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Doing the Math

In the world of operations research/applied mathematics, researchers devise formulas to analyze and resolve real-life problems. With this in mind, transplant surgical fellow Dorry Segev asked his wife, mathematician Sommer Gentry, to help him develop an algorithm for a national paired kidney database. The goal: to figure out how to get the greatest number of kidneys to the neediest people—a concept mathematicians call “optimization.”

After doing some research, Gentry, who is completing her Ph.D. at the Laboratory for Information and Decision Systems at the Massachusetts Institute of Technology, found an algorithm that could be adapted perfectly to the paired kidney exchange situation. “If you have 100 people on your list and a lot of them could trade with others on the list, there are literally millions of different arrangements,” she explained. “But if you just go about matching pairs one by one without considering all possibilities [the current model], rare opportunities for hard-to-match pairs will likely be missed.”

Drawing from data describing end-stage renal disease patients eligible for kidney transplantation and their willing and eligible live donors, Gentry and Segev created virtual patients. The main outcome measures were number of kidneys matched, human leukocyte antigen (HLA) mismatch of matched kidneys and number of grafts surviving five years post transplant. When compared with current pairing schemes, the couple’s national PKE model showed that:

- more patients would be transplanted
- transplants made from the matches would be of higher quality (by antigens, by age, etc.)
- highly sensitized patients—the most vulnerable—would be well served by the system
- patients, physicians and transplant centers would have the flexibility of choosing which priorities are highest for the patient in the system (e.g., a patient

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Toward a National Paired Kidney Exchange



Janet Hiller tells Scott and Lisa Keller what to expect from the surgeries. The couple met at a dialysis center but hope they never have to visit one again.

SCOTT KELLER’S PATIENCE WAS wearing thin. The 31-year-old computer draftsman from Kalamazoo, Mich., has focal segmental glomerulosclerosis—a fancy name for hardened kidney tissue that thwarts the organ’s function. Keller’s wife wanted to give him a kidney, but antibodies from previous blood transfusions would likely launch rejection. Keller had been on dialysis for 15 years. With dialysis came extreme fatigue and osteoporosis, a common renal disease side effect.

While waiting for a cadaveric kidney, Keller heard about the paired kidney exchange program at Johns

Hopkins. Paired kidney exchanges (PKEs) provide organs to patients who have a willing, designated biologically incompatible donor. A kidney from this donor is matched to and transplanted into the recipient of a second donor pair, and vice versa. The transplants are performed simultaneously. Since 2001, 22 successful PKEs have been done at Hopkins Hospital.

Keller decided to find out if he and his wife qualified. “I just wanted to feel halfway normal again,” Keller recalls. They flew to Baltimore, underwent tests and joined the Hopkins database for potential pairing. A year later, though,

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The View from Here

Domino Effect

By Robert A. Montgomery, M.D., Ph.D.

SINCE THE FIRST KIDNEY TRANSPLANT 50 years ago, we've practically mastered the craft. But surgical precision won't fix the problem of too few available kidneys for a growing demand.

Out of desperation, many of us have morphed into organ donation activists—encouraging others to consider organ donation, vying for governmental support and sitting on UNOS committees to champion novel ways of matching potential kidney donors with recipients, who so badly need new kidneys. Thankfully, we've made progress.

On a very small scale here at Hopkins, we've had success matching potential donor/recipient pairs for kidney swaps. But the time has come to expand that pool. At a recent Chicago conference, I had the pleasure of meeting with 100 people who feel the same way. It was exhilarating to partner with transplant centers across the country to make the case



for a national paired kidney exchange (see lead story). A national database would offer hope to the tens of thousands of people in need of kidneys.

I'm well aware that such a plan could take years to implement nationally, and many hurdles have yet to be resolved. But we've started. News about the idea hit major newspapers and Web sites across

the nation. And the *Journal of the American Medical Association* published our paper on a kidney matching algorithm (see front-page sidebar).

