

The Academy of Molecular Imaging

R. Edward Coleman

THE ACADEMY of Molecular Imaging (AMI) was started in 2001 when the leadership of the Institute for Clinical PET (ICP) decided that there needed to be an organization to not only foster the clinical applications of positron emission tomography (PET) but also to include the disciplines and technologies of molecular imaging.^{1,2} Before 2001, the ICP had focused its efforts on education and reimbursement for clinical PET. Much of the success that had been made with the regulatory agencies, such as the Food and Drug Administration (FDA), and the third party payers, such as the Centers for Medicare and Medicaid Services (CMS), has been through the efforts of the ICP. The importance of the scientific basis of molecular imaging was recognized by the leadership of ICP, and AMI was formed to encompass both the basic science and clinical aspects of molecular imaging with the clinical aspect focusing on PET.

HISTORY OF ICP

The first conference devoted to PET and developing an organization in PET was held in Bermuda in 1989. This conference was focused on making clinical PET a reality and was sponsored by Siemens. The initial name of the organization was the Institute for Clinical PET Practice (ICPP). The Bermuda meeting was considered the first annual international PET conference. In 1990, the name of the organization was changed to the Institute for Clinical PET (ICP), and R. Edward Coleman was named as the first president. Siemens and General Electric supported ICP at that time. During the ensuing years, ICP continued to maintain a close relationship with industry while increasing its individual and institutional membership. The budget of ICP became less dependent on industry as the membership increased and the educational effort became productive. The mission of ICP is to promote the clinical use of noninvasive, diagnostic

positron imaging for measuring metabolic and functional activity of cells in the human body.

ICP ACTIVITY

The clinical activities of PET are promoted by providing educational programs for professionals and increasing public awareness of the value of PET. ICP has been heavily involved in working with the FDA on approval of radiopharmaceuticals and working with CMS and other third-party payers for reimbursement for clinical PET studies. In 1998, under the leadership of Steve Larson, MD, the journal, *Clinical Positron Imaging*, was started to provide information about all aspects of clinical positron imaging. This journal became *Molecular Imaging and Biology* with Joyce Barrio, PhD, as editor at the time of the formation of AMI.

The ICP instituted the Distinguished Scientist Award in 1994, and this award has been carried forward to the AMI. The first four awardees were Giovanni Di Chiro, Michael Phelps, Al Wolf, and Louis Sokoloff. In 1998, I was the recipient of this prestigious award. Then, as now, the recipient gave a presentation during the planning session. I closed my presentation with an "Ode to PET," which is included in the Appendix.

The ICP had to deal with several regulatory issues in the 1990s. ICP coordinated the clinical practice, academic and industry efforts to deal with the FDA, the Health Care Financing Administration (now CMS), and other governmental agencies. ICP also had a major effort with legislative activities. These activities were led by Dr. Michael Phelps from UCLA. The efforts resulted in a major change in the method that the FDA was reviewing PET radiopharmaceuticals. In the Food and Drug Modernization Act in 1997, it is stated that PET radiopharmaceuticals in the drug information monographs of the US Pharmacopoeia (USP) have the equivalence of FDA approval. The FDA must work with the PET community to develop a mechanism of regulation of PET radiopharmaceuticals. This interaction has been going on since that time, and this interaction is led by Dr. Jorge Barrio from UCLA.

In 1995, Medicare began coverage for rubidium-82 as a myocardial perfusion imaging agent. During 1996 and 1997, representatives from ICP were interacting with representatives of HCFA

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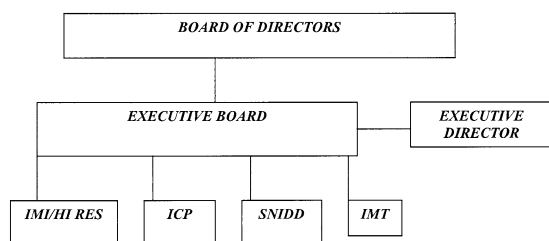


Fig 1. Organizational structure of AMI.

concerning reimbursement for other indications. ICP was working primarily with HCFA because most third party payers have policies to cover at least what Medicare covers. The third party payers refused to cover PET because the administered radiopharmaceutical, 2-F-18 fluorodeoxyglucose (FDG) was not FDA approved. In 1998, soon after FDAMA gave approval for PET radiopharmaceuticals, payment for PET was placed under a national coverage determination. The initial two indications covered by Medicare were the evaluation of the indeterminate solitary nodule and initial staging of lung cancer. Through ongoing interactions, these indications have been greatly expanded over the years to include colorectal cancer, breast cancer, head and neck cancer, esophageal cancer, thyroid cancer, melanoma and lymphoma. Medicare also covers nononcologic indications including FDG-PET brain imaging for refractory seizure disorder being considered for surgery and myocardial perfusion imaging using N-13 ammonia. Several other indications are now under review by CMS including dementia, brain tumor, cervical cancer, small cell lung cancer, testicular cancer, pancreatic cancer, ovarian cancer, gastrointestinal stromal tumors, aggressive prostate cancer and multiple myeloma. In addition to the interactions related to indications covered, the coverage amount has been an issue. With the formation of AMI, the reimbursement issues have been moved to the Institute of Molecular Technology, which is an industry council of the AMI.

