Spotlight: The status of Radiopharmacy in Africa

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1. Introduction

Integral to Nuclear Medicine Practice is the preparation of radiopharmaceuticals. Preparation can be done on a smaller scale in healthcare establishments following the principles of Good Radiopharmacy Practice (GRRP), or on a larger scale in industrial settings following the principles of Good Manufacturing Practice (GMP) [1]. Crucial factors which can alter the in vivo behavior of

a radiopharmaceutical are its purity and quality. These factors influence the subsequent scan interpretation, eventual diagnostic accuracy, and patient outcomes [2]. Above all else, the two cornerstones of a radiopharmaceutical's quality, namely efficacy and patient safety, must be maintained. The European Union now specifies that radiopharmaceuticals must be prepared by a legally authorized person. The regulations on the required qualifications and experience of a 'Qualified Person' vary between countries [3].

The field of radiopharmacy has undergone drastic changes in recent years. Early radiopharmacy practice was predominantly based on the simple addition of sterile technetium-99m pertechnetate to a freeze-dried kit. New radiopharmaceuticals translated into clinical use require more complex operations to produce [4]. Examples are positron emission tomography (PET)-based diagnostic radiopharmaceuticals and the more advanced therapeutic radiopharmaceuticals. While many developed countries were at the forefront of this evolution, other regions are not yet adequately prepared to deal with these changes [4].

Developments in radiopharmaceutical sciences continue to accelerate the availability of novel solutions to clinical problems and increase the availability of better diagnostic techniques and more effective therapies. Radiopharmaceutical technology and its implementation are, therefore, critical to influence the acceleration of more advanced clinical nuclear medicine in Africa. As an example, in-house cyclotrons with the necessary personnel to provide uninterrupted [^{18}F]FDG production is a given in many countries, and in stark contrast, having a basic gamma camera or molybdenum-99 generator might be only a dream in many parts of the African region. The authors are convinced that for the region to progress—both the provision of radiopharmaceutical services as well as increasing available technology are critical parts of the equation that will influence growth in Clinical Nuclear Medicine. From our perspective, radiopharmaceutical sciences and nuclear medicine are two halves of one compartment. The progress in investment, research and application on one side have to be supported by the same level of progress from the other side. Both need to efficiently support the implementation of new radiopharmaceutical agents.

Before recommendations can be made for Africa, the status of professionals practicing radiopharmacy needs to be explored. Information on infrastructure in the region must also be critically evaluated and the stumbling blocks need to be addressed for Africa to fully take its place on the international Nuclear Medicine stage.

2. Radiopharmacy Infrastructure in Africa

The data on radiopharmacy infrastructure in Africa are incomplete with multiple conflicting reports. The responses from countries in surveys were often reported to be extremely limited [5,6,7,8]. The importance of up-to-date information with regard to infrastructure and extent of operations cannot be over-emphasized when the need for human resources is critically evaluated. For instance, in 2022, three sources [7,8,9] reported different numbers of operational cyclotrons in the region: 4, 14 and 17, respectively.

Despite reporting gaps, the region shows promising and growing capacity. It currently has seven operational research reactors, with Egypt and South Africa actively producing molybdenum-99/technetium-99m generators. South Africa also regularly produces germanium-68/gallium-68 generators, while lutetium-177 and iodine-131 are routinely produced on the continent. In addition, Africa has at least two cold kit production sites based in Egypt and South Africa [5, 10].

Information with regards to the number of hospital-based radiopharmacies and the level of operation practiced, is not readily available. Additional information that is urgently needed includes the future growth planned in the region to match the human resources with the planned growth and complexities of Nuclear Medicine operations.

3. Status of Radiopharmacists in Africa

Currently, there are three institutions in Africa which offer post-graduate training in radiopharmacy. Two provide English-driven master's degrees (Stellenbosch University and Sefako Makgatho Health Sciences University, South Africa) and one institution has French as the main tuition language (University Mohamed V Faculty of Medicine and pharmacy-FMPR in partnership with National Center for Nuclear Energy, Science and Technology-CNESTEN, Morocco) with contribution from INSTN (L'Institut national des sciences et techniques nucléaires-France). It is important to highlight that this French program is being developed and implemented within the framework of the IAEA technical cooperation program and the AFRA program [11]. The total number of radiopharmacy graduates (since 2010) and trainee radiopharmacists broken down by country of origin are provided in Fig. 1. Note, these do not include graduates trained on other continents as the information with regard to those individuals is currently unavailable [11,12,13,14].