Pairing kidneys is a slow, complicated process—even on a small scale. UNOS is the logical organization to administer such a plan nationally, but it's new terrain for them. They're used to managing cadaveric kidney matches. In the meantime, transplant centers in Ohio and New England have already decided to begin building a regional pool of potential donor/recipient pairs. We can only hope other regions will follow suit. ■

The Lure of Transplant Nursing

SHE'S SEEN IT ALL: deathly ill patients awaiting a liver or kidney, false starts—when a long-awaited organ is finally available but doesn't quite match—fear, excruciating pain, organ rejection. Yet, after more than 20 years in the field, abdominal transplant coordinator Denise Burrell-Diggs says she wouldn't trade in her specialty for any other.

"The advancements always keep you interested and hopeful. And every case has its own memorable story," she says. In how many specialties, wonders Burrell-Diggs aloud, can you have a lifelong relationship with patients, not to mention respect for your peers?

Currently, 13 abdominal (kidney and liver) nurse coordinators and 11 patient service coordinators (PSCs) share the workload. But it's simply not enough coverage for the endless calls and paperwork as more patients flock



Denise Burrell-Diggs fields calls throughout the day from post-transplant patients.

to the CTC, admits Burrell-Diggs. With about 35 active patients and some teaching duties, she has good reason to feel overwhelmed. "It can get frustrating," she says. "My husband and daughter don't always understand why I can't come home at a normal time."

Every day, Burrell-Diggs speaks to post-transplant patients. She hears about their problems after the transplant

and how the drugs they'll take for life are affecting them. Meanwhile, they want answers to questions like: How much contact may I have with my sick child? I misplaced my meds—what should I do? I was exposed to a live vaccine—now what? And then the more troubling questions: Would you please write a letter to the phone company asking them not to cut off my service? Intervening in such dire situations, Burrell-Diggs

says, makes her feel like she plays a vital role in patients' lives.

Kathryn Dane's career as a transplant nurse coordinator began with a fascination with renal disease. A dialysis nurse for 12 years, she saw lives improve dramatically as more patients received kidney transplants. Eager to be part of medicine's newest frontiers, she joined the Comprehensive Transplant Center in 1997. Since then, Dane has conducted hundreds of "pre-evals" on kidney and pancreas patients. She sometimes visits them in dialysis clinics, answering innumerable questions. Increasingly, Dane, who recently joined the Incompatible Kidney Transplant Program, also screens potential living kidney donors.

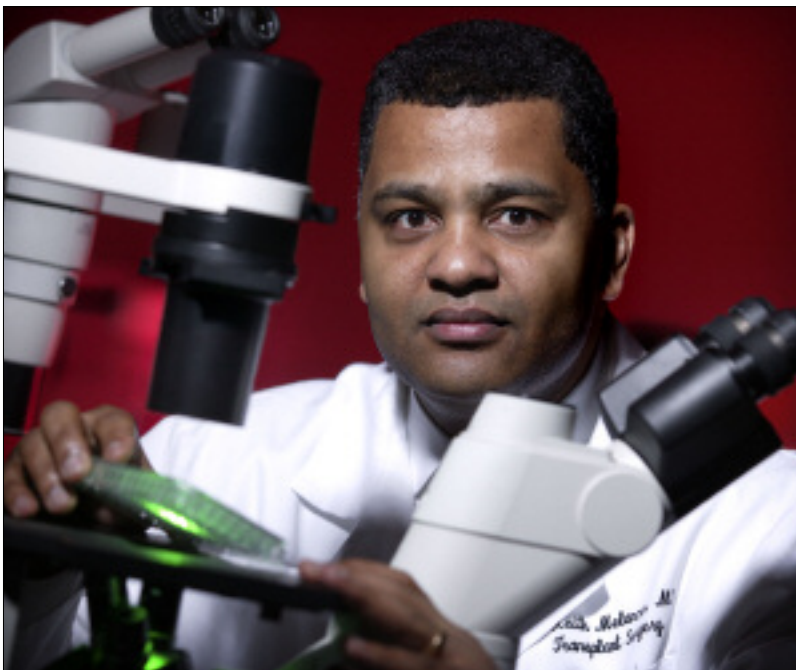
Dane is often more teacher than caregiver, always anticipating questions people might ask about the transplant process. She, too, struggles to keep up with the daily calls. Yet, like Burrell-Diggs, she's never considered any other kind of nursing. "We're in the forefront of new developments, like sensitized donors and paired kidney exchanges. It doesn't get more exciting than that." ■

