Global Issues of Radiopharmaceutical Access and Availability: A Nuclear Medicine Global Initiative Project

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The Nuclear Medicine Global Initiative was formed in 2012 by 13 international organizations to promote human health by advancing the field of nuclear medicine and molecular imaging by supporting the practice and application of nuclear medicine. The first project focused on standardization of administered activities in pediatric nuclear medicine and resulted in 2 articles. For its second project the Nuclear Medicine Global Initiative chose to explore issues impacting on access and availability of radiopharmaceuticals around the world. **Methods:** Information was obtained by survey responses from 35 countries on available radioisotopes, radiopharmaceuticals, and kits for diagnostic and therapeutic use. Issues impacting on access and availability of radiopharmaceuticals in individual countries were also identified. **Results:** Detailed information on radiopharmaceuticals used in each country, and sources of supply, was evaluated. Responses highlighted problems in access, particularly due to the reliance on a sole provider, regulatory issues, and reimbursement, as well as issues of facilities and workforce, particularly in low- and middle-income countries. **Conclusion:** Strategies to address access and availability of radiopharmaceuticals are outlined, to enable timely and equitable patient access to nuclear medicine procedures worldwide. In the face of disruptions to global supply chains by the coronavirus disease 2019 outbreak, renewed focus on ensuring a reliable supply of radiopharmaceuticals is a major priority for nuclear medicine practice globally.

Key Words: radiopharmaceuticals; access; global issues

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Every year more than 30 million patients are diagnosed or treated using nuclear medicine and molecular imaging techniques (*1*). Nuclear medicine comprises diagnostic and therapeutic techniques that use radiopharmaceuticals for applications such as oncology, cardiovascular disorders, and neurologic disorders to provide information at both the molecular and the cellular level for probing, tracking tissue function, evaluating disease progression, supporting treatment planning, guiding tissue sampling, and assessing treatment responses (*2,3*). Nuclear medicine and molecular imaging procedures are among the most powerful analytic tools available today, providing physicians with critical patient information on which important medical decisions are based (*3,4*). These procedures and therapies are a key component to personalized medicine, without which, patients may be required to undergo more invasive and more costly tests and even invasive surgeries (*1,3*). The International Atomic Energy Agency (IAEA) launched in September 2019 IMAGINE (the IAEA Medical Imaging and Nuclear Medicine Global Resources Database), a comprehensive database on availability of nuclear medicine and diagnostic imaging equipment worldwide (*5*). According to IMAGINE, over 140

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countries have availability of SPECT or SPECT/CT, with close to 27,000 systems installed, whereas 109 have PET/CT and over 5,200 systems. The use of nuclear medicine procedures varies between countries, in part due to costs, regulatory issues, training of workforce, and availability of radiopharmaceuticals, although the relative contribution of each of these factors is not well defined (*6,7*).

In 2014, the first Nuclear Medicine Global Initiative (NMGI) reported on the standardization of administered activities in pediatric patients (*8,9*). Based on the success of this first project it was decided that the second project of the NMGI would be to assess the availability of diagnostic and therapeutic radiopharmaceuticals by country and region, to collate and analyze the data and develop a report outlining the current availability and issues preventing patient access to these resources. The aim of the project was to collate information regarding the availability of radiopharmaceuticals worldwide, including the availability of cold kits, generators, and radionuclides; use of central pharmacies; listing of radiopharmaceuticals required but not available; and identification of issues impeding use of radiopharmaceuticals such as access, shipping, cost, regulatory requirements, facilities, and training. This information could inform actions that could be taken to mitigate the identified barriers, ensure improved patient access, and encourage commercial interest and research and development in the field.

MATERIALS AND METHODS

A detailed questionnaire on radiopharmaceutical access, availability, and issues relating to supply and access (supplemental materials; available at http://jnm.snmjournals.org) was sent to key contacts and the nuclear medicine societies (where existing) of all countries listed in the IAEA database. This questionnaire was developed by the NMGI project members (Table 1) and was made available by the Society of Nuclear Medicine and Molecular Imaging (SNMMI) through a secure online portal or through direct correspondence with country nuclear medicine societies. The information obtained was confirmed as applicable for the entire country and was based on country internal information gathering and data compilation. The responses were correlated into continental regions, and whether countries were of low, low-middle, high-middle, or high income, according to World Bank income classification (*10*). Data were compiled and summarized, with verification of information if gaps in initial responses were identified.

