Delivery Methods of Radiopharmaceuticals: Exploring Global Strategies to Minimize Occupational Radiation Exposure

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In the world of nuclear medicine, health care professionals face the challenge of safeguarding themselves and their patients from occupational radiation exposure. As the field experiences exponential growth, driven by the surge in approvals of radiopharmaceuticals for diagnostic and therapeutic applications, it becomes vital to delve into the delivery methods of radiopharmaceuticals. Health care professionals take precautions during radiopharmaceutical administration, including maintaining distance from radioactive sources, using shielding, limiting exposure time, and monitoring radiation levels with badges. Regular evaluations provide compliance with recommended exposure limits, yet concerns persist, especially regarding the cumulative radiation exposure from manual injections over time. Understanding the long-term effects of radiation exposure has spurred the development of cutting-edge medical device technologies, such as autoinjectors, designed to administer radiopharmaceuticals accurately while minimizing total radiation dose to health care professionals. The U.S. Pharmacopeia 825 regulation refers to these devices as "direct infusion systems." Nuclear medicine technologists commonly refer to them as "autoinjectors," whereas device manufacturers may use terms such as injection system, radiopharmaceutical injector, or infusion system. Despite variations in terminology, these devices hold a pivotal role in shaping the future of radiopharmaceutical delivery. In an era of escalating demand for PET procedures worldwide, skilled health care professionals ensure the safe and precise dosing of radiopharmaceuticals. This article explores the state-of-the-art medical devices in radiopharmaceutical delivery, spotlighting transformative medical devices currently revolutionizing the nuclear medicine landscape in the global market.

Key Words: autoinjector; radiation safety; infusion system; radiopharmaceutical delivery system; medical device; direct infusion systems

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Nuclear medicine has evolved significantly, fueled by instrumentation and radiopharmaceutical research breakthroughs (*1*). Radiopharmaceuticals play a pivotal role in diagnostic imaging and therapy, with PET procedures widely used for cancer diagnosis and monitoring. Health care providers in PET and PET/CT procedures must receive thorough training and strictly adhere to safety protocols to minimize radiation exposure to protect their well-being (*2*). Various measures are implemented to mitigate radiation exposure in PET and PET/CT settings. Operators undergo thorough training and education covering radiation safety protocols, radiopharmaceutical handling, and operational procedures, with continuous education maintaining their vigilance in minimizing radiation exposure risks. Training for health care workers in nuclear medicine, particularly technologists, underscores principles such as time, distance, and shielding, along with the ALARA principle (as low as reasonably achievable), aimed at minimizing radiation exposure. Regular monitoring of staff members, achieved through the use of badges capturing and tracking radiation exposure levels, is overseen by radiation safety officers to ensure adherence to safe limits. Additionally, workload distribution is optimized to prevent operators from consistently encountering high doses, which is accomplished through meticulous procedure scheduling management. Facilities install proper shielding and barriers, including lead-lined walls and protective equipment, to minimize radiation leakage and to safeguard personnel (*3*). Another solution for institutions with high patient volumes to mitigate radiation exposure to health care professionals is adopting automated injection systems to enhance workflow efficiency (*4*). The U.S. Pharmacopeia 825 regulation refers to these devices as "direct infusion systems." Nuclear medicine technologists (NMTs) commonly refer to them as "autoinjectors," whereas device manufacturers may use terms such as injection system, radiopharmaceutical injector, or infusion systems. Despite variations in terminology, these devices hold a pivotal role in shaping the future of radiopharmaceutical delivery.