Research Notes

Rejecting Rejection: New Director Aims for Tolerance

THE HOLY GRAIL of transplant surgery," says Keith Melancon, Hopkins' new director of pancreas transplantation, "is tolerance"—meaning, of course, the ability of organs to stave off rejection. Yet tolerance may come with a price, namely the nasty side effects accompanying the very immunosuppressants bringing it. Steroids, for example, long standard post-transplant fare, may leave patients struggling with hypertension, appearance changes, osteoporosis and even diabetes.

Several years ago, Melancon (pronounced Milan-SAN) and other transplant surgeons began to question whether drugs like steroids were worth their costs to patient health. Before joining Hopkins last July, Melancon helped conduct the clinical studies at the University of Minnesota that eventually removed them from kidney transplant patients' drug lineup. He found that those patients who early on ingested high doses of drug cocktails—including steroids—before being weaned off them did well. "You give patients the high doses early to knock out the immune system," he says. Survival rates after this "induction therapy" were high, and rejection was thwarted just as effectively. A follow-up study three years after surgery showed 95 percent patient survival.



Keith Melancon: In search of successful anti-rejection drug cocktails without devastating side effects.

In his new role, Melancon, 36, continues to weigh drug risks versus benefits for kidney patients, but he's especially interested in finding ways to improve pancreatic transplant patients' tolerance. Pancreas demand has mushroomed worldwide, in sync with the rise in diabetes. Last quarter, Hopkins surgeons performed 12 pancreatic transplants—three times as many as last year.

But pancreas patients are the hardest population to treat, Melancon explains, be-

cause their longstanding type I diabetes brings advanced vascular and heart disease, with far more potential complications. He's determined to improve outcomes for these patients. And what frustrates Melancon most is giving newly transplanted pancreas patients anti-rejection drugs that might ultimately cause diabetes—the very disease he's tried to eradicate with a transplant.

Working closely with CTC Director Robert Montgomery, Melancon has focused on characterizing and treating humeral—or antibody-mediated—pancreas rejection, a type more likely to occur in diabetics and patients with other medical complications. By adapting Montgomery's kidney plasmapheresis model—a system that cleanses blood

of rejection-causing antibodies—in rats, the two transplant surgeons and their research team have made some headway recently in keeping the pancreas healthy. "We think highly sensitized pancreas patients can benefit from plasmapheresis, too, but it's never been done before," Melancon says.

Then there's the search for alternatives to whole-organ pancreas transplants, such as injecting insulin-producing islet cells directly into a recipient's liver. Though the procedure avoids the trauma of surgery, islet cells are

difficult to obtain and, like their parent organs, face rejection. None has been successful yet. But Melancon hopes to set up laboratory tolerance models in more complex animals to find out why some animals accept islet cell transplants better than others, leading to human approaches.

In collaborating with scientists who've worked with stem cell pioneer John Gearhart, Melancon hopes insulin-producing stem cells they study may replace pancreas or islet cell transplants. Not only are stem cells replenishable, but because they are not fully mature, they lack the fully formed antigens that would normally lead to rejection. They could be the ultimate solution, he says, to the problem of tolerance.

