Too risky to transplant

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Patients who need organ transplants are dying even while viable organs are being thrown out, as government regulations have forced transplant centers to focus on overall survival rates instead of the well-being of individual patients.

The regulations were implemented by the Centers for Medicare & Medicaid Services in 2007 in response to a series of scandals and medical errors by transplant programs. CMS, the federal agency that oversees the Medicare program and pays for the vast majority of organ transplants in the U.S., opted to use an existing evaluation system developed by the transplant industry itself. The system tracks how many patients and transplanted organs survived at least one year after transplant.

But while the industry system relied on peer review and public disclosure to nudge programs toward improved outcomes, the CMS metrics carry real sanctions. Programs that get flagged for poor outcomes or low volumes twice within a 30-month period can be shut down or forced into a lengthy and expensive remedial process.

“The side effect has been to turn people risk averse,” said Dr. Dorry Segev, a transplant surgeon at Johns Hopkins Medical Center, “to the point where patients who would benefit from transplant are being denied transplants, and to the point where organs that are beneficial to patients are discarded.”

With the ongoing viability of their programs at stake, many centers have taken steps to limit their exposure. Some programs, especially those already flagged once and one step away from CMS action, declined to transplant higher risk patients that had lower odds of survival. They became reluctant to use older or slightly damaged organs that, while usable, had lower survival rates than standard healthy organs.

The result is that patients with even an 80 percent chance of surviving one or more years after a transplant present too great a risk for transplant programs. Centers decline to transplant them even as they are throwing away organs that could give those patients years of additional, good quality life.

Instead centers are “cherry-picking” patients for transplant, said Dr. Michael Abecassis, director of the transplant center at Northwestern University in Chicago.

“Patients might die and not get transplanted even though they may have an 80 percent chance of survival,” he said. “If the target is 90 percent, or you’re going to get flagged, you may look at 80 and say, ‘I’m not going to do that.’ Well, if you’re the patient it’s 80 versus 0. Then 80 is pretty good.”

Transplants plateau

Before the regulations went into effect, the number of transplants in the U.S. had grown each year. But in 2007, the first year centers were being held to the survival benchmarks, the number of transplants dropped and has remained flat ever since.

It is unclear how much of that leveling is attributable to the CMS standards. Organ transplantation is a complex field, affected by myriad players and factors. But anecdotal evidence suggests that centers have become more conservative in response to the new regulations, and that is creating a barrier for patients seeking transplants.

Elaine Herman of Weston, Fla., was denied a lung transplant at two centers where doctors worried that scleroderma, a connective tissue disease that damaged her lungs, could also lead to reflux in her throat. If she aspirated stomach contents into newly transplanted lungs, it could damage the organs, undermining the success of the transplant.

“These entities are very, very concerned about their long-term survival rates,” her husband, Neil, said. “They’re concerned that should their survival rates fall beneath a certain level, if they have enough adverse events, the government could temporarily or permanently shut down their program.”

Eventually, the University of Pittsburgh Medical Center, which performs a large number of transplants and can take a chance on a more complex case, successfully transplanted her.

With great geographical variation in the waiting times, patients often list at multiple sites, and those who are denied at one center shop for other programs that might list them. Studies show, however, it’s mainly affluent Caucasian patients who are able to travel, while lower-income and minority patients often can’t.

There is also the question of how much money the health care system wants to spend on patients at the end of life. A kidney transplant often saves money within two to three years, because patients no longer require dialysis. For other organs, it may take additional years of post-

transplant life for the system to break even. Still, patients and their doctors often spend thousands on last-ditch cancer treatments or other expensive treatments with a far lower success rate. Transplants represent a better return-on-investment, but the field is ultimately limited by the supply of organs.

Organ allocation

Moreover the regulations are skewing the carefully thought-out allocation system, designed to ensure fair access to organs for those who need them most, while making the best use of a limited resource. The transplant community has developed complicated evaluation scores and algorithms to determine who gets the next available organ. Those formulas are supposed to take doctors and centers out of the decision-making process to ensure fairness to patients and the best use of the available organs.