RADIATION EXPOSURE AND SAFETY

In the realm of medical imaging using radioactive materials, NMTs experience varying levels of exposure depending on their tasks. While conducting patient scans, NMTs

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typically encounter a lower dose, averaging around 0.2 μSv/h. However, their exposure can elevate to approximately 2 μSv/h during patient injections. This suggests that NMTs engaged in manual injections of radiopharmaceuticals may undergo nearly 7 times more radiation exposure compared with the average person (*5,6*). In clinical settings, the onset of long-term or stochastic effects becomes apparent at lower radiation doses, with the probability of occurrence rising as the dose increases, although not in a linear trajectory. Among health care practitioners, NMTs potentially confront the highest long-term radiation exposure, primarily because of advancements in imaging technologies and the heightened frequency of nuclear medicine procedures (*6,7*). Consequently, continual adaptation of measures to mitigate radiation exposure for health care professionals, particularly during PET radiopharmaceutical administration, is imperative to ensure safety.

REGULATION OF MEDICAL DEVICES

Before entering the market, medical devices undergo thorough regulatory approval processes to ensure compliance with safety standards for both operators and patients. Regulatory frameworks began to develop in the 1990s, particularly in regions such as the United States, European Union, and Asia (*8*). In the United States, device regulation falls under the jurisdiction of the Food and Drug Administration, whereas in Europe, devices are overseen by the European Medicines Agency, ensuring compliance with EU Medical Device Regulations. Stringent regulations were prompted by incidents such as the Poly Implant Prothèse (PIP) breast implant scandal, leading to the implementation of the EU Medical Device Regulation to strengthen oversight. The Medical Device Regulation emphasizes comprehensive regulation throughout a device's life cycle, including postmarket clinical follow-up studies, reflecting a trend toward prioritizing safety (*9,10*). Users of nuclear medicine infusion systems can potentially offer additional feedback to device manufacturers to ensure that the medical technologies remain current and state-of-the-art. Medical devices are subject to strict regulatory approval processes to enter each market and to be used by operators and patients. It is recommended to verify with local health authorities and the manufacturer of medical devices available in one's market. Disparities in device availability persist globally because of differences in approval processes in each country's jurisdiction and each manufacturer's global footprint capabilities.

NUCLEAR MEDICINE INFUSION SYSTEMS (AUTOINJECTORS)

There are 2 primary methods for intravenously administering radiopharmaceuticals to patients: (1) Manual administration involves using a syringe holder to shield the syringe, which is the most common approach. (2) Automatic administration uses an autoinjector or infusion system.

Using an infusion system offers several advantages, including reduced exposure to the fingers by eliminating the need to manually handle the syringe and push the plunger. Additionally, it decreases the effective dose to the technologist by allowing them to maintain a safe distance from the radiation source (*11,12*). Autoinjectors have demonstrated high accuracy in radiopharmaceutical administration (*13*). The U.S. Pharmacopeia 825, which came into effect November 2023, highlights the role of direct infusion systems, such as portable PET direct infusion systems, in dispensing and administering radiopharmaceuticals directly to patients from multiple-dose containers. This approach significantly reduces radiation exposure to personnel. According to U.S. Pharmacopeia 825 regulations, saline bags attached to direct infusion systems may only be punctured once and used for up to 10 h. Each bag must be appropriately labeled with the puncture date and time, as well as the beyond-use date (*14*). Infusion systems are medical devices equipped with lead and tungsten shielding, dose calibrators, and radiopharmaceutical dose vials. They automate the administration process through computer-controlled mechanisms, using either bulk or single-use radiopharmaceutical sources. These systems enable accurate measurement of patient doses in an ionization chamber before injection, thereby minimizing radiation exposure for health care providers and enhancing dosing precision (*15*). The nuclear medicine department at Jaber Al Ahmad Centre conducted a study comparing the administered doses of ^{18}F-FDG for PET/CT studies using 2 techniques: automatic and manual injection. It was found that patients injected manually exhibited deviations in dose accuracy ranging from −21.87% to 145.1%. Conversely, using an automated injection system resulted in more precise dosing, leading to fewer deviations from departmental guidelines and greater consistency in delivered doses per patient weight (*16*).

