very well informed about genetics in general, particularly about genetic testing and technologies. For most professionals, they have mentally walled off genetics into this separate, kind of abstruse discipline," he says. "The reality is, it's not just that genetic

medicine is on the horizon. It's already here in a number of areas."

This year, the American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics (ACMG) released new guidelines on provision of prenatal cystic fibrosis screening.

The guidelines recommend that screening should be offered to all couples and be recommended to individuals deemed to be at particularly high risk.

"This is a nontrivial issue here; this is for all pregnancies," McInerney notes. "This is now the standard of care."

OB/GYNs should be asking themselves whether they feel they have the appropriate knowledge, training and skills to counsel parents about the implications of seeking prenatal genetic diagnosis, how to interpret the test, and how to provide appropriate follow-up, he adds.

Oncologists have already had to face the emergence of genetic tests for the gene mutations BRCA1 and BRCA2, which have been linked to a higher risk of breast cancer.

A recent paper in the *New England Journal of Medicine* detailed the potential for using the expression array in particular tumors to predict which ones will metastasize or to target treatment by determining which genes the tumor is expressing.

"These things are already here and they are finding their way into clinical practice," he advises. "It's important for clinicians to stop viewing medicine in terms of genetic and nongenetic diseases. The fact is, almost all disease processes have some genetic component. Eventually, we are going to find ways to test for, and possibly treat, most of them."

Family history is key

The first thing most physicians should do in terms of improving their genetic education is learn to take a detailed, three-generation family history.

"A good family history is actually your first genetic test," McInerney says. "A good, comprehensive history is an excellent place to start in terms of learning about a patient's health potential."

The next thing they can do is learn about the genetic screening tests and technologies that are relevant to their practice area.

The medical literature is full of articles on genetic medicine. The *New England Journal of Medicine* is doing a yearlong series on genomic medicine. And there are many web sites that can

provide a wealth of good information, if you know how to look.

"The first thing health care professionals should do is approach their professional organizations and ask what is happening there," he notes. "We work with these societies to develop educational programs."

NCHPEG is developing a new genetics search engine — Genetics Resources on the Web (GROW) — that searches only approved member sites.

NCHPEG has developed procedures to screen organizations that apply to be part of the database, which will ensure the engine only provides links to solid, scientifically valid information.

"There is so much misinformation, there are web sites with even pseudoscience on them," he states. "But we have over 30 organizations involved in our project, and the engine will only search those member sites."

Not just for doctors

It's also important that other health care professionals, not just physicians, realize they need to be up to date on genetic medicine, too, says **J. Vincent Guss Jr.**, MDiv, a chaplain at Inova Alexandria Hospital in Alexandria, VA, and chairman of the bioethics committee for the Association for Professional Chaplains (APC).

Nurses, social workers, and chaplains will also be called upon by patients contemplating genetic testing or the use of genetic technologies to lend their unique perspectives, he says.

"It is incumbent upon us to help patients access information or put them in touch with professionals

For more information

- **The NCHPEG Core Competencies**, information on collecting a genetic family history and other slides and information pieces on genetics are available on the NCHPEG web site at www.nchpeg.org.
- **Information about locating and referring patients to genetic counselors** can be found on the web site of the National Society of Genetic Counselors: www.ngsc.org.
- **The University of Washington sponsors** a genetic medicine information site, called GeneTests. The site has information on different genetic tests in different specialties, where tests are available, who performs the tests, which labs interpret them, the costs of the tests, and who to contact. The site can be found at www.genestar.org.

SOURCES

- **Joseph D. McInerney**, National Coalition for Health Professional Education in Genetics, 2360 W. Joppa Road, Suite 320, Lutherville, MD 21093.
- **J. Vincent Guss Jr.**, Mdiv, Pastoral Care Department, Inova Alexandria Hospital, 4320 Seminary Road, Alexandria, VA 22304.

who have information and then provide spiritual, pastoral, social and psychological support,” he explains. “We are being asked by the people we serve as well as by hospital administrators and doctors wondering where to go for answers.”

The APC recently became a member organization of NCHPEG, which will allow certified chaplains access to education and knowledge about genetics, but will also allow the scientists and researchers working on genetic medicine access to the chaplains’ expertise in managing the spiritual, social and cultural dimensions to the changes new technologies bring.

