THE ROLE OF THE NUCLEAR PHARMACIST IN NUCLEAR MEDICINE

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Nuclear Medicine has grown rapidly during the last decade due to the increased utilization of diagnostic radionuclide techniques and major developments in radiopharmaceuticals. Because of the increased use of radiopharmaceuticals, a need exists to have trained personnel to provide necessary radiopharmaceutical services for the physician. Thus, a number of pharmacy schools offer advanced radiopharmaceutical training. Pharmacy schools that offer training in nuclear pharmacy or radiopharmaceuticals are indicated in table one.

| TABLE 1 |
| PHARMACY SCHOOLS OFFERING ADVANCED COURSES IN NUCLEAR PHARMACY |
| 1. University of Southern California |
| 2. Purdue University |
| 3. Temple University |
| 4. University of Michigan |
| 5. University of Washington |
| 6. University of Nebraska |
| 7. University of Arkansas |
| 8. University of California |
| 9. University of New Mexico |
| 10. Butler University |
| 11. University of British Columbia |
| 12. McMaster University |
| 13. University of Alberta |
| 14. University of Texas |
| 15. Ohio State University |
| 16. University of Wisconsin |
| 17. University of The Pacific |
| 18. University of Utah |
| 19. North Dakota State University |

The Schools indicated in table one represent about 20% of the colleges of Pharmacy in North America. All pharmacy schools, however, have some basic radiopharmaceutical education for the undergraduate pharmacy student.
Before establishing programs designed to prepare pharmacists for the practice of nuclear pharmacy, educators had to define the role of the nuclear pharmacist if delivery of health care to the nuclear medicine patient was to be most effective. Thus, in our training programs, we have defined four levels of competency in nuclear pharmacy:

1. General education,
2. Undergraduate specialization,
3. Graduate training (M.S. or Pharm.D.),

Today, all pharmacists during their five year undergraduate pharmacy curriculum, are exposed to a minimum level of education regarding radiopharmaceuticals. The National Boards of Pharmacy, as well as the local State Boards of Pharmacy, include questions about radiopharmaceuticals in establishing the minimum basic qualifications of a pharmacist to practice pharmacy.

In some pharmacy schools, 6 to 8 hours of lecture within a physical pharmacy course are intended to provide this basic educational requirement in nuclear pharmacy. Other schools have established a required one semester hour orientation course in radiopharmaceuticals to more completely fulfill these needs. The objective of this basic nuclear pharmacy course or series of lectures within a course is to acquaint the undergraduate pharmacist with nuclear medicine, the practice of nuclear pharmacy and with radiopharmaceutical product information. All pharmacists should be able to communicate effectively with physicians and with layiaty regarding the basic
fundamentals of nuclear pharmacy and nuclear medicine. The nuclear pharmacy orientation course provides this ability; clearly it is not intended to qualify a pharmacist to practice nuclear pharmacy.

At Purdue University an undergraduate specialization in nuclear pharmacy is possible for pharmacy students. This specialization requires the basic orientation course in nuclear pharmacy plus an additional 7 to 12 semester hours of nuclear pharmacy courses including topics as, Practical Aspects of Procurement, Handling, Compounding and Dispensing of Radiopharmaceuticals. The student becomes versed in all applicable regulations and licensing procedures. He is especially orientated towards the maintenance of proper records, performance of appropriate quality control procedures and analytical evaluation of radiopharmaceuticals. The courses emphasize possible drug interactions and radiopharmaceutical selection for particular diagnostic procedures, as well as, dosages for adults and pediatric patients.

A similar program exists at the University of Michigan. Its quality control is illustrated in figure 1.
Each student participates in a 30 day internship in an operational nuclear pharmacy. Under the supervision of a practicing nuclear pharmacist, the trainee is exposed to the actual practice of nuclear pharmacy and thereby perfects his skills in the clinical practice of that specialty. The trainee, during this internship, attends scan interpretation sessions and relates pertinate radiopharmaceutical quality control data to the physicians to minimize product variability as affecting scan interpretation. Students who select undergraduate specialization in nuclear pharmacy usually also elect courses that are beneficial to the hospital pharmacist, e.g. parenteral products and manufacturing processes.
The University of Michigan Nuclear Pharmacy uses the nuclear pharmacy undergraduate specialist for the routine day to day handling of all radiopharmaceuticals plus the dispensing on prescription of adjunct pharmaceuticals (non-radioactive) that may be used within the nuclear medicine clinic or prescribed by nuclear medicine physicians.

The graduate training program in Nuclear Pharmacy involves either an M.S. or Pharm.D. degree dependent upon the objectives of the individual. Each program builds upon the previous levels of competence established at the undergraduate training level. In addition, a nuclear pharmacist with an M.S. or Pharm. D. degree is expected to be able to establish nuclear pharmacy services, develop quality control procedures for investigational radiopharmaceuticals, calculate radiopharmaceutical absorbed radiation doses, prepare investigational new drug applications, establish and conduct health physics procedures in a nuclear medicine unit, formulate in-house radiopharmaceuticals from reactors or cyclotrons and serve as a supervisor of a nuclear pharmacy.

