

WILL NUCLEAR MEDICINE SURVIVE OUTSIDE THE U.S.?

As U.S. nuclear medicine faces a tidal wave of troubles, the specialty must be in calmer waters in other parts of the world. Think again.

WITH THE INCREASE IN MANAGED care, turf wars and the regulation of radiopharmaceuticals, many nuclear physicians in this country may have dreamed about opening a practice in another part of the world. Sadly to say, the grass is not always greener. Nuclear physicians in some Westernized countries are bogged down by socialized medicine, which leaves them waiting months or even years for a new gamma camera. Others must deal with regulations in their use of medical isotopes that make the NRC's policies look like Newt Gingrich's anti-regulatory vision.

Nuclear physicians in foreign nations must also contend with problems familiar to their American counterparts. They're having trouble getting referrals from colleagues in other specialties who simply do not know what the tracer and scanner can do for patients. The good news is the dark side of nuclear medicine in Europe and Asia has led many nuclear physicians to action. For instance, German and French nuclear physicians are seeking out referrals by educating their colleagues at conferences and symposia.

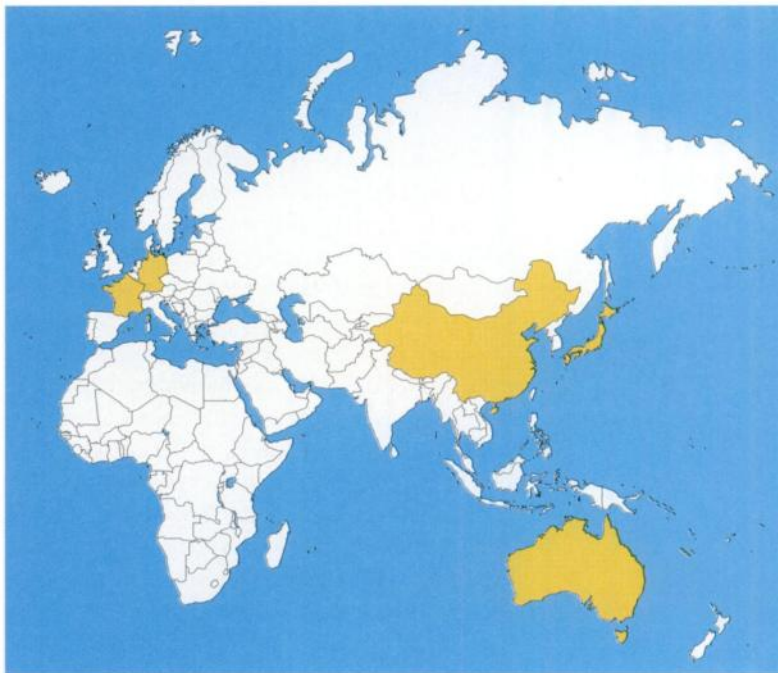
Interestingly, low-level waste disposal does not pose much of a problem in the day-to-day practices of nuclear physicians in other countries since most storage sites are owned and run by their federal governments. In Japan where space for waste is most scarce, a special nonprofit society collects materials from hospitals and transports them to storage sites. Doctors from each of the five countries highlighted (Australia, China, Japan, Germany and France) are facing issues unique to their country as well as universal dilemmas that all nuclear physicians contend with in their daily practices.

Shortage of Gamma Cameras

The biggest issue for French nuclear physicians

is the scarcity of gamma cameras. "We do 10,000 examinations per year with only four gamma cameras," said Serge Askienazy, MD, head of the department of nuclear medicine, Hopital Saint-Antoine in Paris. At the private Centre D'Imagerie Nucleaire, in St. Etienne, just two cameras take 8,000 pictures annually, said Eric Gremillet, MD, a nuclear physician who practices there.

The French Ministry of Health has a tight rein on the number of gamma cameras that it allows hos-



Australia, China, Japan, Germany and France are as diverse in their practice of nuclear medicine as they are in their geographic locations.

pitals to purchase. Buying a new camera requires government approval. "I need to show that I have the money, and then I have to get the permission of the local administrative network for my region of France. From there, it moves to the Ministry of Health where the final decision is made," said Askienazy. "Even if I just want to replace an old gamma camera, I need to follow all the procedures."