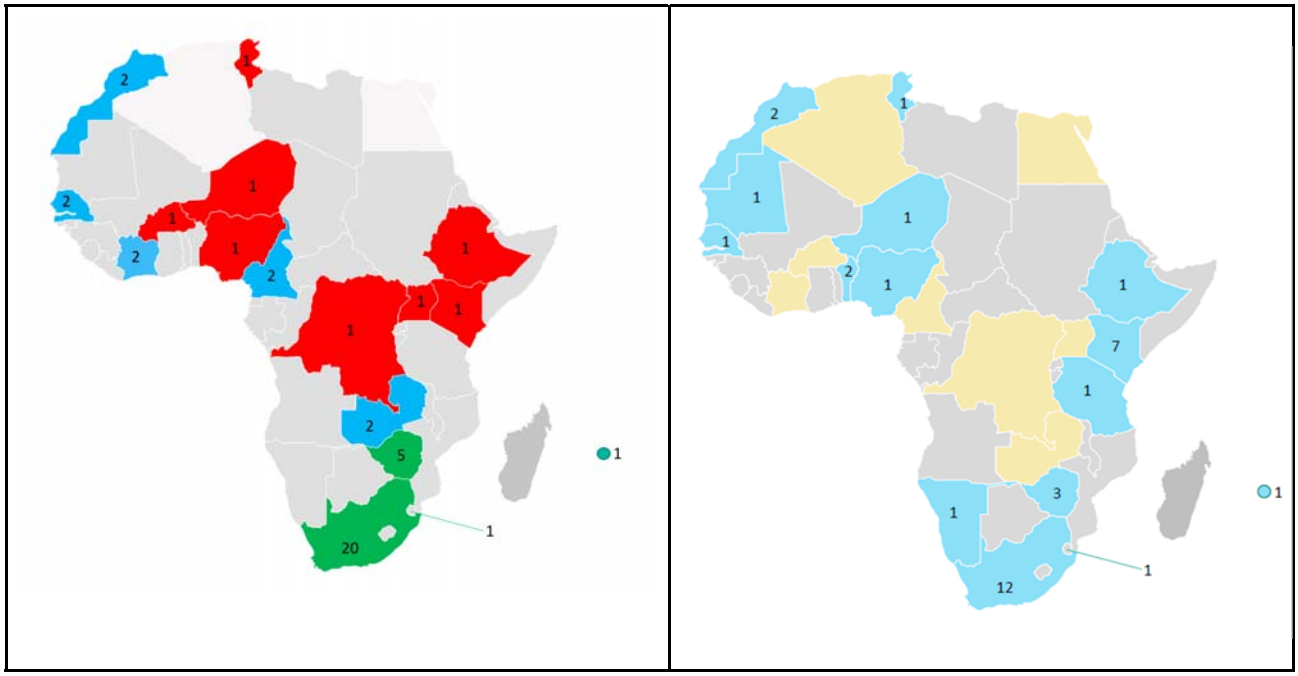

Figure 1: Graduates and trainees in Radiopharmacy enrolled at African based universities at time of publication. A) Qualified Radiopharmacists (with MSc degrees) in Africa B) Trainee Radiopharmacists currently enrolled at African training institutions. Countries with previously qualified radiopharmacists but not currently training are indicated in yellow.

While South Africa has produced the highest number of radiopharmacists thus far, many of them are currently unable to complete the additional 2-year practical work requirement to be eligible to apply for official recognition as radiopharmacists, owing to the lack of official posts in the public sector. Without official recognition, the employment opportunities are minimal, and these graduates are lost to other fields of pharmacy practice.

A unique solution is implemented by Egypt where approximately 60 undergraduate students per year receive a 10-week training course in radiopharmacy (including radiochemistry and clinical Nuclear Medicine). Around two postgraduates follow theoretical courses and thesis-based research training in Egypt per year. Egypt is, therefore, completely self-sustainable pertaining to the training and delivering of radiopharmacists to cover the needs of the country [15]. Egypt also has post-graduate education for Master's and PhDs for the subspeciality radiopharmacy in different Egyptian universities in cooperation between Egyptian Atomic Energy. About 25 qualified

PhD graduates in radiopharmacy are working now in Egyptian Atomic Energy Authority in production and research sectors [15].

