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NUCLEAR PHARMACY: AN UPDATED REVIEW

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ABSTRACT

Nuclear pharmacy is a specialty area of pharmacy practice dedicated to the compounding and dispensing of radioactive materials for use in nuclear medicine procedures. A specialty area of pharmacy practice is one that requires a concentration of knowledge in a once specific area. The development of nuclear pharmacy as a specialty area followed the development of nuclear medicine as a recognized specialty by the American Medical Association in the early 1970's.The present article majorly deals with the development of nuclear pharmacy, nuclear pharmacy education and its harmonization, education approaches in nuclear pharmacy, radiology pharmacy practice, Comparison of nuclear pharmacy with traditional pharmacy and a highlight on current status.

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INTRODUCTION

Nuclear pharmacy has been recognized as a specialty practice for over 20 years. The field has changed from a few innovative pharmacists with advanced degrees located in larger hospitals to a network of centralized commercial nuclear pharmacies located in cities. Various educational approaches have been developed to provide the knowledge base required to work in a nuclear pharmacy

Nuclear Pharmacy involves the preparation of radioactive materials that will be used to diagnose and treat specific diseases. It was the first pharmacy specialty established in 1978 by the Board of Pharmaceutical Specialties. Nuclear pharmacy seeks to improve and promote health through the safe and effective use of radioactive drugs for not only diagnosis but also therapy..[1]

HISTORY AND DEVELOPMENT

Historically, nuclear pharmacy emerged in the late 1960s, at which time nuclear pharmacy practitioners realized the need for improved education and expanded educational opportunities among other things. The issue of manpower needs for the rapidly growing nuclear medicine field encouraged a few pharmacy educators to develop instructional programs in nuclear pharmacy, most of which were very specialized in nature. Some of these individuals have published information based on their successful experiences with these unique training programs in an effort to stimulate interest at other colleges of pharmacy[2,3]

Several textbooks were written to provide a comprehensive introduction to nuclear pharmacy[4,5]. In addition, numerous articles have been published in professional journals over the past 20 years which describe the basic knowledge needed by all pharmacists regarding radiopharmaceuticals and other drugs used for medical imaging.[6]

During the same span of time, additional undergraduate and graduate training programs were developed[7], practice standards written and rewritten,[8] and the Board of Pharmaceutical Specialties (BPS) established. In 1978, nuclear pharmacy became the first recognized pharmacy specialty.

nuclear pharmacy board certification

In 1982, the first nuclear pharmacy board certification examination was offered. As of September 1995, 340 nuclear pharmacists are currently board certified by BPS. The BPS(Board of Pharmaceutical Specialties) appointed a Council on Nuclear Pharmacy to develop the procedures necessary to award board certification in nuclear pharmacy. The council was asked to establish knowledge areas, determine requirements for eligibility, prepare an examination and, ultimately, administer an examination and set scores for passing.

Nuclear pharmacy specialty certification examination (NUSPEX) was developed . The exam was based on the official criteria for recognition as a specialty and the Nuclear Pharmacy Practice Standards, developed by the Section on Nuclear Pharmacy. The exam discriminated between the competencies of nuclear pharmacy specialists and those of general practitioners.

The incentives for becoming board certified are gradually increasing in number. In October 1989, the Nuclear Regulatory Commission (NRC) announced changes to the Code of Federal Regulations (10 CFR Part 35),recognizing for the first time that a board certified nuclear pharmacist possessed sufficient education and training to be employed as a radiation safety officer (RSO)[9].

criteria necessary to be recognized as an ANP

In December 1994, NRC revised 10 CFR Parts (30,32 and 35); this NRC ruling specifies the criteria necessary to be recognized as an "authorized nuclear pharmacist" (ANP).[10] According to the NRC, an ANP is a nuclear pharmacist who: (*i*) is board certified by BPS; or (*ii*) has received 700 hours of structured instruction under the supervision of an ANP and has received written certification of such training or such individuals are permitted to compound, dispense and monitor radiopharmaceuticals in a manner that encourages the provision of optimal pharmaceutical care.