INFUSION SYSTEM IN U.S. MARKET AND GLOBALLY

The introduction of the MEDRAD Intego PET Infusion System (Bayer) brought about a significant transformation in PET procedures globally (Fig. 1). The system, approved by the Food and Drug Administration, is available in the United States market as well as in major global markets around the world, including Europe and Australia. The infusion system has been tested and approved to administer ^{18}F-FDG or ^{18}F-NaF to patients, prioritizing effective radiation shielding for medical staff (*12*), with approximately 600 installations worldwide and over 8 million injections delivered to date (*17*). The MEDRAD Intego PET Infusion System comprises essential components such as a radiopharmaceutical pump, a saline pump, a dose calibrator, an air detector, and comprehensive system shielding. The system offers dose flexibility, allowing programming based on activity only or activity per patient weight, with precise delivery of ^{18}F-FDG within ±10% of the prescribed dose (*17*). Research conducted at BC Cancer Vancouver uncovered a decrease in radiation doses, including a 43% reduction in whole-body exposure, 83% in the right ring and 71% in the left ring, highlighting the contribution of the MEDRAD Intego PET Infusion System in mitigating radiation

FIGURE 1. MEDRAD Intego PET Infusion System first entered United States and European markets in 2008 (*17*) .

exposure to medical personnel, especially in facilities catering to large patient populations (*18*).

EUROPEAN MARKET INFUSION SYSTEMS

In contrast to the limited options in the U.S. market, the European market presents a variety of radiopharmaceutical infusion systems available for sale. These include, but are not limited to, the MEDRAD Intego, the Karl 100 (Tema Sinergie), IRIS (Comecer), Posijet (Lemer Pax), Jetti (Lemer Pax), and ARTAUTA (GlobalPET). The MEDRAD Intego has been previously discussed. Let us now turn our attention to the Karl 100 system. Developed by Tema Sinergie, the Karl 100 is an automated dispensing and injection system designed specifically for PET and SPECT procedures. This autoinjector can administer ^{18}F-FDG and a wide range of radiopharmaceuticals. Currently, there are approximately 171 Karl 100 units in use, collectively facilitating over 350,000 injections (*19*). The Karl 100 key features include operator and patient safety, flexibility, and user-friendliness. The system is automated to uncap lead pots and perforate multidose vial septum with a fully shielded compartment, ensuring protection throughout the procedure. In terms of patient safety, the Karl 100 maintains radiopharmaceutical sterility, and each syringe is automatically linked to the main disposable set within an isolated, vented box featuring a filtered and controlled atmosphere (Fig. 2) (*19*). At Santa Maria della Misericordia Hospital in Italy, the introduction of the Karl 100 for ^{18}F-FDG delivery revealed significantly reduced radiation exposures compared with manual injection methods. A study conducted in 2020 showed a 31% decrease in average body exposure for technicians, with a remarkable 78% reduction in equivalent dose to their hands (*20*).

IRIS, an automated multidose injection system developed by Comecer and the legal manufacturer Comecer Netherlands B.V., is available in the European market (*21*). According to the manufacturer, IRIS is an automatic fractionator and injector of radiopharmaceuticals that performs calibrated injections, starting from multidose solutions of FDG to many other radiopharmaceuticals, including unit dose therapies (Fig. 2). The system is designed to administer the radiopharmaceutical via a disposable kit, requiring replacement of only the terminal portion after each patient injection. The radiopharmaceutical activity is measured by the ionization chamber within the fractioning system. The multidose mother vial is directly inserted into the device. The highest activity permissible for the multidose mother vial is 30 GBq (^{18}F or equivalent) (*22*).