4. The path to register as a radiopharmacist worldwide

The path to register as a radiopharmacist or nuclear pharmacist varies considerably depending on the region or registration requirements (Table 1). Countries for which no requirements are published include (but is not limited to) Austria, Canada, Germany, Italy, the Philippines, Uruguay, and Morocco. African countries such as Mauritius, Nigeria and Kenya require a 2-year post-graduate master's degree qualification and valid registration as a pharmacist to practice as a radiopharmacist in most facilities. However, for these countries, no official published guidelines are currently available.

The Netherlands opted to promote the role of clinical radiochemist which is an expert in radiochemistry (PhD or MSc in radiopharmaceutical development) and laboratory operations with additional training in Good Manufacturing Practice and radiation safety. This person oversees all technical aspects of decentralized production of radiopharmaceuticals and collaborates with the unspecialized Hospital Pharmacist [3]. In Germany, while there are no specific regulations for the hospital radiopharmacist, there are additional requirements to become a 'Qualified Person' in an industrial radiopharmaceutical production setting. Germany also adopted the EANM Postgraduate Certificate course in Radiopharmaceutical Chemistry/Radiopharmacy as advantageous in the process of providing evidence of qualification. It must be noted that only Switzerland currently officially recognize the EANM Radiopharmacy certificate.

Table 1: Current registration requirements to become a radiopharmacist, a non-exhaustive list of global examples

	Qualifications	Additional requirements	Practical work	Exam	Ref
USA	Basic training in radiation physics, protection, biology, and radiochemistry	Registration as pharmacist	A total of 4000 hours of practical experience in a nuclear Pharmacy	BPS Nuclear Pharmacy Certification	17
Belgium	6 months training: Practical training and theoretical classes	Registration as pharmacist. MSc in Pharmaceutical Sciences	No additional training outside 6 months diploma.	Federal agency for Nuclear Control	18
UK	Post-qualification diploma or MSc degree in clinical pharmacy or pharmaceutical technology including modules on radiopharmacy	Registration as pharmacist	No additional practical work prescribed	No examination	19
South Africa	An approved master's degree qualification (2 year) in Radiopharmacy	Registration as pharmacist	Two year's post-qualification	Optional	20
Egypt	Basic training on radiochemistry, radiation protection and radiopharmacy	Registration as pharmacist	One year's post-qualification	Nuclear Regulatory Licencing	21

5. Perception of the role of radiopharmacists in developing countries.

Nuclear pharmacies/radiopharmacies in many countries have been staffed by nuclear medicine technologists for years. This practice is not only observed in Africa, where resources are limited, but also in the United Kingdom where nuclear medicine technologists undertake tasks of many of their colleagues in the nuclear medicine department [20]. The tasks include managing production of radiopharmaceuticals, which is the role of radiopharmacists, and complicated equipment quality control, which is the role of a medical physicist [20].

These role substitutions can negatively impact the safety and quality of care offered to patients [21]. Even though nuclear medicine technologists' core competencies include some basic radiopharmacy training, pharmacists have a professional responsibility and mandate to participate in all activities where medicines are concerned, including contrast media and radiopharmaceuticals used in hospitals [22, 23]. It is also clear that with the advent of new advanced radiopharmaceuticals, including radionuclide therapies, role substitution is no longer a viable solution to address the shortage of radiopharmacists on the continent, as specialized knowledge on radiochemistry and GMP are required in these instances.

6. Radiopharmaceutical Research in Africa

When a radiopharmaceutical is investigated in humans, it should be considered an Investigational Medicinal Product (IMP), and then, the requirements prior to injection become of critical importance. Hence, during clinical evaluation, the matter becomes more nuanced and the involvement of radiopharmacists more critical. The EU regulations for clinical trials involving radiopharmaceuticals (Art 61 par 5) are evolving [24] where, in general, credit is now being given for their low-risk profile of RPs compared to many other drugs. The Regulation (Art. 61.5.b of Regulation 536/2014) introduces substantial changes in the field of diagnostic radiopharmaceuticals used as diagnostic investigational medicinal products where this process is carried out in hospitals, health centers or clinics, by pharmacists or other persons legally authorized. In this regard, the 'persons legally authorised' are of key importance to advance research from bench to bedside. Such a person also needs clinical trial-specific training. The European approach is reliant on the Postgraduate Certificate Course in Radiopharmaceutical Chemistry/Radiopharmacy. The EANM Radiopharmacy Board awards such certificates to individuals suitably qualified having attended the appropriate courses of the radiopharmacy syllabus (listed in Appendix I), completed a 2-year period of experience in a radiopharmacy department, and completed a nationally recognized course on radiation safety [25, 26].