In the late 1980s nuclear pharmacy practitioners realized the need to provide patient care in areas of radiology in addition to just nuclear medicine. As a result, certain pharmacists have developed specialized practices which encompass the use and monitoring of contrast agents, brachytherapy devices, as well as

traditional and positron-emitting radiopharmaceuticals. To recognize this expanding practice area, the American Society of Hospital Pharmacists (today the American Society of Health-System Pharmacists [ASHP]) renamed the Specialty Practice Group (SPG) on nuclear pharmacy to the SPG on radiologic pharmacy.

approval of resolutions by AACP

In 1975, the American Association of Colleges of Pharmacy (AACP) House of Delegates approved two resolutions which, first, sought to recognize the emerging technologies associated with radiopharmaceuticals and radiopharmacy practice and, second, advocated the need for all colleges of pharmacy to begin making this new knowledge base available to students.[11]

One resolution stated that "all pharmacy students should be introduced to the basic aspects of radiopharmaceuticals and their application in nuclear medicine." The second resolution recommended a prescribed list of competencies for students in specialized nuclear pharmacy education programs, and further stated that these programs should include a period of supervised clinical experience in the practice of nuclear pharmacy. These resolutions appear to be no less relevant today than they were 20 years ago. In fact, the importance of these resolutions has increased due to the growth of nuclear medicine (and other imaging modalities) and the expansion of pharmaceutical care responsibilities into all of radiologic medicine.

creation of department of bionucleonics

The initial lecture and laboratory courses created by Christian at Purdue University led eventually to the creation of the Department of Bionucleonics. The educational efforts of this group resulted in the training of many nuclear pharmacy researchers and practitioners, several of whom are recognized as nuclear pharmacy pioneers. The Purdue program is still in operation today under the apt leadership of Stanley Shaw, who is head of the Division of Nuclear Pharmacy. The current program was established in 1972 by Shaw and Gordon Born and has produced hundreds of nuclear pharmacists.[12]

early leaders

While few pharmacists were involved, individuals such as William H. Briner and John E. Christian Briner had started the National Institutes of Health (NIH) Radiopharmacy in 1958. He had been developing procedures for radiopharmaceutical services by pharmacists and encouraging pharmacy involvement through training and in publications. Briner also trained several individuals at the NIH radiopharmacy who contributed significantly to the development of nuclear pharmacy.

Christian was responsible for the first monographs on radiopharmaceuticals published in 1955 in the 15th revision of the US Pharmacopoeia (USP). Furthermore, in 1947 he initiated courses in the School of Pharmacy at Purdue University that provided fundamental concepts of nuclear physics, instrumentation and applications of radiotracer methodology applicable to research in pharmacy and the life science.

John E. Christian, at Purdue University, had encouraged pharmacists to be involved with radiopharmaceuticals and radiotracer studies, both through research and hospital pharmacy services.[13,14]

TABLE 1[15]

nuclear pharmacy pioneers

David R. Allen	John E. Christian	Mark T. Hebner	Larry Oliver
William J. Baker	Clyde N. Cole	Kenneth R. Hetzel	William C. Porter
Robert W. Beightol	James F. Cooper	Dennis R. Hoogland	Richard Sakasitz
Gordon S. Born	Nunzio Desantis	David Hurwitz	Robert Sanchez
Barry M. Bowen	J. William Dirksen	Rodney D. Ice	Stanley M. Shaw
Kenneth Breslow	Raymond J. Farkas	Michael P. Kavula	Anne C. Smith
William H. Briner	Monty Fu	Tom K. Kawada	Arthur C. Soloman
Ronald J. Callahan	Thomas R. Gnau	Richard Keesee	Dennis P. Swanson

Nuclear Pharmacy Education And Harmonization

Education of nuclear pharmacists exists in many countries around the world. The approach and level of education varies between countries depending upon the expectations of the nuclear pharmacist, the work site and the economic environment. In Australia, training is provided through distance learning. In Europe and Canada, nuclear pharmacists and radiochemists receive postgraduate education in order to engage in the small-scale preparation and quality control of radiopharmaceuticals as well as research and development. In Europe an educational approach has been developing under the direction of committees and individuals in the European Association of Nuclear Medicine ultimately resulting in the recommendation for the establishment of a postgraduate program within the framework of the European School of Nuclear Medicine.