—Katherine Unger

Joseph "Keith" Melancon

Born: 1969, Lafayette, La.
Education: M.D. and surgical residency, Tulane University. Multi-organ transplantation fellowship, University of Minnesota
Family: Wife, Lisa, three sons

KIDNEY, LIVER & PANCREAS *Outreach*

A Liver Program for the 21st Century

ABDOMINAL TRANSPLANT surgeon Warren Maley has had a circuitous route back to Hopkins. His four-year hiatus began in 2001, when he left East Baltimore to join a general and vascular surgery practice in Pittsburgh. But instead of finding fulfillment in the private sector, he discovered he missed transplant surgery—more than he could ever have imagined.

A good friend at Louisiana State University at Shreveport persuaded Maley to join him there to assist with abdominal transplants. Maley signed on at LSU in 2003. Not long after Maley arrived in Shreveport, Bob Montgomery was named CTC director. The two surgeons had a good relationship, and Montgomery knew Maley's departure was a huge loss for Hopkins.

Last fall, Montgomery called Maley and urged him to return, this time to head up the liver program. Intrigued by the opportunity to focus on liver transplantation—his favorite specialty—and knowing how much his family had missed Baltimore during those four years, Maley, now 46, agreed to come back.

Are you here to stay?

I certainly hope so. I'm thrilled to be doing what I love best—taking care of patients, doing procedures, seeing people go from deathly ill to vibrant after a liver transplant.

What are your goals as new director of liver transplantation?

To shore up the service, especially the living donor liver program. So many more people can be helped. Unfortunately, the tragic loss of a donor life at Mt. Sinai Medical Center a few years ago frightened everyone. Yes, we must continue to be vigilant about safety, but we also need to move forward—even push boundaries.

How do you mean?

When I was in medical school in Pittsburgh, I spent a month on the liver transplant service with Tom Starzl, who pioneered this field at a time when cyclosporin wasn't around to keep organs viable. Up until the late 1970s, the survival rate for liver transplantation was only about 20 percent. So you have to wonder why Starzl took such risks. But if he hadn't, we'd know nothing about liver transplantation. And look how many lives he saved.

You and former CTC director Andy Klein performed the first Hop-



Warren Maley (right) catches up with Bobby (left) and Eric (center) Hansberger, six years after Eric donated part of his liver to his father.

kins adult-to-adult liver transplant in 1997. Would that be an example of “pushing boundaries”?

Exactly. To this day, I'm still in awe that they [51-year-old recipient Kathleen Reilly and her 22-year-old son Daniel, the donor] believed we could do it. We had never done it before! I get emotional just thinking about that kind of trust. But we assured them we could, and I knew we could. They did well, and we've done many more since.

The United Network for Organ Sharing requires two surgeons trained in liver transplantation in the OR. Who accompanies you?

Bob Montgomery has been doing both kidney and liver transplants, and he's now assisting me. He went to Korea to gain additional experience in living donor liver transplantation. [Globally, Korea and Japan do the most living donor liver transplants.]

Do you think living donor liver donation is now safe?

For the most part, yes. Across the world there have been nine donor deaths. In the best of hands, there's still a 0.3 percent mortality risk. That doesn't sound like a lot, but we'd like it to be better.

The CTC's focus has long been on deceased donor liver transplants. Why the big push for living donor transplantation?

That's true—our mainstay is cadaveric transplantation, and we have excellent outcomes. But we still have patients dying on the waiting list because there are too few deceased donors. Every living donor transplant means one less person on the cadaveric liver waiting list. ■

Kidney Exchange

(continued from page 1)

the search had turned up no matches. Contributing to the delay was the dearth of potential donors in the database. How to expand this pool has been a riddle the Comprehensive Transplant Center has long sought to solve.

Now, CTC director **Robert Montgomery** is on a mission to bring together leading transplant centers to launch a *national* paired kidney exchange. The United Network for Organ Sharing approved a proposal



Dorry Segev and Sommer Gentry: The pair behind the pairing scheme.

last fall for such a program. And in March, the inaugural consensus-building meeting took place in Chicago. Subsidized by Margery Pozefsky, a patient who benefited from a transplant at Hopkins, the conference was the first joint effort to launch a national PKE plan.