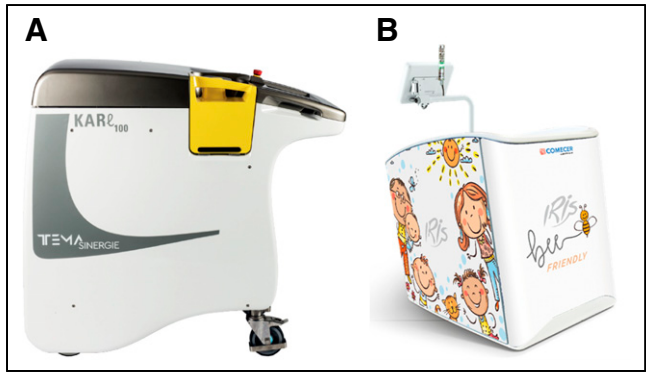

FIGURE 2. (A) Karl 100 automatic radiopharmaceutical dispensing and infusion system is available in European and Australian markets (*19*). (B) IRIS automated multidose injection system is available in European markets (*21*).

In research conducted in Lucknow, India, investigators assessed the impact of automated injection on extremity radiation exposure. Evaluations involved ring and head dosimeters. Both manual and automated injections using the IRIS system were analyzed. Results showed significant reductions in staff radiation exposure with automated injection: a 97% decrease in left-hand extremity doses, a 98% decrease in right-hand extremity doses, and a 30% decrease in eye-lens doses. These findings underscore the potential for automated systems to drastically reduce staff radiation exposure (*22*).

Posijet, developed by Lemer Pax, is a shielded radiopharmaceutical injection and preparation unit for PET and SPECT. The Posijet is a compact, self-contained, radiation-protected radiopharmaceutical fractionating and injection unit that collects, measures, and injects the required patient dose. Posijet supports a wide range of radiopharmaceuticals (Fig. 3). At the University Hospital Zurich, investigators studied finger dose radiation exposure levels for myocardial perfusion PET/CT studies. They identified that the Posijet injection system significantly lowered radiation exposure to technologists by up to 60% (*23*). For NMTs, it is crucial that research is focused not only on new imaging methods or advanced tracers but also on state-of-the-art medical technologies to further reduce occupational radiation exposure for staff. Katerina Stypsanelli, working at Aghia Sophia Children's Hospital in Greece, notes that the department's staff appreciates the reduced radiation exposure when using Posijet during the preparation and injection of FDG radiopharmaceuticals. Overall, they find Posijet easy to use and efficient, aiding in the quick and accurate administration of FDG doses for children (*24*).

Jetti is an automatic radiopharmaceutical injection system designed by Lemer Pax for PET procedures (Fig. 3). The Jetti injection unit is both mobile and adaptable, facilitating the transportation of patient doses to the injection room for automatic or manual administration. This system ensures radiation protection and sterility conditions tailored to the needs of both patients and users. With a 40-mm-thick lead glass shield, users maintain full visual control over the patient and injection site throughout the entire radiopharmaceutical

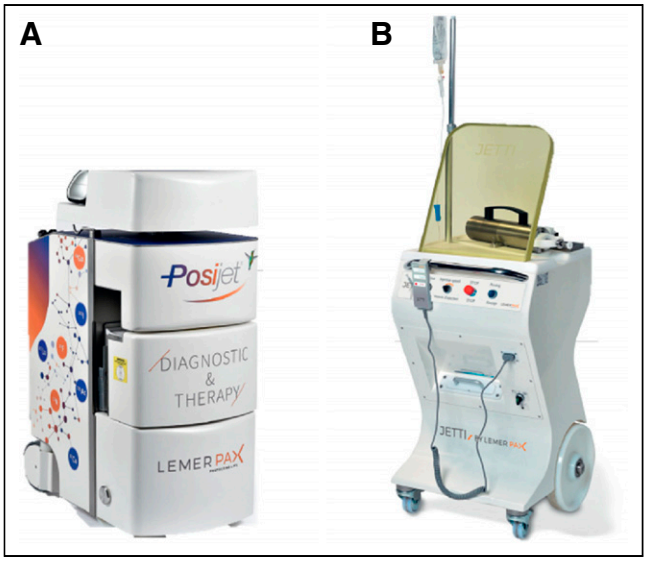

FIGURE 3. (A) Posijet shielded radiopharmaceutical injection and preparation unit for PET and SPECT is available in European markets (*23*). (B) Jetti shielded automatic radiopharmaceutical injection system is available in European markets (*25*).