In the U.S.A., nuclear pharmacy practitioners obtain basic knowledge primarily through undergraduate programs taken when pursuing the first professional degree in pharmacy. Licensed practitioners in pharmacy enter the practice of nuclear pharmacy through distance learning programs or short courses.. In the U.S.A nuclear pharmacy education was first formalized as a M.S. degree in Radiopharmacy in 1969 at the University of Southern California. Initially, in the U.S.A., nuclear pharmacists were located in larger hospitals, universities and medical centers.

Within a few years the concept of a commercial centralized nuclear pharmacy (CCNP) was established. The CCNP operates as a business in a manner similar to a retail pharmacy. Unit doses are provided to hospitals within a city and surrounding regions by automobile. The CCNP concept plus the availability of non-radioactive kits and the technetium-99m generator increased the need for nuclear pharmacists. The type of practice conducted in a CCNP allowed the utilization of a quality pharmacist with a first professional degree. Thus, several schools of pharmacy developed programs that allow specialized knowledge in nuclear pharmacy to be obtained through elective courses while attaining the first professional degree.

While different approaches to education exist, there is a basic core of knowledge and a level of competence required of all nuclear pharmacists and radiochemists providing radiopharmaceutical products and services. It was with this realization that efforts were initiated to develop harmonization concepts and documents pertaining to education in nuclear pharmacy. The benefits of international harmonization in nuclear pharmacy education are numerous.

Assurance of the availability of quality professionals to provide optimal products and care to the patient is a principle benefit. Spanning national barriers through the demonstration of self governance and unification in education will enhance the goal of increased freedom of employment between countries. Harmonization endeavors will improve existing education programs through sharing of innovative concepts and knowledge between educators. Documents generated will benefit new educational programs especially in developing nations.[16]

committee on harmonization

A committee on harmonization in nuclear pharmacy education was formed consisting of educators and practitioners from the international community. A working document on education was developed and each knowledge area considered as either essential, familiar or unimportant to training in nuclear pharmacy. The committee considered a majority of the knowledge areas as important based upon the results indicating that the knowledge was either essential or when combining designations of essential and familiar.

The committee on nuclear pharmacy education revise the working document and reconsider each knowledge area. The second working document sent to additional educators and practitioners for input. The document presented for discussion at a symposium on radiopharmacy, revised appropriately and sent to individuals in nuclear pharmacy throughout the international community. The finalized document on nuclear pharmacy education made available through an international pharmacy organization.

A committee on harmonization in nuclear pharmacy education was established with members from several countries. Members are: Professor Dr. Peter Cox, Chair

(University Hospital, Rotterdam, NL); Mr. Peter Eu (Peter MacCallum Cancer Institute, Victoria, Australia); Dr. M.C. Gil (Chilean Nuclear Energy Commission, Santiago, Chile); Dr. Stuart Hesselwood (Birmingham Regional Radioisotope Center, Birmingham, England); Mr. William Hladik, III,(University of New Mexico, Albuquerque, U.S.A.); Professor Dr. H.J. Machulla, (Eberhard Karis University Tubingen, Tubingen, Germany); Dr. J. Mallol (Technologia Farmaceutica,
Tenerife, Spain); Dr. Stephen Mather (St. Bartholomews Hospital, London, England), Dr. Charles Sampson (Addenbrookes Hospital, Cambridge, England); Dr. Stanley Shaw (Purdue University,West Lafayette, U.S.A.) and Professor Dr. Len Wiebe (University of Alberta, Edmonton,Canada). The committee acts under the direction of a steering committee composed of the chairs from two other committees on harmonization, the chair of the committee on education, and two other members.

