

“The Institute of Medicine is supporting the view that we’ve held all along about the importance of the NBTF.”

ing or even firmly estimated the cost of the facility. Advocates of NBTF hope the new report will speed things up. “It’s the first time a panel of experts without a vested interest in medical isotope production has come out saying this facility is necessary,” said David Nichols, a government relations spokesman for SNM and ACNP.

DOE Urged to Drop Molybdenum Plans

While the authors of the report cited the need for a new accelerator, they also recommended that the government drop plans for producing ^{99}Mo , the “parent” of the reactor-produced $^{99\text{m}}\text{Tc}$ radiopharmaceutical. All U.S. hospitals rely on a single source for molybdenum: a reactor operated by the Canadian government. The emergency shut-down and narrowly averted strike that occurred a few years ago at the Canadian reactor in Chalk River, Ontario, have stirred unease among nuclear medicine physicians. They question the wisdom of relying on a sole supplier for a product vital to their practices.

But the Institute’s panel came to a different conclusion after interviewing representatives of the leading radiopharmaceutical firms in the U.S. In the report, they stated they were convinced that the molybdenum situation “is no longer precarious.” More specifically, they concluded that production of reactor-produced radionuclides, including ^{99}Mo , is sufficient at least in the short term. “Radiopharmaceutical companies state that the present domestic and foreign suppliers are reliable and have or will soon sign long-term supply contracts with existing producers,” the report stated.

As it stands now, the Institute of Medicine’s experts estimated that the DOE’s Office of Isotope Production and Distribution would need between \$10 million and \$20 million to outfit a reactor at Sandia National Laboratory as a back-up supplier of molybdenum. The panel stated flatly that the money would be better spent on beefing up university research reactors to ensure the supply of reactor produced radionuclides other than molyb-

denum. The University of Missouri Research Reactor Center (MURR) earned special mention in the report. Of all the university research reactors, the authors noted that only MURR currently makes substantial quantities of radionuclides for research on medical diagnostic and therapy agents.

Despite these recommendations, Owen Lowe, the director of DOE’s isotope production program, said the government may yet produce ^{99}Mo again. “The Institute of Medicine report has a different view of the need for a back-up source for molybdenum than those in the medical community who have expressed their concern to us,” Lowe said. “We have to take [the Institute of Medicine’s] recommendations seriously into consideration and explore the basis for that recommendation. In the meantime, we will go ahead with the project.” Current DOE plans call for producing molybdenum at a research reactor at the Sandia National Laboratories. DOE officials have estimated they’ll need about \$11.4 million (on the lower end of the panel’s estimates) to modify Sandia’s Annular Core Research Reactor for medical isotope production.

Next Hurdle: Budget Politics

Just days after the Institute’s report was released, the Clinton Administration announced plans to squeeze \$10 billion out of the Energy Department. The news has some nuclear medicine experts concerned that—despite all the logical arguments to be made—the NBTF and other radioisotope production plans could die under the budget ax. Nichols said a lot will depend on future estimates of what the NBTF will cost. Nichols said he sees no indication that the DOE’s medical applications and medical isotope production are more vulnerable than other DOE programs. Still, he acknowledges that gaining funds for an ambitious new facility won’t be easy. “It’s one thing to have a report endorsing radionuclides from the Institute of Medicine, but it’s quite another to get a strong endorsement from Capitol Hill.”

J. Rojas-Burke

NUCLEAR RENAL SCAN OFFERS HOPE TO TRANSPLANT PATIENT

RANDALL CURLEE SUFFERED FROM advanced diabetes for years and knew the day would come when he would need a new kidney. The 46-year-old marketing director’s malfunctioning kidneys already contributed to his heart disease, circulatory problems and extreme

fatigue. His doctors told him a new kidney would help control many of his medical problems and that he could die without one.