From an African perspective, this (or a similar) approach can be adopted which will accelerate the approval of new radiopharmaceuticals for First-in-Human studies but at the same time harmonize the approach between different hospitals, regions and countries and put such research on a sound ethical footing.

7. Roadmap towards the future of Radiopharmacy in Africa

7.1 Strengthening local legislation and guidance by authorities

The local legislation and health regulatory boards need to update policies pertaining radiopharmaceutical production and the scope of practice of the radiopharmacist. This includes regional guidelines for licensing of radiopharmacists as a field of specialization and safeguarding the scope of practice of such individuals. Regional guidelines for the registration and handling of radiopharmaceuticals as medicines also needs attention, as this is also a global issue that is receiving attention worldwide. Trained and experienced health regulatory inspectors needs to be cultivated and involved in both hospital radiopharmacy and industrial manufacturing. Other considerations should be regional pharmacopeias and GxP (Good Practice) guidelines that are self-aware of the unique situation in the African region.

Adoption of the WHO “International Pharmacopoeia” and the section on radiopharmaceuticals or the “PIC/S guideline to good practices for the preparation of medicinal products in healthcare establishments” can be a good starting point to develop local legislation. In fact, recently (June 2023), the South African Health Products Regulatory Authority published a “Guideline for Good Medicine Compounding Practice” for comments, that suggests that the compounding of radiopharmaceuticals in hospital settings should take place under the guidance of a pharmacist and should follow the PIC/S guidelines Annex 3 “Good practices for the compounding of radiopharmaceuticals in health care establishments”. It is with interest that the progress on adopting these proposed guidelines is followed and to what extend the practice of radiopharmaceutical preparation in South Africa will be changed [27, 28].

7.2 A unified approach to training requirements and scope of practice of radiopharmacists

It is not within the scope of this spotlight to suggest guidelines for the harmonization of education in radiopharmacy. It is, however, a finding from this evaluation that such harmonization is desired within Africa, but also surprisingly on a global scale. It is our suggestion that it is now a matter of urgency that a virtual platform is created with theoretical training that could be supported with short visits to technically advanced sites within the region. The current platforms that exist must receive wider application and engagement. A regional version of the EANM Postgraduate

Certificate course in Radiopharmaceutical Chemistry/Radiopharmacy could be established but in a way that is self-aware of the unique constraints faced in Africa.

It is clear that a trained radiopharmacist should have a set of competencies including (but not limited to) day-to-day maintenance of equipment and stock control, as well as impeccable knowledge of radiopharmaceutical preparation. The required practical knowledge or training must be supplemented with knowledge on radiochemistry principles governing radiolabeling and quality control, in-depth knowledge of good manufacturing practice and good radiopharmaceutical practice, including quality control and quality assurance. The radiopharmacist must also be able to provide the Nuclear Medicine Clinical team with guidance on the selection of radiopharmaceuticals with a sound understanding of radiopharmacology, radiopharmacodynamics and radiopharmacokinetics, and have a current knowledge of the guidelines and legal aspects governing the production of radiopharmaceuticals and the provision of radiopharmaceutical services. In essence, the radiopharmacist must have the complete package of practical skillsets enhanced by in-depth scientific knowledge and a bridge between physics, chemistry, pharmaceutical principles, and the clinical application

The scope of practice of radiopharmacists and the role within the Nuclear Medicine community also needs further clarification and strengthening.

7.3 Mentorship within the region and abroad post-qualification

The availability of mentorship for professionals in the region has received support in the past, most notably by funded scientific visits through the International Atomic Energy Agency (IAEA). However, it is important that junior radiopharmacists or scientists should be mentored by senior professionals in the region to ensure that they do not get lost in the system. A sustainable platform, including a virtual community, should be created for continuous training, mentorship and technical advice and experience sharing.