“With their background in pastoral and clinical training, our certified chaplains have a unique perspective because they counsel people of all cultures and religions. We can contribute by providing NCHPEG resources from our disciplines,” Guss says.

It will be important for chaplains and others with sensitivity to different religious and cultural perspectives to guide medical professionals in approaching and treating patients, he adds.

“We have experience with the different perspectives on the use of fetal tissue for example — we are not saying it is right or wrong — but will help provide information about which traditions would have a greater sensitivity to it and which would not,” he notes.

Chaplains, social workers and other professionals will help enhance consideration of questions related to questions about privacy, the role of genetic information in society, and the dignity of human beings, he points out. “Bringing a pastoral theological approach to that helps to create a dimension of humanity that might be missing from the sterile, scientific, clinical, or legal perspective.”

A NCHPEG working group developing the Core Competencies for Genetics, a statement of what the coalition thinks health care professionals should learn and understand about genetics.

“I think the most important statement we make in them is that health care professionals should be

able to acknowledge their own capabilities and the limitations of their own expertise,” McInerney adds. “If you are a responsible professional, you know where your expertise ends and you need to either pick up the phone or go to the literature.”

In particular, if health care providers don’t feel comfortable discussing complex genetic information or explaining genetic principles to patients, he or she needs to know how to make an appropriate referral to a genetic counselor — someone trained in genetics and how to communicate this information to patients.

The same is true of doing pre-test education, counseling, and informed consent, he adds. “If a primary care provider doesn’t feel comfortable doing that, that is something a genetic counselor can do.”

In the two years since the competencies have been published, different organizations have looked at the document and chosen which competencies are appropriate for their disciplines and which are not, he adds. “I think that is fine, if they focus on those and not on the ones they feel are less appropriate.” ■

Group purchasing orgs review ethics standards

New code of conduct being developed

Following Congressional scrutiny of their business practices, hospital group purchasing organizations (GPOs) are moving to adopt new standards governing how they collect fees, contract with vendors, and manage potential conflicts of interest.

GPOs are groups of member hospitals that cooperate to negotiate large contracts with vendors to buy supplies, medications, and medical devices. Some GPOs are for-profit entities, while others are made up of, and owned by, not-for-profit member hospitals.

The industry experienced phenomenal growth in the mid-to-late 1990s, and ethical guidance didn’t always keep pace with evolving business practices, say experts. The new effort at standardizing practices and developing guidelines also may provide guidance for other health care entities facing similar growing pains.

“There are a number of elements in the code of

conduct that are highly, if not directly, transferable to hospitals, in particular their purchasing and materials-related functions, just less broadly," notes **Rick Norling**, chairman and CEO of San Diego-based Premier Inc., a health system alliance that operates one of the nation's two largest GPOs. "But the first step is to build learning and understanding because you never have guidelines and prescriptives that cover every situation."

Following rapid mergers and consolidation in the health care vendor market in the 1990s, health systems responded by banding together to gain enough buying power to negotiate better prices for products they all needed to purchase, Norling explains.

Premier, for example, is an alliance of more than 200 independent hospitals and health care systems that completely own and operate the company. The alliance has many functions, one of which is group purchasing.

As the industry expanded, a number of business practices emerged that potentially compromised GPOs' ability to independently advocate on behalf of their member hospitals.

GPOs make money by collecting administrative fees for the contracts they negotiate — usually a percentage of the contract's total "buy." Larger administrative fees have the potential to induce the organization to contract with a vendor that might not offer the best deal or the best products for the member hospitals.

Overall, there has been no set limit on GPO administrative fees, though the U.S. Department of Health and Human Services monitors contracts for health care products that involve administrative fees greater than 3% of the total contract amount.

In addition, some GPOs formed outside relationships with vendors aside from the product contracts negotiated — separate licensing agreements for products and equity investments in vendor companies. And some board members or executives also had investment relationships with vendors.

To drive competition for best prices, GPOs engaged in contracting strategies such as bundling different products into single contracts, and the use of sole-source contracting, which award large, multi-hospital contracts to a single vendor.

Such relationships led some medical device manufacturers to charge that the climate had virtually shut them out of the business market.

Last year, the antitrust subcommittee of the Senate Judiciary Committee held hearings on the issue and urged the industry's trade association the

Health Industry Group Purchasing Association (HIGPA) to develop a code of conduct for its members to follow.