ORGANIZATION OF AMI

Figure 1 is the organizational structure of AMI. The AMI consists of a 12-member Board of Directors with ex officio members being the chairs of the councils and the journal editor. The Executive Board consists of the President, President-Elect, Secretary, and Treasurer. The Executive Director reports to the Executive Board. There are

four councils, including the Institute for Molecular Imaging and High Resolution Imaging Council, ICP, Society for Nuclear Imaging in Drug Development (SNIDD), and Institute for Molecular Technologies. Each council has its own leadership with governance and support provided by the Board of Directors and Executive Board of the AMI. The Executive Director provides administrative support to the Board of Directors and the Executive Board of the AMI, as well as to the councils.

AMI has the broad focus of examining the molecular basis of biologic processes in mammalian systems, from the mouse to the patient. To better understand molecular imaging, isolated cells, tissues and other organisms may be studied. Structural and functional imaging related to molecular imaging is included in AMI. The various imaging technologies provide unique information and have their advantages and limitations. We are now seeing the advantages of combined PET-CT, SPECT-CT, MRI-PET, and optical images with PET and MRI.

The Institute for Molecular Imaging and HIRE groups have joined together to form a council that focuses on the basic science of molecular imaging. This group has particular interest and expertise in optical imaging, small animal PET, CT, and MRI, and in the molecular basis of disease processes.

The ICP continues to focus on the clinical applications of PET and works closely with IMT on regulatory and reimbursement issues. A major focus of the ICP has been in educational efforts, and the annual meeting is a major effort of this group.

SNIDD consists of individuals interested in using nuclear imaging in drug discovery. Individuals in this council consist of persons from academia and industry. Many of the members are in research divisions in large pharmaceutical companies. The IMT is the industry group and employs lobbyists who work with them in their efforts to obtain reimbursement and to sustain reimbursement levels.

JOURNAL

Molecular Imaging and Biology is the journal of AMI and is published by Elsevier. The journal publishes original research contributions on the utilization of molecular imaging and problems of relevance in biology and medicine. The primary

objective of the journal is to provide a forum for the discovery of molecular mechanisms of health and disease through the use of imaging techniques. In addition to the journal, AMI provides a quarterly newsletter to its members.

SUMMARY

AMI is a major organization that has expanded the focus of ICP to include more basic science investigations and to be more active on the regulatory and reimbursement fronts. ICP continues its efforts in PET education and in support of IMT in the regulatory/reimbursement issues. IMI and SNIDD provide the basic sciences of molecular imaging that will result in new procedures in molecular imaging and PET. AMI provides the organizational structure for these activities to occur.

APPENDIX

Ode to PET

The technology of PET is phenomenal
To some it seems unconventional
Cyclotron and tomograph
Chemistry and staff
Are what make PET so traditional

The cyclotron is a marvelous device
Accelerates particles precise
Ernest Lawrence knew
With Livingston and crew
That the medical uses would suffice

A positron is a necessity
Its range determined to a T
It goes with distinction
Into extinction
When with an electron it is no longer free

Carbon, oxygen, nitrogen, fluorine
Isotopes that give us esteem
The half-lives of minutes

Don't require acts of Senates
To show body chemistry serene

The tomograph design was a feat
'Twas something saved for the elite
Phelps, Hoffman, Mullani, Ter-Pogossian
Developed the device companion
To image body chemistry complete

FDG is the main pharmaceutical
Wolf made the chemistry practical
Alavi injected
Kuhl's device detected
The first FDG tomographical

'Twas time for organizational PET
For regulatory and reimbursement unmet
ICPP was the start
But did not seem smart
And the name ICP was set

Coleman, Mazziotta, Frick, Wahl and Wagner
Larson, Kirchner, Garcia, Valk and Tesar
The leaders of ICP
With the help of industry
Have led PET to clinical Nirvana(r)

The opportunities in PET are tremendous
The challenges we face are horrendous
The power of PET
Has us set
To demonstrate to all that it's stupendous

It is an honor to provide you some diction
For you to listen to my story-nonfiction
Clinical PET is the goal
Of my heart and soul
And thank you for the recognition

The HCFA and FDA are challenges still
And they know ICP's iron will
Stevens and Connell at our side
We are along for the ride
From the bottom to the top of the hill

REFERENCES

1. Garcia EV, Shreve PD: A voice for clinical positron imaging, a voice for ICP. Clin Pos Imaging 1:5-14, 1998

2. Phelps ME: A message from the academy of molecular imaging. Mol Imaging Biol 4:3-4, 2002