administration process. For enhanced patient safety and to prevent extravasation risks, Jetti includes 2 pressure sensors and an injection speed regulator. Its specialized injection kit construction ensures the integrity of the radiopharmaceutical, enabling users to dilute patient doses and administer required NaCl rinses seamlessly, regardless of the volume needed (*25*).

JAPAN'S NUCLEAR MEDICINE INFUSION SYSTEMS

The Japanese pioneered the development of a nuclear medicine radiopharmaceutical injector with the M-130 system, created by Sumitomo Heavy Industries Ltd., and introduced it to the market in 2004 (*26*). Additionally, 3 other systems are available: UG-05 and UG-1000M, developed by Universal Giken, and AI-300, developed by Sumitomo Heavy Industries Ltd.

Manufactured by Universal Giken Ltd. and detailed in Figure 4, the UG-05 automatic dispensing system underwent a rigorous review and approval process through Japan's Pharmaceuticals and Medical Devices Agency regulatory pathway on its introduction in Japan in 2008. The UG-05 system dispenses ^{18}F-FDG, both produced in-house and supplied by pharmaceutical manufacturers, for automatic administration to patients. Shielded and capable of storing numerous undiluted vials, it aims to minimize radiation exposure and enhance dispensing efficiency. Operations conducted by nurses or laboratory technicians are facilitated by a simple touch control panel, allowing for quick and interactive operation with minimal training. Safety features prevent overdosing, with radioactivity measured and administration halted if deviations occur. Weight-based dosing is used for radiopharmaceuticals administered based on body weight parameters (*27*).

Eleven years after introducing the UG-05 automatic dosing system, Universal Giken launched the UG-1000M, an

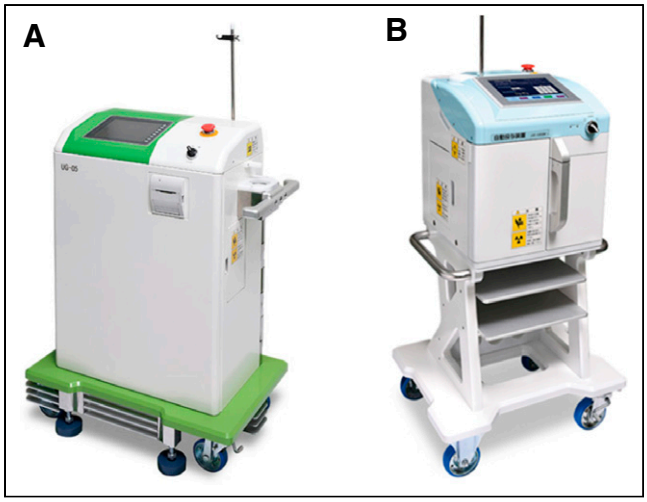

FIGURE 4. (A) UG-05 automatic dispensing system for radiopharmaceuticals first entered Japanese market in 2008 (*27*). (B) UG-1000M automatic dosing system first entered Japanese market in 2019 (*28*).

enhanced and updated version, in June 2019. The UG-1000M is the first device with a dispensing function for delivery formulations, accurately dispensing and administering radioactivity doses tailored to individual patients. It enables the preparation and administration of precise radioactivity doses, previously unattainable, by entering either the radioactivity amount or the patient's weight. The system automatically reads chemical information from label barcodes, eliminating manual entry errors and saving time. Installation is simplified with a cartridge-type infusion set, reducing setup errors and facilitating disposal. The system calculates and displays the effective dose, which can be printed or exported externally. Safety is enhanced with strengthened shielding, including 25-mm lead shielding for the housing and 20-mm lead shielding for the syringe and filter (*28*).