Leading the program with Montgomery were several other live kidney transplant pioneers, including incoming UNOS president Frank Delmonico of Harvard University, Lloyd Ratner of Columbia University, Michael Rees of Medical College of Ohio, and E. Steve Woodie of the University of Cincinnati. In all, about 100 surgeons, nephrologists, nurse coordinators, regulators, psychiatric professionals, social workers, and informatics and database ex-

perts shared best practices at the two-day meeting.

“The payoff in making these matches is huge,” Montgomery said, as he rattled off alarming statistics. Currently, 60,000 Americans are awaiting kidneys; 3,718 people died last year because suitable organs couldn’t be found in time. But even when there’s a willing kidney donor pair—as in the Kellers’ case—almost a third of potential donor/recipient pairs won’t match because certain antibodies could jeopardize an organ’s survival. “Every day, it’s like looking for a needle in a haystack,” says Janet Hiller, transplant nurse coordinator, a.k.a. “the kidney matchmaker,” for the Incompatible Kidney Transplant Program.

The Hopkins Immunogenetics Lab has long had a computer program that facilitates difficult tissue type matches to potential donors. But, admits Co-Director Sue Leffell, the pool isn’t large enough to match the growing number of people with rare antigens. Instead, many patients opt to

undergo plasmapheresis—the blood filtering process that removes harmful antibodies—so that a loved one with an incompatible blood or tissue type can donate. “By swapping donors from a bigger pool,” Leffell notes, “we can avoid the risks and expense of desensitization protocols for some patients.”

Leffell represents Hopkins on the UNOS Kidney and Pancreas Transplantation Committee, which approves allocation of those organs—and the first committee to endorse a national PKE proposal. Leffell believes one important goal of the plan is to set uniform standards for immunologic testing. “That would eliminate confusion and complications when pairs must travel for matches,” she said.

Immunologic disparities are but one

barrier to creating a national PKE database. Other obstacles include patients’ insurance coverage and willingness to travel, and the availability of plasmapheresis at other centers for those who need it. Ethical and psychosocial issues arise as well—like feeling no emotional connection to a recipient.

Yet, insisted Montgomery, the benefits of a national PKE database far outweigh the barriers. To prove the point, the CTC hired mathematician Sommer Gentry to develop an algorithm (see sidebar), making the most of combinations while respecting patients’ preferences. Meanwhile, focus groups at the conference analyzed obstacles and offered possible solutions.

Hiller hit numerous snags as she tried to match the Kellers with another donor/recipient pair. In the end, she made an unconventional but successful one-on-one match with a man who suited Scott genetically but who had a different blood type. Keller needed to have his spleen removed and plasmapheresis before the transplant, but his prognosis is good.

In May, as Scott received the new kidney, his wife donated one of hers to another compatible recipient. And Hiller had found a third pair to match that day. It took a little longer to orchestrate all this, but, in Hiller’s view, prolonging life for several people simultaneously was worth the extra effort. ■

The Math

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who prefers to stay within his own region but who might travel for a better organ.)

Shortened wait times are obvious benefits of a national PKE plan. But the financial incentive is also noteworthy. “Even if only 7 percent of patients awaiting kidney transplantation participated in a national PKE,” Gentry argued, “the health care system could save as much as \$750 million.” ■

Segev and Gentry are lead authors of a paper on the subject, which appeared in the April 20 issue of the Journal of the American Medical Association.

HEART & LUNG *Outreach*

New Lungs Now Will Go to the Neediest

AS OF THIS SPRING, the United Network for Organ Sharing is giving priority for lungs based on severity of illness and projected outcome, not accumulated time on the waiting list. With only about 1,000 available lungs a year for the 3,750 people waiting (2002 data), UNOS wants to ensure they go to those who need them most and with the best chance for survival.