The M.S. degree is considered a research degree while the Pharm. D. degree is considered a professional degree. Although the basic course work is the same in each, the difference depends upon whether a thesis or a hospital oriented clinical experience option is selected. Only pharmacists are admitted to the Pharm. D. program. Undergraduates, majoring in the biological, chemical or physical sciences, may be admitted into M.S. and or Ph.D. programs.
While basic science graduate curricula for nuclear pharmacists and radiopharmaceutical scientists are similar, only personnel who have established pharmacy qualifications as determined by successful completion of standard Board of Pharmacy examinations, are recognized to dispense finished radiopharmaceuticals.

Nuclear Pharmacy, as practiced at the graduate specialization level of M.S. or Pharm. D. degree requires a basic pharmacy education program as indicated in Figure two.

![Image of a diagram showing the essential educational components for the practice of nuclear pharmacy.]

*Figure Two. Essential Educational Components for the Practice of Nuclear Pharmacy.*
As shown in figure two the training of a nuclear pharmacist is dependent upon the basic undergraduate education of a pharmacist. To that basic education are added courses in Radiation Biology, Health Physics, Advanced Radionuclird Methodology, Nuclear Pharmacy and Radiological Physics. Thus, the nuclear pharmacist specialist at the graduate level is qualified to handle any aspect of regional nuclear pharmacies or radiopharmaceuticals. It is the additional in depth knowledge in the radiation science aspects that allows the graduate level specialist to do more than the undergraduate pharmacist.

Developmental research is a major factor in the production of a radiopharmaceutical to the point of clinical usefulness. Our pharmacists, at the graduate specialization level, have been influential in developmental research projects. Recently published developmental research projects are indicated in table two.

TABLE 2

UNIVERSITY OF MICHIGAN DEVELOPMENTAL RESEARCH PROJECTS 1972-1974

1. "Pharmaceutical Quality of Technetium Sulfur Colloid"
2. "Dosimetry of $^{131}$I-19-Iodocholesterol"
3. "Thermal and Radiolytic Decomposition of $^{131}$I-19-Iodocholesterol"
4. "Limitations of the Limulus Pyrogen Test"
5. "Pharmaceutical Quality of Technetium Macroggregated Albumin"
6. "Clinical Nuclear Pharmacy"
7. "Radiation Protection in a Nuclear Pharmacy"
In addition, graduate specialists in nuclear pharmacy are very helpful in the development of new radiopharmaceuticals, e.g. $^{131}$I-19-Iodocholesterol being distributed by the University of Michigan Nuclear Pharmacy.

The fourth level of defined competency in nuclear pharmacy is the Ph.D. degree. The Ph.D. degree with specialization in Nuclear Pharmacy or in Radiopharmaceutical Science requires all the preliminary courses previously discussed for the undergraduate and graduate specialization in nuclear pharmacy plus the courses necessary for the particular research objective of the Ph.D. student. The Ph.D. degree, with emphasis on radiopharmaceuticals, is available to students with basic degrees in the biological, chemical, pharmaceutical or physical sciences. The major emphasis of the Ph.D. degree is basic radiopharmaceutical research, teaching in radiopharmaceutical or nuclear pharmacy programs, and direction of radiopharmaceutical or nuclear pharmacy programs.

The University of Michigan College of Pharmacy training program in nuclear pharmacy is oriented predominately at the Ph.D. level in radiopharmaceutical sciences or nuclear pharmacy. As such, the degree objective is oriented towards a particular dissertation topic, but in addition, each candidate must become thoroughly versed with the production of radiopharmaceuticals from their conception through radiochemical synthesis, quality control, animal testing, IND's, clinicals, and NDA's.
The University of Michigan Nuclear Pharmacy program is directed by a Ph.D. nuclear pharmacist and has three major components. The first component of the program is the clinical nuclear pharmacy which is headed up by an M.S. nuclear pharmacist and operated by B.S. level nuclear pharmacists. The second component of the nuclear pharmacy program involves basic radiopharmaceutical research and is in close collaboration with the clinical nuclear medicine unit and the organic medicinal chemistry sections of the college of pharmacy. In addition to the director, three chemists are in the basic radiopharmaceutical research program. The third component of the nuclear pharmacy program involves the training of nuclear pharmacists at each of the different levels of competency previously indicated. The Nuclear Pharmacy Program, as developed, is interdisciplinary, affiliated with Nuclear Medicine, but retains both financial and responsibility autonomy. The clinical nuclear pharmacy dispenses radiopharmaceuticals on prescriptions only, carries a full line of radiopharmaceutical manufacturer's products and has been financially successful.

The advent of increased utilization or radiopharmaceuticals and the evolution of radiopharmaceuticals as complex dosage forms has dictated the need for the involvement of Nuclear Pharmacists. Nuclear pharmacists are being trained at different levels of competency. For the 200 bed community hospital, the B.S. undergraduate specialist in nuclear pharmacy may be all that is needed. Here, the pharmacists might fill a part-time role in the hospital pharmacy and a part-time role with the nuclear medicine unit.
When radiopharmaceuticals are either being developed or prepared extemporaneously in quantities for new products or commercially unavailable products, then a pharmacist trained at the M.S. or Pharm. D. level is required. These pharmacists can meet the needs of new product development research.

For basic research in radiopharmaceuticals, as now being done by major universities or industrial radiopharmaceutical firms, then a qualified nuclear pharmacist or radiopharmaceutical scientist at the Ph.D. level is required. The teaching of nuclear pharmacy has been accomplished by graduates at the M.S., Pharm. D. or Ph.D. level.