benefits of international harmonization

The benefits of international harmonization in nuclear pharmacy education are numerous. Assurance of the availability of quality professionals to provide optimal products and care to the patient is a principle benefit. Spanning national barriers through the demonstration of self governance and unification in education will enhance the goal of increased freedom of employment between countries. Harmonization endeavors will improve existing educational programs through sharing of innovative concepts and knowledge between educators. Documents generated will benefit new educational programs especially in developing nations. Indeed, harmonization is a worthy endeavor in order to bring together the strengths and experience of the international community for the benefit of all nations.[17]

Educational Approaches

elective series in the first professional degree

The pharmacy student may obtain the fundamental knowledge necessary to enter nuclear pharmacy through a series of elective courses while completing a first professional degree program.

advantages to this approach

There are several advantages to this approach. The student learns the material at a reasonable pace with a degree of repetition and reinforcement. The student may have an opportunity to gain practice experience through a summer internship or as part of an externship. Having been exposed to multiple courses and a practice experience the student is aware of the negative and positive aspects of nuclear pharmacy practice. The student may discontinue the elective series at any time. Thus, at graduation a student entering nuclear pharmacy has a high probability of retention. A student that does not complete the entire series of elective courses can still benefit from a greater understanding of the importance of diagnostic imaging in pharmaceutical care and drugs associated with procedures.

The elective series approach allows for a large number of students to be prepared as specialists each year. The cost to an employer is minimal and may be only through support of an internship or externship program. The expense to the university may be significant as faculty, laboratory equipment and physical facilities are required to teach the fundamental principles for nuclear pharmacy.

advantage of short courses to the pharmacy employer

The advantage of short courses to the pharmacy employer is that a greater number of people can be trained as needed in a shorter period of time. The employer no longer needs to wait for the yearly group of pharmacy graduates from schools of pharmacy. Corporations can use the short course for company orientation as well as nuclear pharmacy training. The employer may reasonably expect to retain a pharmacist trained with company funds until the terms of the employment contract have been met.

residency program

A pharmacist with a first professional degree may enter nuclear pharmacy practice through a residency program. The residency is usually one year and takes place in a medical center. By the nature of the location, the residency has a greater clinical component than undergraduate programs or short courses. If the resident has not obtained the fundamental knowledge elsewhere, didactic material must be provided through courses taught by the nuclear pharmacy staff or by other professionals that teach nuclear medicine

physicians or technologists. The level of competence and potential for retention attained by the resident should be high after an entire year of experience within a nuclear pharmacy located in a nuclear medicine department. The training program requires a considerable commitment from the supervisory pharmacist and is limited in the number of individuals that can be trained at one time. Difficulty in identifying sources of money for resident support is another problem encountered in this approach to education.

master of science degree

Some pharmacists elect a MS degree program as a means to enter nuclear pharmacy practice. The MS degree allows considerable opportunity for the pharmacist to become well schooled in the knowledge base needed for practice as well as the development of basic research skills.

The added knowledge gained through the MS degree allows the pharmacist to participate in teaching and increases the potential for employment in a large medical center. A MS degree program may be directed to the more traditional practice of nuclear pharmacy or emphasize the preparation, dispensing and clinical applications of radiopharmaceuticals used for positron emission tomography (PET) imaging.

postgraduate short courses

Although several pharmacy schools offer nuclear pharmacy education at the undergraduate level, there are not sufficient numbers of qualified practitioners available. Also, traditional programs cannot meet personnel shortages that arise from unexpected pharmacy turnover at odd times of the year. As a supplementary means to meet the demand, short courses have been developed to offer intensive education over a short period of time. The course may be structured to last five to six consecutive weeks at a training site or for two-week intervals followed by practice in a nuclear pharmacy for a total of six weeks of didactic training. Another approach utilizes the concept of a certificate program where the trainee uses videotapes and workbooks for self-study while working in a nuclear pharmacy followed by a two-week session at the school of pharmacy.[18,19,20]