Ten years later, in January 2014, Sumitomo Heavy Industries Ltd. introduced the AI-300 injector system after

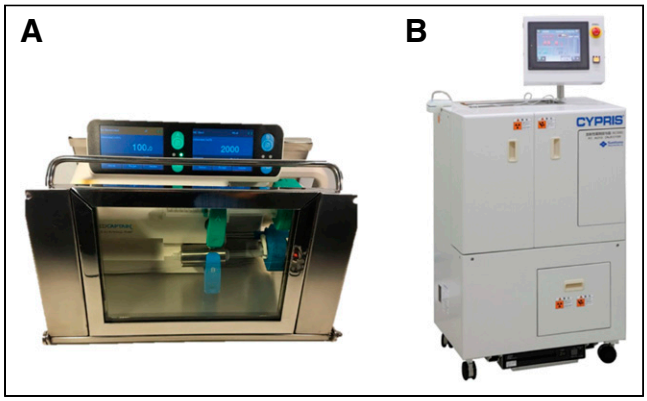

FIGURE 5. (A) ARTAUTA PET injector consists of a dual-channel infusion pump, one for serum and one for radiopharmaceutical (*29*). Device is shielded with 10 mm of lead. (B) AI-300 autoinjector used for PET procedures to deliver ^{18}F-FDG. AI-300 entered Japanese market in 2014 (*26*).

receiving approval from the Pharmaceuticals and Medical Devices Agency (Fig. 5) (*26,29*).

CONCLUSION

Professor Alfred Buck, from the University Hospital in Zurich, emphasizes that radiopharmaceutical infusion systems allow health care professionals to deliver predetermined radiopharmaceutical doses to each patient with exceptional accuracy. Some injection systems are also designed to facilitate efficient responses to schedule changes, patient delays, and additional patients (*15*). Institutions with high patient volumes have increasingly adopted autoinjectors into the workflow to help further reduce occupational exposure, optimize dose accuracy, and enable efficient workflow. A study performed in Lithuania analyzed data from active personal dosimeters worn by medical physicists, NMTs, and administrative staff between 2014 and 2018. The study focused on dispensing and injecting ^{18}F-FDG using 2 autoinjectors. Results indicated that NMTs responsible for injection procedures consistently recorded the highest levels of radiation exposure, irrespective of the type of automatic infusion system used, compared with physicists and administrative staff (*30*). Hence, exploring alternative strategies to further minimize radiation exposure among NMTs is crucial. Infusion systems are designed to streamline and standardize the administration of radiopharmaceuticals, with the goal of reducing occupational radiation exposure, ensuring accurate dosing, and mitigating human errors. Over the last 16 y, NMTs have noted a consistent 5-fold rise in PET procedures, underscoring a significant increase in demand and workload (*17*). Despite notable advancements in radiopharmaceutical approvals, many professionals in nuclear medicine question the delay in progress regarding radiopharmaceutical delivery systems. Research suggests that a significant percentage of companies focusing on medical device innovation fail to yield substantial returns for investors compared with pharmaceutical launches (*9*). Furthermore, the initial cost of these medical devices necessitates an upfront investment for nuclear medicine departments, for which some facilities may not have the financial capacity. Moreover, the variability in the medical device approval process across different countries and regions contributes to disparities and delays in availability. Autoinjectors or radiopharmaceutical infusion systems play a pivotal role in advancing the field of nuclear medicine. It is essential to note that the medical devices discussed in this review are not exhaustive, but they represent a significant portion of available nuclear medicine infusion systems available globally.

DISCLOSURE

Hinna Shahid, Lois Miller, and Peter Seidensticker are employees of Bayer, and Obaid Kazmi is a contractor. No other potential conflict of interest relevant to this article was reported.

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