But there are two key decisions that remain in doctors' hands: who gets listed and whether to accept an organ when an offer is made.

Parameters for listing are determined by each center individually and are not overseen by industry or regulatory agencies. When a patient is recommended for transplant, he or she is evaluated by a team of specialists who then present their recommendations to a transplant committee. But that gives centers and their doctors great leeway in deciding whether a patient meets their listing standards.

"If you don't get on the list to begin with, it doesn't matter how you allocate the organ, you're not going to get a transplant," said Alexandra Glazier, vice president and general counsel for the New England Organ Bank and chair of the Organ Procurement and Transplant Network's Ethics Committee. "And it's the same argument with the acceptance or decline of the organ."

When donor organs become available, they are offered to programs that have matching candidates. But the transplant surgeons then have the discretion to decline the organ.

"In many individual cases, the surgeon is making the decision for their particular patient," Glazier said.

Centers aren't evaluated based on the patients they don't list, or even the patients who die on the waiting list. But a patient who dies after transplant is potentially a threat to the viability of the program.

"Your death on the waiting list, though it is a number that is maintained, it is not one which CMS has penalties for," said Dr. Andrew Cameron, a liver transplant surgeon at Johns Hopkins. "In that regard, you are encouraged

to cherry pick, even among the cherry-picked group that's made it onto the waiting list, in an effort to maintain one-year survival."

Expanding supply

Some in the transplant world argue that with a limited supply of organs, passing over higher-risk candidates for those with greater odds of living longer with the donated organ makes sense. But survival benchmarks also discourage centers from expanding the supply of organs by using lesser quality but still viable organs. In the 1990s, centers began using a category of organs, known as expanded criteria donor organs, defined as having only 70 percent of the survival rate of a standard kidney. So while standard kidneys have a one-year survival rate of 90 percent and last an average of 10 years post-transplant, ECD kidneys have a one-year survival rate of 82 percent and last an average of 5 years.

That could still represent a doubling of life expectancy for patients on dialysis, and might be a viable option for older individuals whose limited life expectancy might discourage use of a younger healthier kidney.

At the University of California, Los Angeles, Dr. Abbas Ardehali has a long history of matching older or higher risk patients nobody wants to transplant with marginal kidneys nobody wants to use. In 2008 he reported on 50 patients ages 65 to 72 receiving lung transplants. Eighty percent lived for one year, and 74 percent lived at least three years after transplant. Nearly half of the lungs transplanted were considered marginal in quality, organs that many other centers would typically reject.

"Some of the organs that are considered unacceptable might still be usable," Ardehali said. "The fact that we're using not-so-good lungs and putting them in older recipients that still turn out to be OK just proves the point."

Meanwhile, organ procurement organizations, the groups that recover organs from organ donors, are evaluated based on the number of organs they can procure from each potential donor. They continue to procure more of the marginal organs that wind up being thrown out because centers aren't willing to use them.

According to data from the Organ Procurement and Transplant Network, more than 4,000 organs were discarded in 2012, including some 2,700 kidneys, nearly 700 livers and 180 lungs. In that same year, 6,467 individuals in need of a transplant died on the waiting list.

Not all of the discarded organs were suitable for transplant, and in many cases organs were either not a match or too far away to transplant into individuals who could use them. But many believe the CMS regulations

are deterring programs from using these lower quality organs.

“Getting the right organ to the right person is not as simple as it sounds. But by the same token, a liver that’s gone in the garbage can that’s perfectly good for transplant? That’s crazy and that’s what we’ve got to stop,” said Dr. Peter Stock, a transplant surgeon with the University of California, San Francisco. “Any organ that goes into a waste bucket is someone who died.”

Declining offers

Yet marginal organs are routinely turned down, a trend many in the transplant industry say has increased under the pressure to meet the survival rate benchmarks. An analysis of organ-sharing data by surgeons at the University of California, San Francisco, found that 84 percent of patients who died waiting for a liver had received at least one organ offer and an average of six offers. Most were declined by the surgeons due to donor age or quality of organ.

“Wait-list deaths are not simply due to lack of donor organs as many of us assume,” lead author and transplant surgeon Dr. John Roberts said.