RESULTS

A total of 35 countries provided complete data for the survey and are listed in Table 2. Of the country responders, 16 were from the Asia-Pacific region, including Australia, 4 countries responded from Europe, 8 from Africa, 5 from Latin America, and both the United States and Canada. To facilitate the analysis, Mexico was included in Latin America. Based on data from the IMAGINE database (*5*) on individual country activity (numbers of SPECT and PET cameras), this cohort represents 76.4% of global SPECT camera sites and 71.1% of global PET camera sites (Table 3).

For North America, Latin America, and Australia the data represent 91.3%–100.0% of nuclear medicine camera sites, whereas in Asia more than 73% of sites are represented. African country responses were more than 50% of nuclear medicine camera sites, with responses from both low-income and middle-income countries with nuclear medicine sites. Country responses from Europe were low, which reflected the challenges in obtaining accurate country-based data in this region for the purpose of this analysis.

TABLE 1
NMGI Organizations and Representatives

Organization	Representatives
SNMMI	Cathy S. Cutler
	Sally Schwarz
	Fred Fahey
	Gary Dillehay
World Federation of Nuclear Medicine and Biology	Andrew Scott
	Sze Ting Lee
Latin American Association of Societies of Biology and Nuclear Medicine	Fernando Mut
Australian and New Zealand Society of Nuclear Medicine	Vijay Kumar
	Elizabeth Bailey
Asia Oceania Federation of Nuclear Medicine and Biology	Henry Hee-Seung Bom
Asian Regional Cooperative Council for Nuclear Medicine	Jun Hatazawa
China Society of Nuclear Medicine	Lin Li
European Association of Nuclear Medicine	Arturo Chiti
	Savvas Frangos
IAEA	Ravi Kashyap
	Rodolfo Nunez-Miller
	Pilar Orellana
	Diana Paez
Japan Society of Nuclear Medicine	Hiroki Kato
Korea Society of Nuclear Medicine	Seung Jun Oh
	Dong Soo Lee
South African Society of Nuclear Medicine	Lizette Louw
Society of Nuclear Medicine, India	Guru Bandhopadhyaya
	Prasanta K. Pradhan

^{99m}Tc Generators

Responders were asked to name the manufacturer and supplier of ^{99m}Tc generators (Table 4). There were 32 ^{99m}Tc generator suppliers globally, with 18 only supplying to a single country, leaving only 10 manufacturers that supply to multiple continents or countries and 6 producers that supply to 4 or more countries. The United States is the major user of ^{99m}Tc, representing approximately 50% of the global market even though it relies on only 3 suppliers of generators. The supply to Africa is the most limited, with most countries reliant on a single generator supplier. The Asia-Pacific region has a large number of suppliers of generators, often imported from Europe, but also locally produced. It is probable that the data for Europe are not representative of the actual situation due to the limited number of respondents from European countries.

TABLE 2
Countries Responding to Survey

Country	Region	Income category
United States	North America	HIC
Canada	North America	HIC
Brazil	Latin America	UMIC
Chile	Latin America	HIC
Mexico	Latin America	UMIC
Colombia	Latin America	UMIC
Uruguay	Latin America	HIC
Australia	Australia	HIC
Japan	Asia	HIC
Korea	Asia	HIC
Bangladesh	Asia	LMIC
India	Asia	LMIC
Indonesia	Asia	LMIC
Iran	Asia	UMIC
Israel	Asia	HIC
Jordan	Asia	UMIC
Malaysia	Asia	UMIC
Mongolia	Asia	LMIC
Pakistan	Asia	LMIC
Philippines	Asia	LMIC
Singapore	Asia	HIC
Taiwan	Asia	UMIC
Thailand	Asia	UMIC
Algeria	Africa	UMIC
Ghana	Africa	LMIC
Morocco	Africa	LMIC
Niger	Africa	LIC
South Africa	Africa	UMIC
Tanzania	Africa	LIC
Uganda	Africa	LIC
Zambia	Africa	LMIC
Austria	Europe	HIC
Cyprus	Europe	HIC
Estonia	Europe	HIC
Poland	Europe	HIC

HIC = high-income country; UMIC = upper-middle-income country; LMIC = lower-middle-income country; LIC = low-income country.

