

Facing New Horizons, Meeting New Challenges

When I was first asked to run for president of SNM, I agreed. What I didn't realize was that by the time I became president, SNM would represent not just nuclear medicine but the entire molecular imaging community with a \$5 million capital campaign. In the past 2 years, the pace of change has not decreased; if anything, it has increased. In part, that is because this is perhaps the most exciting time for our field in terms of the new horizons to be explored at the advent of personalized medicine.

The basic list of tasks that SNM faces has not changed. They include the 3 R's: reimbursement, regulatory affairs, and research funding. The following further explains these 3 items and gives a view of where SNM should be a year from now.

Reimbursement: At the Molecular Imaging Summit in February 2008, the last session focused on outreach and patient advocacy. Three of the speakers represented the community of non-Hodgkin's lymphoma (NHL) survivors, and the frustration and anxiety over the lack of adequate reimbursement for radioimmunotherapy (RIT) for NHL was palpable. Here is a treatment with the potential to radically improve the prognosis for these patients, yet reimbursement by the Centers for Medicare and Medicaid Services (CMS) for this treatment is for less than half the actual cost. Needless to say, the utilization of RIT is not meeting expectations—in large part for that reason. This situation is, in microcosm, what we face in developing new diagnostic and therapeutic radiopharmaceuticals. As we develop new imaging agents that can better inform us about the physiologic, metabolic, and other functional activity in the body or its pathology, we need to ensure that they will be adequately reimbursed in order to be effectively utilized. The same is true for therapeutic radiopharmaceuticals. The challenge is to work internally to craft clinical trials that will convince referring physicians and CMS of the value of imaging studies and to partner with industry to ensure that these studies are reimbursed at levels that will not be punitive to the imagers or patients.

Regulatory affairs: Early in the development process, imaging agents must undergo extensive testing to demonstrate their safety and effectiveness in order to be approved by the Food and Drug Administration (FDA). Although many radiopharmaceuticals, especially PET agents, are administered in tiny quantities in concentrations far below those expected to generate a physiologic response—much

less toxicity—we continue to be held to standards of toxicity that are far more onerous than can be considered reasonable to protect the safety of the patient. In addition, the FDA has traditionally tested effectiveness, for example, based on demonstrating the presence or absence of a tumor. We are now able to monitor the effectiveness of treatment by observing metabolic or physiologic changes.

This is a fundamental paradigm shift that requires spending a lot of time making the SNM case to the FDA and other stakeholders. SNM's role has included helping to identify potential staff with imaging backgrounds to be hired by FDA. On another regulatory front, SNM will continue to work with the Technologist Section to secure passage of a CARE bill that actually has enforcement power.

Research funding: SNM scored a victory for the field by successfully getting Congress to restore funding in the Department of Energy budget for research and development of new instrumentation and radiochemistry for nuclear medicine. The administration added funds in the fiscal year 2009 budget for that purpose, although at a lower level than Congress appropriated in 2008. This increase doubled the overall funding for nuclear medicine research, according to figures provided by the National Institute of Biomedical Imaging and Bioengineering. We are also working with other medical societies to increase National Institutes of Health (NIH) clinical research funding, which has been stagnant for several years. In many cases, the clinical studies needed to convince FDA and CMS of the effectiveness of imaging and therapy using nuclear techniques are funded by NIH. In an environment in which the budget for clinical research is actually decreasing (when inflation is taken into account), this presents a daunting picture.

In addition to the 3 R's, we have other challenges. Maintenance of certification has generated a need for SNM to provide more high-quality continuing education and continuing medical education for its members. The introduction of PET/CT into routine clinical use has created a demand for CT training for the nuclear medicine physician. The recent announcement that Atomic Energy of Canada, Ltd., will not bring the MAPLE reactors online means that a long-term solution to ^{99}Mo production in North America has been eliminated.



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None of these challenges will be solved in a single year. There has been a concerted effort to develop a comprehensive strategy among the leadership of SNM to ensure a continuity of approach beyond any individual's presidency. Immediate Past-President Alexander McEwan, MD, has worked hard to develop a consensus with President-Elect Michael Graham, PhD, MD, and me, and with SNMTS immediate Past-President David

Gilmore and President Mark Wallenmeyer, so that many of these initiatives will continue. I have pledged to continue this collaborative approach. Our commitment is vital to the health and welfare of our field, those who work in it, and those we treat.

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with the major manufacturers of medical imaging devices to improve the accuracy and reproducibility of quantitative results associated with imaging methods.

The imaging device manufacturers will come together under a new initiative called the Quantitative Imaging Biomarkers Alliance to identify specific problems they can solve in pursuit of our mutual goal: more accurate and reproducible quantitative results. Creating and providing public access to large datasets of images and associated clinical outcome

data is another important task which, so far, has been difficult to accomplish and needs more concerted attention. Many attendees used the term "eye opener" to describe the meeting, and participants requested future opportunities for continued communication and coordination of activities.

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Most physicians currently demonstrate their competence to their licensing boards only once—when they first apply for a license to practice medicine. When state medical boards implement MOL requirements, physicians will be expected to demonstrate their competence periodically in order to maintain active medical licenses.

The American Board of Nuclear Medicine (ABNM) expects that its maintenance of certification (MOC) require-

ments will satisfy the MOL requirements of the state medical boards. The ABNM will do everything it can to make sure that diplomates participating in MOC will be required only to document their participation in MOC in order to maintain their licensure.

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