The CMS regulations have also had a chilling effect on research, as programs know that experimental protocols are likely to have lower survival rates until the new methods are perfected. Several centers have ceased doing clinical trials or abandoned more complex treatment protocols that don’t have as high a survival rate. That further limits the availability of organs and access to transplants.

The Johns Hopkins transplant program pioneered the practice of paired kidney exchanges where an incompatible live donor and patient are matched with another donor-patient pair. They also run the largest desensitization program for kidney patients with high levels of antibodies. By filtering out the antibodies, they are able to find matching kidneys for patients who would otherwise have little hope of finding a compatible donor.

Two years ago, Hopkins surgeons published research in the New England Journal of Medicine showing that people who undergo desensitization for live donor kidney transplant have twice the survival benefit at eight years than those who wait for a compatible organ from a deceased donor.

“If that were a chemotherapy agent, they would be lining up across the Atlantic,” Segev said. “What happened to us performing this service? We almost got shut down by CMS.”

It took nine months of often-tense negotiations to convince CMS to exempt those transplant patients from Hopkins' survival rate calculations. CMS officials now point to the Hopkins kidney program example as proof of the flexibility in the system.

"We on the ground, having gone through that, consider it a huge side effect," Segev said. "A lot of programs doing incompatible transplants stopped or drastically reduced their incompatible volume because of what was happening."

CMS didn't intend for any of that to happen. The regulations were aimed primarily at improving the quality of care at transplant centers. They ensure that centers have sufficient staff and robust quality improvement programs in place. And post-transplant survival rates have reached all-time highs.

"Individuals waitlisted in those programmes cited by CMS for subpar outcomes may face lower odds of receiving a transplant at least temporarily due to the tendency of such programs to reduce volume as they regroup to improve their outcomes," Thomas Hamilton, the CMS director of survey and certification wrote in a medical journal last year. "But people who do receive transplant from such programmes have much improved prospects for post-transplant survival."

The evaluation metrics also include some risk adjustment, to account for sicker or more complex cases. But surgeons say the system isn't accurate enough to truly offset the risks, and many programs have learned to avoid the types of patients for which the adjustments are inadequate.

Changing expectations

Transplant surgeons argue that additional lives would be saved if they could transplant more patients, even if overall survival rates dropped a bit.

"The transplant community feels there is a group that is high risk that they'd like to transplant that they aren't transplanting because of this need to generate benchmark outcomes," Cameron, the Hopkins liver transplant surgeon, said. "And I think the numbers would go up and that's probably what the public wants."

Surgeons should be allowed to use organs that are going to be otherwise discarded, he said, in order to give those critically ill patients a good shot at prolonging their lives.

"It will give a good result if we say that 60 percent predicted survival is acceptable for that patient," Cameron said. "It is stunning that we're not doing that right now, because 60 percent is a miracle to the family and

the doctors. It is unacceptable to CMS."

That's left transplant medicine as possibly the only place in health care where the doctor is not free to do what's best for the patient. While financial resources may limit what doctors can do in other areas of medical treatment, they can take long shots to help patients with no other option. The limited supply of organs precludes transplant surgeons from taking the same approach. But the CMS regulations may be making that shortage of organs even worse by insisting on centers achieving very high survival rates.

"If you have 5 percent or even 10 percent lower outcomes, you're still doubling people's life expectancy," Segev, the Hopkins kidney transplant surgeon, said. "Yet now I have to worry about my program, because if I don't worry about my program, then none of my patients will get transplanted."

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Photo caption: Dr. Andrew Cameron, far left, a liver transplant surgeon at Johns Hopkins Medical Center says more lives could be saved, if transplant centers weren't being held to strict post-transplant survival benchmarks.

(submitted photo)

Dr. Andrew Cameron, pictured far left, the surgical director for Johns Hopkins' liver transplant program, say: "All the programs have done the math and have determined that if your outcomes are trending low into a gray zone, the best way to get out of the gray zone is to go conservative. Whether we want to say that that is an appropriate correction ... or whether we see this as the problem, governmental scrutiny is resulting in fewer transplants and more conservative centers." Submitted photo