For the patient, this means delays of three weeks for a bone scan, two weeks for a heart scan and "something like six weeks for a thyroid scan," said Askienazy. Gremillet said his center must stay open 70 hours a week in order for physicians to complete all imaging sessions on just two cameras. Such is the difficulty in obtaining new cameras that nuclear medicine centers, for the most part, use cameras which are "good for everything and good for nothing," said Gremillet, rather than cameras that are

German patients must wait one to two months for radioiodine treatment for thyroid disease. In France, patients may wait weeks or months for any nuclear scan.

dedicated for imaging a specific organ.

Because equipment is lacking, there is a shortfall of 5% to 10% per year in the number of new physicians entering the field, said Askienazy. "There are large areas of France where nuclear medicine procedures aren't available." Since patients often must wait days or weeks for an imaging procedure, referring physicians have started to circumvent nuclear physicians and look for other ways of getting a diagnosis, he says.

The lack of referrals being encountered by French nuclear physicians can also be attributed to a lack of knowledge about nuclear medicine procedures—a problem well-known to American nuclear physicians. Askienazy and his colleagues are trying to solve this dilemma in France by educating primary care physicians and specialists in other fields. He has made several presentations on nuclear medicine at the conferences of various specialties.

Anti-Nuke and Over-Regulated

In Japan, the greatest interference in the day-to-day practice of nuclear medicine comes from stringent regulations over the use of radionuclides. All injections and imaging procedures must be performed in lead-lined rooms that are meticulously monitored—the legacy of Japan's role as a nuclear victim in World War II. Since the number of patients waiting to have procedures often outnumbers the number of lead-lined rooms, patients often must travel back and forth from the rooms to hospital wards in between the injection and imaging, according to Nagara Tamaki, MD, a nuclear physician at Kyoto University Faculty of Medicine. For an immobilized patient in pain, the repeated trips on a hospital gurney can cause undue discomfort.

In addition, many smaller hospitals simply can't afford to install these isotope rooms, and thus do without nuclear medicine procedures. Although the rooms make it easier to contain contamination in the event of radionuclide spills, most Japanese nuclear physicians agree that these rooms are an unnecessary expense and are overkill for safety. Fortunately, regulations have relaxed somewhat. Nuclear physicians have recently been permitted to use radionuclides in intensive care and cardiac care units, which had been prohibited in the past.

Another obstacle facing Japanese nuclear physicians: A variety of radiopharmaceuticals are not available commercially such as ¹¹¹In-pentereotide, ¹⁸⁶Re- and ¹⁸⁸Re-compounds, ¹²³I-D2 ligand and various labeled monoclonal antibodies, according to Kinichi Hisada, MD, a nuclear physician at Kanazawa University School of Medicine, and chairman of the board of directors of the Japanese Soci-

ety of Nuclear Medicine. He said this is partly due to a lack of chemists and physicists trained in radiopharmaceutical design.

The scarcity of nuclear medicine services and products in Japan can be blamed partly on perceptions inherent in Japanese society about anything "nuclear." "Many Japanese are against the concept of radiation," said Tamaki. "This stigma may be holding back the widespread application of nuclear medicine procedures." What's telling are the numbers: Only four nuclear medicine departments exist in Japan. The vast majority of the 800 board-certified nuclear physicians are trained in radiology or internal medicine. In fact, nuclear medicine has existed as an independent specialty for only five years.

Nonetheless, the quality of nuclear medicine "is quite satisfactory," said Tamaki. Furthermore, nuclear medicine technology societies are making leaps and bounds in the development of clinical guidelines for various procedures such as bone, heart and brain scans. Japan also houses 22 PET centers. As in the U.S., PET scans aren't covered by health insurance, so most procedures are performed for research purposes.

Not-So-Communist China

Whereas the U.S. is moving more and more towards managed care and government-controlled medicine, China is slowing backing away from socialized medicine. As of the beginning of this year, patients are now required to cover the full cost of nuclear medicine procedures. (Government employees, however, need to pay only 10% of their medical bills.) Patients as well as nuclear physicians are beginning to feel the effect. For example, patients are now required to foot the bill for a myocardial perfusion test which costs between \$80 and \$100, said Cheng Gang Zhang, MD, director, department of nuclear medicine, Shanxi Medical College in the city of Taiyuan. Although the government-controlled prices are much lower than those in the U.S., they are still costly for the average Chinese. Zhang worries that many patients will opt not to have emission computed tomography or a nuclear myocardial procedure because they cannot afford it. At the same time, local suppliers of radiopharmaceuticals are raising prices. "Every year the cost is rising," explains Zhang, "which means we have to charge patients more."