Balancing innovation and cost savings

The association complied with eight-page "Code of Conduct Principles" that covered how GPOs should set up conflict-of-interest policies and compliance plans, establish procedures for handling member relations, product evaluation and vendor grievances, and disclose payments and other benefits received from participating vendors.

HIGPA will monitor the compliance of its member organizations with the new code of conduct, says HIGPA's director **Robert Betz**.

"The code requires the organization to have a compliance officer who will make annual reports to HIGPA detailing compliance," he explains.

And this first year, the association will distribute a compliance survey to its members and publish the results. Although the Congressional hearings prompted the release of the code, HIGPA had already been in the process of examining several of the issues involved and in working with its members to develop guidelines, he adds.

"We have had a working group looking at these issues for some time and have sponsored several key studies of the impact that GPOs have on the functioning of their member hospitals," he says.

The key ethical issue for GPOs is how maximize cost savings for member hospitals, while at the same time allowing and encouraging investment in new technologies that will improve patient care and outcomes, Betz says.

To foster competition among vendors, GPOs utilize tools such as sole-source contracting, commitment-level requirements (stipulating that member hospitals will commit to a certain purchase level), contract lengths, and multiproduct line discount arrangements.

Without guidance, some of these arrangements could unfairly tip the balance in favor of larger vendors, limiting member hospitals' exposure to and access to smaller vendors who may have better products or technology.

The code establishes common goals each contractual arrangement should meet. The code requires the GPO to consider all of the following factors in each arrangement:

- the market share of participating vendors;
- size of the GPO;

- number of vendors available to provide the relevant product or service;
- the ability of the participating vendor to meet the needs of the GPO's members;
- the occurrence of innovation in the relevant product or service category.

Each of these factors must be evaluated in light of its impact on the GPO's ability to meet the twin goals of promoting the quality of patient care and achieving price savings and cost reductions for member hospitals.

Individual hospitals, whether they participate in a GPO or not, still have the responsibility to make purchasing decisions and do not abdicate this process to anyone, Norling reports.

But GPOs are able to aggregate the potential volume of hospitals in a series of product categories and they negotiate contracts through which hospitals can purchase products at a significant discount.

"They are not required to purchase products this way, they simply can purchase this way," Norling explains. "The contracts are also not for every product and are not all single-source."

Typically, GPO contracts only address 60%-65% of all the supplies needed by a hospital. The remaining 35%-40% of purchases are done by hospitals individually. Usually, GPO contracts represent bulk purchases of items many hospitals use, while hospitals will individually contract for the remaining amount.

At Premier, clinical advisory boards comprised of representatives from the member hospitals review all proposed contracts for products and services and vote on which vendors to contract with, Norling says.

In return for getting a better deal through a GPO contract, member hospitals are required to commit to a buy at a certain level under a contract. This is what is known as a "commitment level."

At Premier, no contract requires a commitment level of 100% — that a hospital buy all of its supply of a particular product or service through that contract. Contracts should, and do, leave room for alternative purchasing arrangements.

Not all committed contracts are "sole-source" (product supplied by a single vendor) either, Norling adds.

"With committed contracts, the hospitals commit in advance, but they are aware it will get them substantially better pricing and terms," Norling says. "There are always exceptions, and it is never a 100% commitment."

The fees GPOs receive have also come under scrutiny by the government and public.

For more information

- **Copies of the Health Industry Group Purchasing Association (HIGPA) Code of Conduct Principles** are available on the association's web site at www.higpa.org/pressroom/pressrm_index.asp.
- **Copies of the Hanson report, Best Ethical Practices for the Group Purchasing Industry**, can be obtained on the Premier Inc. web site at www.premierinc.com. Click on the link for "Newsroom" then "Resource Center." There are a list of documents on ethical business practices to choose from.

Typically, GPOs make money on administrative fees paid by the vendors for negotiating the contract. The fees are usually a percentage of the total commitment buy under a particular contract.

Because Premier is owned by not-for-profit health systems, its goal is to take in only enough administrative fees to cover the costs of negotiating and administering the contracts, Norling says.

Funds that are collected beyond what it costs to break even are redistributed to member hospitals.

"The ultimate point here is that we are in the business of maximizing the GPO as a business entity — either you are trying to maximize the profitability of the GPO or you are trying to maximize the value to your customers. In our case, we believe the latter to be our duty."

In addition to the new HIGPA code, Premier also commissioned an industrywide study of ethical issues by business ethics expert **Kirk O. Hanson**, executive director of the Markkula Center for Applied Ethics at Santa Clara (CA) University.