Data are from World Bank (*10*).

Cold Kits

The concept of the cold kit which contains all the ingredients except the radionuclide was developed originally at Brookhaven National Laboratory (*11,12*) to simplify the production of radiopharmaceuticals and enable consistent formulation at multiple sites to support clinical trials and eventual drug development. Figure 1 shows the number of countries where the most commonly used cold kits for radiopharmaceuticals were available.

Tables 5 and 6 list the 53 companies indicated in the survey that sell cold kits for radiopharmaceutical preparation and the continents they supply. Over half of the 33 radiopharmaceutical kit manufacturers provide to only a single country, 8 provide cold kits to 2 countries, 1 manufacturer supplies to 3 countries, 5 manufacturers supply to 4 countries, and 6 distribute to 5 or more countries. The data for the United States indicated only 8 suppliers for diagnostic kits and 5 suppliers of kits for therapeutics, with local pharmacies supplying ^{131}I capsules and solutions.

Responders were further asked to state the radiopharmaceuticals they used by imaging category and their utility in each category. The responses were divided into 3 groups: SPECT imaging, PET imaging, and therapy.

SPECT Radiopharmaceuticals

Figure 2 shows the radiopharmaceuticals used for SPECT diagnostic imaging and the number of countries where they are available. SPECT imaging was dominated by ^{99m}Tc. For brain imaging a total of 13 different radiopharmaceuticals were listed, with the highest country use—based on survey responses—being ^{99m}Tc-hexamethylpropyleneamine oxime and ^{99m}Tc-diethylenetriaminepentaacetic acid at 74%, followed by ^{99m}Tc-ethylcysteinate dimer at 51%. For thyroid imaging the most commonly used was ^{99m}Tc-pertechnetate at 89% followed by ^{131}I at 86%. Parathyroid imaging had ^{99m}Tc-sestamibi, with the highest use at 97%, followed by ^{99m}Tc-pertechnetate at 80% for subtraction scanning, and ^{201}Tl at 23%. For pulmonary imaging the highest use was seen for ^{99m}Tc-macroaggregated albumin at 86% for perfusion scans, followed by ^{99m}Tc-diethylenetriaminepentaacetic acid aerosol at 63%, and Technegas (Cyclomedica Asia Pacific) at 34% for ventilation scans. Cardiac myocardial perfusion imaging had ^{99m}Tc-sestamibi with the highest use at 94%, and ^{201}Tl-chloride and ^{99m}Tc-tetrofosmin having similar use at 45%.

The liver/biliary agent demonstrating the highest use is ^{99m}Tc-hepatoiminodiacetic acid at 51% of countries followed by ^{99m}Tc-macroaggregated albumin at 43% (shunt studies), ^{99m}Tc-mebrofenin at 40%, and ^{99m}Tc-sulfur colloid at 34%. For imaging the spleen and bone marrow the most highly used agents were ^{99m}Tc-denatured red blood cells at 43% (for spleen imaging), followed by ^{99m}Tc-sulfur colloid at 34% and ^{99m}Tc-tin colloid at 31%. The agent with the highest use for renal imaging was ^{99m}Tc-diethylenetriaminepentaacetic acid at 94%, followed by ^{99m}Tc-dimercaptosuccinic acid at 89%

TABLE 3
Survey Countries' Representation of Regional Nuclear Medicine Activity

Region	SPECT cameras (%)	PET cameras (%)
North America	100.0	100.0
Latin America	94.9	91.3
Europe	5.1	5.0
Africa	53.9	57.9
Asia	73.5	74.3
Australia	100.0	100.0
Global	76.4	71.1

SPECT and PET camera numbers are based on IMAGINE database (*5*).