The concept of moving the sickest patients to the top of the list is not new. It's based on the UNOS model for end-stage liver disease (MELD) liver allocation system. With the lung allocation system, UNOS assigns each patient a score, factoring in medical urgency and potential for post-transplant success—what UNOS calls “net transplant benefit”—calculated from diagnostic tests. The higher the score, the higher the priority for lung offers. Tests are repeated at least every six months to reassess the patient's status.

Why change the old system? The answer is simple, says UNOS: A system based on wait time alone severely disadvantages patients with certain lung disorders that lead to rapid death. Of course, the change is controversial. Many who have been waiting their turn will now move down on the list.

Seth Kramer received a transplant in 1999, after waiting his turn. Now 31 and in good health, Kramer appreciates why UNOS revamped the system. Yet he's torn. There's no question that the new plan makes better use of the limited number of organs available, Kramer says, “but my heart goes out to people who've waited a long time and suddenly are bumped down on the waiting list.”

“We get attached to people like Seth Kramer,” says lung transplant coordinator Terri Cook, who with colleague Gina Pace is spearheading Hopkins' transition to the new system. “It's hard to say no to them after they've waited so long.” On the positive side, she adds, the frequent retesting patients must undergo might move them back up on the list. The transplant team tries to identify people who are sick enough to be transplanted but not so sick that they won't have a good survival rate.

Required diagnostic measures for the new program include distance covered in a six-minute walk, forced vital capacity—the amount of air one can breathe out after breathing in as deeply as possible—and the New York Heart Association functional status classifications, which measure the effect lung disease has on performing daily activities.

As transplant centers across the country scramble to comply with new UNOS requirements, most transplant physicians and nurses are optimistic. “The basic premise of the new plan is fair,” says Director of Lung Transplantation Jonathan Orens. “Patients should understand that the UNOS formulas for different diseases preclude bias. The computer calls the shots.”

That's not to say there aren't flaws.



Transplant coordinators Gina Pace (left) and Terri Cook review a lung patient's status, based on the latest test results, with Jonathan Orens.

Test results will naturally vary among lung disease groups. UNOS has tried to account for variations, yet some patients feel disadvantaged because test data may not paint the full picture of how well they might fare with a transplant. A patient who cannot walk very far on a six-minute walk test, for example, isn't necessarily a poor candidate for a lung transplant.

Hope, Kramer says, lies in the constant evaluation process at UNOS, where he represents the patient perspective. Kramer, who was considered a high-risk candidate for transplantation, says the situation is much more complicated for lung patients, who have higher mortality than those in other organ groups. Ultimately, observes the young lawyer, “we have to ask ourselves if it's more equitable to have patients wait their turn—a concept they all too well comprehend—or to have a system that more objectively makes better use of organs.” ■

On the Path of a Killer: Familial Cardiomyopathy

GIVEN HER FAMILY HISTORY, Becky Galica, 42, feels lucky to be alive. Born with an enlarged heart with abnormally thick walls—a condition known as hypertrophic cardiomyopathy—she’s been monitored like a hawk all her life, with good reason. Galica’s younger brother died suddenly at 14 from the same disease, and their father had two heart transplants before his death at 59. Of her three siblings, only one sister was born with a healthy heart.

Nine years ago, after enduring catheterizations, long-term medications, congestive heart failure and a difficult pregnancy, Galica received a heart transplant at Hopkins. Today she holds two jobs and lives with her 17-year-old daughter, Emily, who appears to have a normal heart. Still, Galica is vigilant about follow-up appointments for both of them, hoping testing will detect abnormalities before they take an unexpected turn.

And that—in a nutshell—is the goal of the Johns Hopkins Familial Cardiomyopathy Initiative: to slow the progression of a disease that has no cure and to detect a genetic predisposition for it. Director of Transplantation Robert Montgomery launched the program in 2002, in memory of his brother and father, who died suddenly from cardiomyopathy. “An important part of my life is helping other families devastated by this disease discover that it is treatable,” he says. “They don’t have to live in fear of the next tragedy.”