7.4 Upgrade of infrastructure

The focus on the infrastructure in the region should be to optimize the use of the current infrastructure available. However, for progress to be made, vast financial investments are required for this upgrading. For this, the involvement of local governments is crucial. Areas of insufficient

use of current infrastructure must be identified to mobilize current infrastructure more effectively, including collaboration with neighboring countries. In-depth investigation on the current utilization of infrastructure is important, such as the example published by Orunmuyi et al. [29]. Another factor that should not be neglected is private sector investment, where a balance between sound business investment and increased Nuclear Medicine services to the public can be effectively maintained. Initiatives such as the 'Rays of Hope' launched by the IAEA also continue to make high impact within the African region.

7.5 Research endeavours and collaboration

Decentralized research endeavors in the field of Nuclear Medicine in the region should be identified and promoted. It is important that integration of research in the different African countries is fostered with the focus on the region's unique burden of disease as well as unique challenges. A platform for continuous scientific collaboration should be created, such that once qualified, the radiopharmacist can apply the principles within their own country or institution. Furthermore, they can replicate research design principles, including radiopharmaceutical services for clinical research (GRPP).

8. Conclusion

Many publications summarize the status of radiopharmacy in Africa as having a lack of trained and highly qualified personnel, underwhelming infrastructure, and dependence on assistance from other continents [8]. We would like to highlight that by just providing qualified personnel to the region, although a valid cause, the issues faced by the community are not adequately addressed. The proposed areas of improvement should not be addressed in silos but, rather simultaneously to effect change or provide solutions.

The African region must insist on the rightful place of the Nuclear Medicine clinic in the hospital setting and demand investment from local governments and infrastructure initiatives. Furthering this process, radiopharmacy needs more attention during budget allocations, as the strength of Nuclear Medicine lies in the number and range of procedures that the clinic can offer which is in turn influenced by the radiopharmacy's production capacity.

Author's contributions

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Conceptualizing: All authors
Writing: JK, JRZ, TS, NB, SM, SDP, BS
Fact checking: All authors
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Approval of manuscript: All authors

Competing Interests:

The authors have no competing interests to declare that are relevant to the content of this article.

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Supplementary A

Theoretical Components of the radiopharmacy syllabus

Module I: Pharmacy

- Pharmaceutical Technology
- Implications of Good Manufacturing Practice
- Sterile Manufacture
- Pharmaceutical microbiology
- Parenteral Products
- Formulation and Packaging
- Pharmaceutical Analysis
- Pharmacopoeial monographs
- Quality Assurance and Product Performance
- Quality Control Procedures
- Stability and Shelf Life
- Regulations and Legal Aspects
- Marketing Authorisations
- Responsibilities of Personnel
- Biopharmacy (Pharmacokinetics, membrane transport, biodistribution, metabolism)
- Radiotracer transport, pharmacokinetics, modelling

Module II: Radiopharmaceutical chemistry

- History of radiopharmaceutical chemistry
- Physics of radioactivity
- Properties of carrier-free substances, separation techniques
- Production of radionuclides in nuclear reactor and cyclotron
- Targetry, nuclear chemistry, generators
- Synthesis of labelled compounds
- Chemistry of biomolecules chelator attachment
- Purity and stability of labelled compounds, radionuclidic and radiochemical purity
- Radionuclides in analytics, autoradiography
- The radiotracer principle
- Criteria for radiopharmaceuticals
- Production of radiopharmaceutically relevant radionuclides
- ^{99m}Tc- generator
- ^{99m}Tc-radiopharmaceuticals I, basics
- ^{99m}Tc-radiopharmaceuticals I, kit preparation
- Other radiometals
- Radioiodination
- Cell labelling
- PET - radiopharmaceuticals (^{18}F, ^{11}C, ^{13}N, ^{15}O)
- Animal models, disease models, animal protection regulations , ethical issues

Module III: Radiopharmacology and clinical radiopharmacy

- Radiopharmacology and Clinical Radiopharmacy (in-vitro assays, tissue culture)
- Toxicology
- Specialised aspects of biological radiopharmaceuticals
- Drug interventions and interactions/ adverse reactions
- Aspects of biochemistry and molecular biology
- Research and Development techniques
- Nuclear Medicine - aspects of clinical practice
- Radiation therapy and other imaging modalities.
- Immunology
- Adverse reactions
- Statistics: practical exercize