As of press time, Zhang was anticipating "major trouble" for nuclear physicians by the end of this year, as more and more patients decided to forgo scans. Pricing has become a matter of great controversy within Zhang's department. Some doctors are advocating reductions so that more patients

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World Tour*(Continued from page 16N)*

can receive scans. Others argue for the status quo to bring in more money and ensure that doctors are able to spend more time with each patient.

Regardless of Chinese physicians' preferences, they are unlikely to have much influence, Zhang said. For one thing, they are less organized than in other countries. The association of nuclear physicians meets every three years, and the next meeting isn't for another year. They are also less politically inclined than doctors in other countries, possibly because under the legacy of their hard-line Communist government, lobbying is an alien notion.

Some familiar problems—other doctors' ignorance of nuclear diagnostics and competition with echocardiography, MRI and CT scans—also steer patients away from nuclear scans, said Xiu-Jie Liu, MD, a nuclear physician at the Cardiovascular Institute & Fu Wai Hospital in Beijing. In fact, the cost of CT scans is actually cheaper than nuclear scans in China because nuclear imaging requires more resources such as obtaining radionuclides. As a result of these factors, "liver and brain scans have significantly decreased in the past ten years." Zhang estimates at least 25% of patients who have CT scans would be better served by nuclear scans.

Rising Costs, Declining Products

In Australia, the specter of health care reform looms large as the federal government begins to clamp down on medical spending—targeting nuclear medicine in particular. Australia has a single-payer national health care system called Medicare (which covers everyone not just the elderly). The budget for Australian Medicare has been rising at "9% to 10% per annum while inflation is declining by 1% to 2%," said Dick McLean, MD, immediate past president of the Australia New Zealand Association of Physicians in Nuclear Medicine. Meanwhile, the nuclear medicine portion of the budget has been surging at 20% to 25%.

To remedy the situation, Australia is embarking on a relative value study which "has some ominous implications for technology-based procedures," said McLean. The relative value study is similar to the one being conducted in the U.S. by the

Health Care Financing Administration to make adjustments in U.S. Medicare and Medicaid reimbursement rates for different procedures. "There is a possibility that coverage for nuclear medicine procedures will be reduced," said McLean. Unlike in China, Australian nuclear physicians are lobbying hard to maintain their reimbursement rates. "Our association has hired consultants to assist us in negotiations with the government."

Interestingly, some Australian nuclear medicine leaders are heartened by the possibility of a reduction in reimbursements for nuclear medicine. "We're finding it hard to staff hospital positions in nuclear medicine because of the large difference in income between hospital-based and private practice physicians," said Christopher C. Rowe, MD, director of nuclear medicine at the Queen Elizabeth Hospital in Adelaide. "There have been some departments in major hospitals that have been without proper nuclear medicine staff for several years." He feels the combination of reduced reimbursement for private practice and more flexibility with hospital salary packages might provide the incentives for nuclear physicians to transfer from private practices to hospitals.

Like the Japanese, Australian physicians also face a shortage of new radiopharmaceuticals. Australia, with a population of 17 million, is a small market and its location at the far end of the globe isolates it from many radiopharmaceutical distributors. Moreover, the major supplier of radiopharmaceuticals, Australian Radioisotopes, is partially run by the government. Although prices are less expensive than in the U.S. or Western Europe, the company does not contribute much money towards research and development of new radiopharmaceuticals, said Wayne Melville, sales manager for Dupont Pharma, the Sydney-based division of Dupont de Nemours & Co.

The Therapeutic Goods Administration (TGA), the Australian equivalent of the Food and Drug Administration (FDA), has further aggravated the situation. All radiopharmaceuticals approved in the U.S. or Europe that enter Australia must meet TGA's stringent standards. "Their drug approval process is similar to the FDA's, except tougher and slower," said Melville. "Once you submit a new drug application,

you cannot add any new data until they ask for it." He said Dupont will probably not attempt to get approval for its technetium-labeled brain perfusion agent, NeuroLite, which was recently approved by the FDA. "We will be more cost-effective in the longer term by putting the same time and money into the U.S. market."