TABLE 4
Technetium Generator Suppliers

Supplier	Total no. of countries	United States and Canada	Europe	Asia-Pacific	Africa
GE	7	1	3	2	1
IBA/CIS Bio France	10		1	8	1
Monrol	4			3	1
Polatom	5		1	2	2
ANSTO	2			2	
BAEC (Bangladesh)	1			1	
IPEN	3	2	1		
Mallinckrodt/Covidien	6	1	1	4	
Amersham	4				4
Parsisotope (Iran)	3			3	
Sam Young Unitech (Korea)	1			1	
Pinstech (Pakistan)	1			1	
BRIT (India)	1			1	
Jubilant DraxImage	1			1	
Saxons Health Care	1			1	
SDS Life Sciences	1			1	
Vishat Diagnostic Priv. Ltd.	1			1	
Polatom	2		1	1	
NTP South Africa	2				2
Lantheus	3	2		1	
Rotop	2	1		1	
BSM	1	1			
Nihon Medi-Physics Co Ltd. (Japan)	1				1
Fujifilm RI Pharma (Japan)	3			2	1
CGM Nuclear	1	1			
Positronpharma (Chile)	1	1			
Comision Chilena Energia Nuclear (Chile)	1	1			
Elumatac	1			1	
Quantarad Priv. Ltd.	1			1	
Pinstech	1			1	
MDS Nordion (Canada)	1	1			
Alumina Chrom Column	1	1			

and ^{99m}Tc-mercaptoacetyltriglycine at 83%. Adrenal imaging is performed predominantly with ^{131}I-metaiodobenzylguanidine (MIBG) at 60%, followed by ^{123}I-MIBG at 37%, ^{131}I-norcholesterol at 17%, and ^{131}I-aldosterol at 11%. For bone scanning, ^{99m}Tc-methylene diphosphonate was the most common at 97%, followed by ^{99m}Tc-hydroxymethylene diphosphonate at 34% and ^{99m}Tc-hydroxymethylene diphosphonate at 29%. For gastrointestinal imaging the highest use was observed for ^{99m}Tc-pertechnetate at 71%, followed by ^{99m}Tc-sulfur colloid and ^{99m}Tc-red blood cells at 57%.

For SPECT tumor imaging, the highest use by responders was ^{131}I-MIBG at 60%, followed by ^{67}Ga-citrate at 46%, ^{201}Tl-chloride at 43%, and ^{123}I-MIBG at 34%. A total of 10 agents were supplied by responders as being used for infection and inflammation imaging. The most highly used was ^{99m}Tc-radiolabeled WBC at 57%, followed by ^{67}Ga-citrate at 49% and LeukoScan (sulesomab; Immunomedics, Inc.) and ciprofloxacin at 11%.

Sentinel lymph node imaging was reported to be performed with 7 agents, 3 of which are restricted to use in a single country. Those used in multiple countries are ^{99m}Tc-nanocolloid with a use of 74%, ^{99m}Tc-sulfur colloid with a use of 20%, ^{99m}Tc-antimony colloid at 11%, and ^{99m}Tc-phytate at 9%. South Africa was the sole user of ^{131}I-sunflower oil for confirmation and localization of a lymphatic leak. In vitro studies were performed using only 4 agents: ^{14}C-urea at 26% use, ^{51}Cr-chromate at 17%, ^{51}Cr-ethylenediaminetetraacetic acid at 9%, and ^{125}I-human serum albumin at 6%. These agents see limited use due to restricted availability.