Curlee is just one of thousands of patients in this country who need kidney transplants. But his story made national news when doctors discovered that

his fiancée, Victoria Ingram, 45, had a kidney that was a perfect match for donation. The drama heightened after a routine test injured one of Ingram's kidneys and threatened the transplant. The transplant team recommended a nuclear renal scan to see if the injured kidney was still functioning properly. The result would determine whether the transplant was viable.

An estimated 440,000 nuclear renal scans are performed each year in the United States, but only a small number of these are performed on kidney transplant donors, said Andrew Taylor, MD, professor of radiology and codirector of nuclear medicine at Emory University School of Medicine in Atlanta, Georgia. Nuclear physicians have been doing renal scans since the 1950's to evaluate functional problems such as an obstruction or reflux in the kidneys. They also commonly perform the scans on transplant recipients to monitor blood flow and make sure the kidney is working properly. However in most hospitals, kidney donors don't have renal scans before the transplant—unless a complication arises.



Victoria and Randall Curlee at their wedding in the chapel at Sharp Memorial Hospital in San Diego.

A Match Made in Heaven

The only complication on Curlee's and Ingram's minds when they first met involved real estate. Curlee walked into an open house sale and enlisted Ingram, a real estate agent, to sell his own house in Orange County, CA. The house successfully sold, Ingram and Curlee starting dating and became engaged last February. A few weeks later, Curlee found out he needed a kidney transplant as soon as a match could be found. Since his immediate family members were unsuitable candidates for donation, he put himself on the national waiting list and was told one probably wouldn't be available for at least three years. Ingram decided to see if she was a match for her fiancé although doctors discouraged her saying her chances were slim.

"Looking at Randy was like looking death in the face," Ingram said. "I knew he wouldn't have survived the wait on the national list." She insisted on being tested as a possible candidate for donation, and by sheer luck she was.

Wanting to make her wedding ceremony more symbolic, Ingram decided to push up the wedding before the transplant took place. And what better place to get married, the couple decided, than the chapel in the Sharp Memorial Hospital in San Diego where the transplant was going to be performed

the next day. About 20 friends and family came to the ceremony as well as dozens of reporters and television cameramen. "I think our situation lifted people's hearts and made them realize you don't have to die to be a donor," said Ingram (who now goes by the name of Curlee). She had hoped to encourage other donors with her wedding present.

A day after the wedding and two hours before the transplant was to have taken place, a radiologist at Sharp Memorial performed a routine angiogram on Ingram, threading a narrow catheter tube through her renal arteries to ascertain their location and placement and whether there were any anatomical abnormalities. During this procedure, he accidentally nicked a small accessory artery in Ingram's left kidney, partially compromising the blood supply to a lower area of the kidney. "My doctors told me there was 25 to 35 percent chance that I would not be able to donate a kidney to my husband," Ingram said.

Enter the Nuclear Renal Scan

Ingram had two options: She could wait a month to see if the injury would heal on its own, or she could have a nuclear scan performed immediately to evaluate the extent of the injury. "My wife insisted on having the nuclear scan that same day," said Curlee. "We were both nervous and didn't want to wait several weeks to find out if the transplant would be possible."

To determine the perfusion and function of both kidneys, William Carter, MD, director of nuclear medicine at Sharp Memorial performed the nuclear renal scan. He decided to do the scan using ^{99m}Tc MAG3 (10 mCi) injected intravenously into the patient. He did rapid sequential imaging during the vascular phase and then delayed imaging through 45 minutes during the perfusion phase. Carter said he chose the newer radionuclide MAG3—over more commonly used radionuclides like ^{99m}Tc DTPA—because he has had good results with it in his experience.

The transplant team had speculated that, worst case scenario, the left kidney would die as a result of the nicked artery. But the nuclear scan showed both kidneys equally filled up and the drainage went into the bladder perfectly, according to Carter. He reported the good news to the Curlees. "I think it was important to offer a non-invasive test to a patient who has undergone an invasive procedure with a complication," said Carter. "The renal scan wasn't painful, and the result reassured the couple that the transplant could take place."