Obtaining ^{99m}Tc for the production of technetium is currently not a problem in Australia because there is a small reactor in Sydney. This could, however, become an issue within the next few years when the reactor reaches the end of its lifespan. Citizen rights organizations have already begun to voice their opposition to building a new one, said McLean. Australian nuclear physicians may have to gear up for yet another political battle.

Greener Pastures?

Getting a glimpse at the problems of nuclear physicians in other countries may trigger feelings of relief among U.S. nuclear physicians that they are practicing in America. There is, however, one country that U.S. physicians may envy, namely Germany. "A few months ago, I had this discussion with some physicians in the United States and got the impression that we German physicians should be very satisfied," said Christopher Reiners, director of the Klinik und Poliklinik für Nuklearmedizin der Universität Würzburg.

The reason? German nuclear physicians have an iron-clad grip on their turf. Ever since the specialty was formally established in 1974, the German Medical Association implemented strict guidelines over who was qualified to practice any type of nuclear medicine, explains Reiners. "We have no debate about whether a cardiac study can be done by a cardiologist, because no cardiologist is allowed to do the study until he has specialized in nuclear medicine." The requirements for certification are 18 months of training for one organ.

The strict separation of specialties in Germany is partly a matter of culture. But the requirement that nonspecialists have training in nuclear medicine in order to perform imaging procedures is part of German radiation protection law, said Reiners. And German nuclear physicians have jockeyed ►

for a strong position to strengthen these laws. "German nuclear physicians have always offered themselves as experts concerning radiation protection of the general public." As a result, the 16-member Radiation Protection Committee of the German Ministry for Radiation Protection and the Environment usually includes two nuclear physicians.

Although they are better off in some aspects, German nuclear physicians are not practicing in a utopia. As in France, referrals are limited by other doctors' ignorance of nuclear medicine's benefits. The problem worsened when a cap was imposed on the ambulatory care sector in 1992, as part of German health care reform. The cap is enforced through a system which, for purposes of reimbursement, translates each service into point values and sets a limit on the total number of points covered. "It's a zero sum game," explains Uwe Reinhardt, professor of economics at Princeton University. "If everyone bills services freely, the fees automatically go down." Referrals are made only reluctantly if the referring

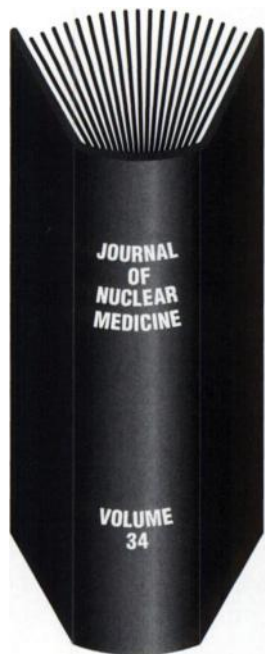
doctors find they absolutely cannot treat the problems themselves.

Some issues that German doctors are contending with should be alleviated by their joining the European Community. In general, Germany has stricter rules for the regulation of nuclear medicine practices and radiopharmaceuticals in comparison to other European countries. For instance, following radioiodine treatment for thyroid disease, patients must remain in controlled areas of the hospital until body activity has dropped below 95 MBq. "We have thousands of patients with iodine deficiency induced functional autonomy of the thyroid and only 1300 beds for radioiodine treatment all over Germany," said Reiners. The lack of beds combined with the quarantine forces patients to wait at least one to two months for treatment. Since Germany has agreed to adopt a standard set of health rules as part of joining the European Community, Reiners anticipates the radiation emissions for thyroid patients will be increased to 300 MBq, thereby alleviating the problem.

The Community could also help speed up the slow pace of approvals for new PET radiopharmaceuticals in Germany. "Up until now, the federal drug administration considered every PET radionuclide as a pharmaceutical, which required approval," said Reiners. "The delay from application to approval is between six months and four years." (Radiolabeled antibodies and other products of genetic engineering take six months; conventional drugs take one to four years.) Luckily, the drug approval process has become centralized for the entire European Community, so a drug approved in one country must be automatically approved in all the others. "I think the union will help nuclear medicine as a whole," said Askienazy. "The Community has recognized nuclear medicine as a separate specialty. This means that any member country that does not currently have a nuclear medicine specialty must, in theory, recognize and certify nuclear physicians as independent specialists."

David Holzman

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