"Group purchasing was sort of a sleeper industry for a long time," explains Norling. "We were not really front and center in the minds of a lot of folks, And last year in particular, a number of questions were raised about the industry."

Hanson was commissioned to study the industry and recommend ethical best practices for possible adoption by Premier.

Hanson's report, presented to the company in October of last year, addressed some of the same issues as HIGPA's Code of Conduct, but went further in some of its recommendations.

For example, whereas the HIGPA code stipulates that all GPO employees in a position to influence contracting decisions should be barred from having equity interest in participating vendors and accepting gifts, entertainment, favors, honoraria, etc., from the vendors; the Hanson

SOURCES

- **Robert Betz**, Health Industry Group Purchasing Association, 1100 Wilson Blvd., Suite 1200, Arlington, VA 22209.
- **Rick Norling**, Premier Inc., 12225 Camino Real, San Diego, CA 92130.

report would expand the prohibition to all management employees of a GPO, not just those in positions to influence contract decisions.

The Hanson report also goes further to recommend that contracts for physician preference products and services be multisource and that contracts for these products be written without commitment levels.

The report also recommends that administrative fees be capped at no more than 3% of the contract's total buy.

"We reached the conclusion that we wanted to drive value for our not-for-profit hospitals and trimming our group purchasing costs is more important," adds Norling. "Our average administrative fee is 2.1% on medical products contracts, and that more than covers the fully loaded costs of operating a group purchasing organization."

Preset administration fees

In addition, following Hanson's recommendations, Premier also will move to preset administrative fees for certain contracts that will just be part of the offered terms and conditions of a contract for that type of good or service.

"We are unique, we believe, in harmonizing our administrative fees, so that, in any contract, where you might have a product set in which you are going to go out and talk to multiple vendors about, we have a set administrative fee. We don't want any possible implication that the GPO would choose a vendor for a contract based on the amount of fees paid compared to the ultimate value to the customer."

The HIGPA code is intended to be the minimum ethical standards of practice for the industry as a whole, and the association encourages its members to adopt more specific guidelines that cover their individual business models, says Betz.

"The HIGPA code could not address such issues as commitment levels or administrative fees without running afoul of federal antitrust laws," he notes.

The association approves of Premier's efforts to study ethical practices and develop recommendations and hopes others will do the same, he adds.

In developing the code of conduct principles, HIGPA also established a process by which the code will be periodically reviewed and updated as new realities in the GPO industry require closer scrutiny. ■

NEWS BRIEF

Supreme Court upholds any-willing-provider laws

The Supreme Court has upheld two 1994 Kentucky laws requiring HMOs to open their networks to any health care provider willing to accept the insurer's reimbursement rates and contract terms.

About half of U.S. states have similar laws, known as "any-willing-provider" statutes.

Lawyers for a group of Kentucky HMOs and a managed-care trade association argued the laws improperly regulated employee benefits, a duty reserved for Congress. However, the justices ruled unanimously that the state was within its rights to regulate insurance companies operating in the state. ■

COMING IN FUTURE MONTHS

■ Federal attempts to ban partial-birth abortions

■ Treating female sexual dysfunction

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■ Privacy issues in organ donation

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CME Questions

CME subscribers: Please save your monthly issues with the CME questions in order to take the two semester tests in June and December. A Scantron form will be inserted in those issues, but the questions will not be repeated.

17. What coexisting medical condition will almost always make a patient ineligible for an organ transplant?
 - A. Diabetes
 - B. Cancer
 - C. Obesity
 - D. None of the above

18. According to our article, what should be a person's first genetic test?
 - A. Prenatal screening for cystic fibrosis
 - B. BRCA1 screening
 - C. A family history
 - D. None of the above

19. Which of the following is *not* true of most hospital group purchasing contracts?
 - A. Member hospitals are required to participate at 100%.
 - B. The contracts do not represent 100% of all the member hospital's supply-related contracts.
 - C. They are negotiated with the approval of advisory boards of medical professionals from member hospitals.
 - D. None of the above

20. According to the survey of women heart patients covered in this issue, what percentage of respondents reported dissatisfaction with their health care?
 - A. More than half of respondents
 - B. Less than 10% of respondents
 - C. More than 80% of respondents
 - D. None of the above

Answers: 17-B; 18-C; 19-A; 20-A

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