PET Radiopharmaceuticals

Of the 35 countries that provided responses to the survey, only 28 indicated they provided PET services. Low- and low-middle income countries had the lowest numbers of PET sites. Survey responders indicated they used a total of 34 PET agents, and 5

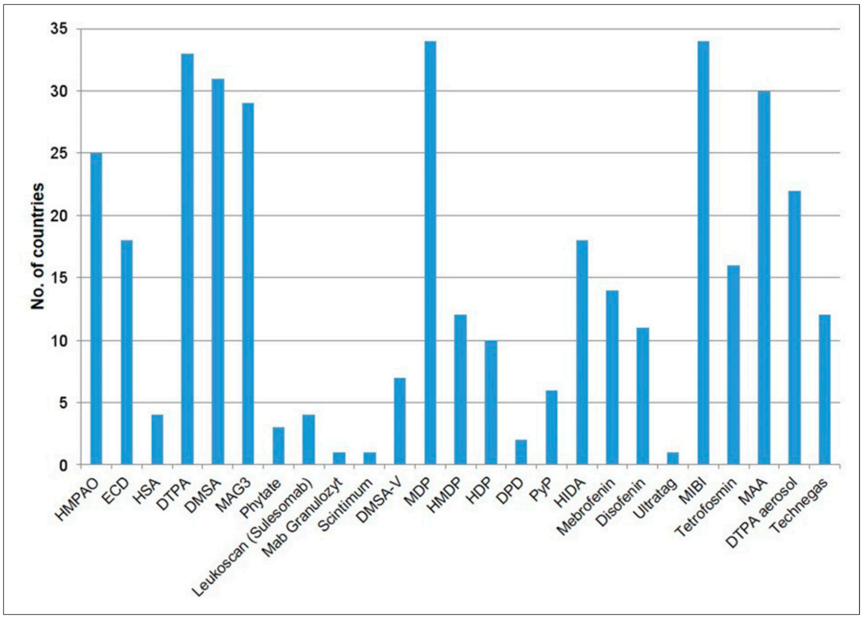

FIGURE 1. Range of most commonly available cold kits and ventilation agents in countries surveyed.

radiometal radionuclides (^{82}Sr/^{82}Rb, ^{64}Cu, ^{89}Zr, ^{68}Ga, and ^{44}Sc) were listed (Fig. 3). The most highly used PET agent is ^{18}F-FDG (Fig. 3A). Eleven other ^{18}F-labeled PET agents were listed (Fig. 3B).

^{68}Ga has experienced significant growth due to its availability via a long-lived generator that now sees wide availability. The most highly used ^{68}Ga tracer was ^{68}Ga-prostate-specific membrane antigen, which is at 50% use, followed by ^{68}Ga-DOTATATE (also known as NETSPOT; Advanced Accelerator Applications) at 46% and ^{68}Ga-DOTATOC at 25% use (Fig. 3C).

Several radiopharmaceutical agents have been developed with ^{11}C, and the 2 most highly used were ^{11}C-methionine and ^{11}C-choline at 32%, followed by ^{11}C-Pittsburgh compound B, which is used at 25% (Fig. 3D).

Therapeutic Radiopharmaceuticals

The use of radiopharmaceuticals for therapeutic applications is shown in Figure 4, and for ^{131}I (imaging and also therapeutic use) in Figure 2. The responses indicated limited use other than ^{131}I, mainly due to limited access and high cost. ^{131}I was used for hyperthyroidism in 94% of countries and for thyroid cancer in 91% of countries. A total of 16 radiopharmaceuticals were provided by responders as being used for therapy, with the next most prevalently used being ^{153}Sm-ethylenediaminetetramethylene phosphonate for bone pain palliation at 51% use, and ^{131}I-MIBG was used in 51% of countries. ^{177}Lu-DOTATATE was reported to have 29% use, ^{177}Lu-DOTATOC 11%, and ^{90}Y-DOTATATE 11%. ^{177}Lu-prostate-specific membrane antigen was mainly under research use at the time of the survey. Restricted availability of ^{32}P was noted, with several countries indicating they would use ^{32}P if it was available.

Training and Education

All countries noted a lack of trained and qualified staff to perform certain tasks, including radiopharmaceutical quality assurance and quality control, cell labeling, production, manufacturing, and final dispensing. Low-income and low-middle-income countries in particular identified the lack of education and training of staff, including clinicians, physicists, radiochemists, and radiopharmacists, as a barrier to providing certain services. This resulted in their being unable to offer complex procedures such as cell labeling, radionuclide therapy such as ^{177}Lu-targeted therapies, and other new radiopharmaceutical tracers that required in-house quality control and quality assurance. Even in some high-income countries, a lack of training in quality control/quality assurance and good manufacturing practices, as well as drug release and radiation safety personnel, were noted as inhibiting growth and patient access.