Cardiologist Dan Judge, who oversees the program, works closely with genetic counselor Nicole Johnson to monitor patients at risk for several known types of familial cardiomyopathy. All its forms interfere with the heart’s ability to pump blood. Galica had heart walls that were too thick, but 36.5 of 100,000 people have abnormally thin heart walls, not due to coronary artery disease—known medically as idiopathic dilated cardiomyopathy.

A third of Americans with idiopathic dilated cardiomyopathy have a

familial form of the condition, Judge says, but it’s alarmingly underdiagnosed. It is established when at least two family members have been diagnosed with cardiomyopathy. “Our mission,” he says, “is to increase recognition of familial heart disease so we can treat it aggressively.”

So far, Judge and Johnson have seen about 90 families from around the world, referred here for heart failure. Although there’s no drug to cure advanced heart failure, early recognition of poor heart function without symptoms can be treated with ACE inhibitors and beta-blockers—drugs proven to delay congestive heart failure and the blacking out that typically sends patients to emergency rooms. Medicine is the first line of defense, followed by more drastic measures, like pacemakers, cardiac surgery and transplant, as a last resort.

The psychological impact of the disease can be as profound as the physical

setbacks. And, insurance companies are often reluctant to provide coverage for tests and long-term management. Johnson advocates for these families and helps them absorb the devastating news that they or loved ones have the disease. She’s one of a handful of certified genetic counselors working primarily with cardiovascular conditions. “The very awareness of the disease can help patients take charge of their lives and save other relatives,” Johnson says.

Becky Galica is finally well enough to take charge of her life. She’s paid a heavy price. Eight months after her transplant, she developed lymphoma. Chemotherapy damaged her bones so much, she needed two hip replacements. “It’s been so tough on Emily,” says Becky, who plans to marry next year. “At least I know she can get physical and emotional help from the cardiomyopathy program if she needs it.” ■



Cardiologist Dan Judge and genetic counselor Nicole Johnson monitor patients with a strong family history of cardiomyopathy.

Outreach Calendar

For more information, call the Comprehensive Transplant Center, 410-614-5700

Transplant Educational Support Groups

MULTI-ORGAN EDUCATIONAL SUPPORT GROUP

Be as Healthy as You Can Be: Learn about nutrition, exercise and healthy living

July 12, 2005, 7 p.m.

Cader Room, Harvey 508
Refreshments served

MULTI-ORGAN EDUCATIONAL SUPPORT GROUP

Transplant Surgery: What to Expect: from the phone call, surgery, hospital and immediately post transplant

October 18, 2005, 7 p.m.

Cader Room, Harvey 508

MULTI-ORGAN EDUCATIONAL SUPPORT GROUP

Multi-Organ Patient Panel: hear from patients from each organ group about their transplant experiences

November 15, 2005, 7 p.m.

Cader Room, Harvey 508
Refreshments served

Seminars/Conferences

SEVENTH ANNUAL UPDATE IN PULMONARY AND CRITICAL CARE MEDICINE

July 23 – 27, 2005

Eldorado Hotel
Santa Fe, N.M.

PERIOPERATIVE MANAGEMENT

August 15 – 18, 2005

The St. Regis Aspen Hotel
Aspen, Colo.

HEPATO-BILIARY UPDATE

September 10 – 11, 2005

Hyatt Regency Hotel
Cambridge, Md.

Outreach Events

TISSUE TYPING: A PRIMER

June 22 – 23, 2005, 5 p.m.

Johns Hopkins
Immunogenetics Lab

NATIONAL MINORITY DONOR AWARENESS DAY

August 1, 2005

Details to follow on
Web site.

“GIFT OF LIFE” CTC ANNUAL HOLIDAY PARTY

December 5, 2005, 6–8 p.m.

Turner Concourse
Hopkins Hospital

Physicians are welcome to attend all educational and outreach events.

OUTREACH

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Editor/Writer:

Judith Minkove

Contributing Writer:

Katherine Unger

Photography:

Keith Weller

Designer:

Max Boam

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