Nuclear Pharmacy Practice Is Quickly Giving Way To A Term Of Even Broader Scope, Namely Radiologic Pharmacy Practice

The term nuclear pharmacy practice is quickly giving way to a term of even broader scope, namely radiologic pharmacy practice. This is due to the realization that the pharmacist can have a significant impact on patient care not only in nuclear medicine, but also in all areas of radiology including computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), ultrasound, and positron-emission tomography (PET), since all of these modalities use medications to help acquire diagnostic information and monitor therapeutic interventions.

Presently, the scope of radiologic pharmacy practice is evolving, and as more and more pharmacists become introduced to, and involved in, this practice area, its importance in the provision of comprehensive pharmaceutical care will become evident.[21]

Comparison Of Nuclear Pharmacy With Traditional Pharmacy

When we look at a nuclear pharmacy, its operation is not much different than that of a traditional pharmacy - a "prescription" for a particular product is presented, and the nuclear pharmacist must prepare and dispense that "prescription". Where a traditional pharmacist will dispense doses in milligram weight units, a nuclear pharmacist will dispense in millicurie activity units. Where a traditional pharmacist dispenses tablets and capsules, a nuclear pharmacist dispenses the radioactive material in liquid or capsule form. Where a traditional pharmacist will generally dispense the prescription to the patient, the nuclear pharmacist will dispense to a hospital or clinic nuclear medicine department where the dose will be administered to the patient. In general however, the two branches of pharmacy are strikingly similar.

There are some inherent differences in nuclear pharmacy practice, which ultimately warranted its designation as a specialty pharmacy practice. There are certain areas of practice unique to nuclear pharmacy, as well as a separate class of drugs that are used. The most striking would be the fact that radioactive material is being used to create the final products. While the

quantity used is small, there are still certain precautions that must be taken into account when handling on a day to day basis. The nuclear pharmacist is extensively trained in radiation safety and other aspects specific to the compounding and preparation of radioactive materials.[22]

Current Services Supplied By Nuclear Pharmacists

Today the services supplied by nuclear pharmacists are accepted as routinely as are those of a staff pharmacist in any hospital. Radiopharmaceuticals as unit doses arrive on time containing the right amount of radioactivity prepared for individual patients. Radioactive products that are used infrequently now are available the same day. Radioactive waste is minimized in the clinic. The required space is minimal for preparing and dispensing radiopharmaceuticals.

Today information on products, drugs used in interventional procedures, and drugs that may interfere with the biodistribution of a radiopharmaceutical is just a local telephone call away. In larger medical centers, the nuclear pharmacist may assist in clinical trials or research associated with investigational radiopharmaceuticals. The nuclear pharmacist may take an active role in teaching nuclear medicine technologists and/or nuclear medicine residents. These services and others that are taken for granted today hardly existed before.

Current Status

From the small number of pharmacists serving nuclear medicine in the early 1970s, the specialty has grown to more than 1,000 nuclear pharmacists located today in hospitals or centralized commercial nuclear pharmacies. Several centralized nuclear pharmacy corporations exist as well as many independent nuclear pharmacies. Dedicated nuclear pharmacy service is a rapidly expanding area as well. The services and benefits to patients and personnel in nuclear medicine have come into existence as a result of the vision, dedication and efforts of a few individuals that realized the importance of pharmacy involvement in radiopharmaceuticals. Twenty-five years after the official formation of the Section on Nuclear Pharmacy, it is appropriate to recognize the efforts of these individuals by documenting the events leading to the emergence of the specialty of nuclear pharmacy.

CONCLUSION

The specialty practice of nuclear pharmacy has been instrumental in leading pharmacy into the development and the recognition of specialties in pharmacy. The dedication of early pioneers and the support of professional pharmacy organizations have been of great importance. Nuclear pharmacy education has developed in various ways leading to the overall development of nuclear pharmacy.

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