With all the advantages of the renal scan, logic would dictate that hospitals perform it on all trans-

plant donors in addition to performing angiograms. After all, a typical renal scan costs between \$300 and \$500, which adds little to the cost of an angiogram averaging \$1,500 to \$2,000. However, the utilization of renal scans varies from hospital to hospital. Most perform renal scans on transplant recipients to evaluate the functioning of the new kidney. The evaluation of transplant donors with renal scans, on the other hand, isn't standard practice at many hospitals.

For example, surgeons at Sharp Memorial perform 65 to 70 kidney transplants and an estimated 250 renal scans a year. Although nuclear physicians routinely give renal scans to transplant recipients, they almost never perform them on donors. "The Curlees's case was one of the few times I've ever performed a nuclear renal scan on a donor," Carter said. The protocol for doing nuclear renal scans depends solely on the practicing techniques at individual hospitals. Unlike Sharp Memorial, Emory University Hospital routinely administers an angiogram and a nuclear renal scan to all kidney donors. "The scan tells us a lot about the functioning of the kidney," said Taylor. "It can show if one kidney has a lower level of functioning than the other or if there is a prob-

lem that would impede transplantation."

After she had the original renal scan, Ingram received another scan the day of the transplant to monitor blood flow in the renal arteries. Originally scheduled for October 12, 1994, the transplant was finally performed successfully on November 9. Without the results of the nuclear scans, Curlee's transplant would have been delayed for at least a month or more, said Robert Mendez, MD, renal transplantation director at Sharp Memorial.

Since the transplant, Curlee has received periodic nuclear scans, which all indicate his new kidney is working properly. Curlee said he now feels great, has energy and is able to look forward to a healthier future. He has even volunteered to enter an islet cell transplant study to see if the experimental treatment can reduce the severity of his diabetes. As for Ingram, she is thankful she was able to give her husband the wedding present of life and is looking forward to future prospects. She's participated in several television and newspaper interviews, and she may be immortalized on the silver screen. "Disney has approached us about buying the rights to our story!"

Stacey Silver

COMMENTARY — Part 2

THE NUCLEAR MEDICINE INDUSTRY: STRATEGIES FOR SURVIVAL



Peter C. Vermeeren

IN ORDER TO SURVIVE, THE radiopharmaceutical industry must make some fundamental changes during the remaining half of this decade. The road to change will be difficult since there are no simple solutions to the fundamental economic problems we're facing. However, with some innovative thinking, we should be able to strengthen the industry's prospects. The following six strategies may serve as a useful starting point for assuring the survival of the

nuclear medicine industry through the 1990s and into the next century:

1. Innovative products, not volume: We need to focus on the profitable sale of innovative, proprietary products—not on increasing the sales volume of low margin or unprofitable generic products. This strategy cannot be achieved through marketing efforts alone: It requires continued, prudent investments in research and development activities; accelerated regulatory approval processes to reduce overall cost-to-market; a product

focus that concentrates on effective therapeutics and patient management improvements; and close cooperation between companies and scientists in academia.

2. A unified vision: All the players in the industry—both physicians and scientists as well as manufacturers and suppliers—must work toward a common vision of nuclear medicine's role in health care. In order to create this vision and communicate it effectively, all the players must be willing to participate in open and honest discussions. For example, it's essential that brilliant scientific ideas are challenged by people with aggressive business instincts. It's also vital for equipment companies and radiopharmaceutical suppliers to harmonize their development activities in order to ensure that equipment and software will be available when new imaging products are introduced.

3. Cost/benefit studies: These studies must be undertaken to prove that nuclear medicine procedures are both more useful and more cost-effective than other modalities. Similarly, studies must be conducted to show that nuclear medicine procedures reduce costs by permitting early diagnoses thereby avoiding the need for invasive exploratory surgery. In addition, the industry should fund studies to prove the cost/benefit