DISCUSSION

This project has highlighted several important issues regarding radiopharmaceutical access and availability at a global level. As with the first NMGI project, there was variability in response among countries and regions; however, the survey obtained country-based responses that covered approximately 75% of global nuclear medicine sites. Moreover, the data obtained spanned all geographical regions and country income statuses (Table 3). Although there were limited data available from European countries, the results from comparable socioeconomic countries with similar nuclear medicine infrastructure (IMAGINE database) in our cohort suggest that our data still provide a valuable portrayal of the current availability and use of nuclear medicine and the challenges that restrict its use and future growth.

Despite multiple efforts including the IAEA, the U.S. Department of Energy, Nuclear Medicine Europe, and high-level working groups to ensure a sustainable supply of ^{99}Mo/^{99m}Tc generator equipment, our survey showed a lack of availability of generators as an ongoing issue, with many countries having only a single supplier, deliveries limited to once a week or once a fortnight, and problems with reliability of supply. This was identified as an issue particularly in low- and middle-income countries. This problem of supply chains has also been highlighted in the recent coronavirus disease 2019 (COVID-19) pandemic, where generator supplies to many countries have been markedly reduced due to flight restrictions (*13–16*).

The survey data highlight the dependency of the nuclear medicine field and individual countries on single-source manufacturers or distributers of their radiopharmaceutical cold kits. There were several cold kits that are no longer available, especially in developing countries, including ^{99m}Tc-hepatoiminodiacetic acid, sulfur colloid, antimony colloid, ^{99m}Tc-macroaggregated albumin, ^{99m}Tc-mercaptoacetyltriglycine, brain perfusion agents (both hexamethylpropyleneamine oxime and ^{99m}Tc-ethylcysteinate dimer), ^{99m}Tc-hydroxymethylene diphosphonate, and ^{99m}Tc-pyrophosphate. This was reported to be due to the high costs to import the products, only having a single sole supplier of cold kits with limited product availability, and regulatory

TABLE 5
Commercial Radiopharmaceutical Kit Suppliers: Part 1

Supplier	Total no. of countries	United States and Canada	Europe	Asia-Pacific	Africa
BRIT (India)	1			1	
Jubilant DraxImage	1			1	
Saxons Healthcare	1			1	
SDS Life Sciences	1			1	
Vishat Diagnostic Pvt. Ltd.	1			1	
Sanlar Imex Service Pvt. Ltd.	1			1	
GE	13	1	4	6	2
Polatom	11		4	5	2
TINT	1			1	
GMS	2			2	
Biogenetech	1			1	
IBA/CIS Bio	11	1	2	6	2
Mallinckrodt/Covidien	8	1	3	3	1
Monrol	4			3	1
Izotope	4			3	1
JPT/IDB	1			1	
Bristol-Myers (Hungary and Canada)	1				1
Amersham	2				2
DRAXImage	4	1		1	2
AAA	5	1	3		
Bayer	6	1	2	3	1
Nihon Medi-Physics Co Ltd. (Japan)	1			1	
Fujifilm RI Pharma (Japan)	1			1	
CGM Nuclear (Chile)	1	1			
Positronpharma (Chile)	1	1			
Coimision Chilena Energia Nuclear (Chile)	1	1			
Rotop	3		1	2	1
Atomic High Tech China	1			1	
Medi-Radiopharma	4			3	1
Immunomedics	4		2	1	1
San Yung Tosh	2			1	
Kibion	1			1	
Pinstech	1			1	

factors (preventing importation). Surprisingly, many countries do not have any access to ventilation agents for performing a ventilation–perfusion scan and commonly perform perfusion-only imaging.

Non-^{18}F-FDG PET tracers had limited availability in most countries, predominantly due to barriers such as high cost, no access to a cyclotron, regulatory restrictions, studies not being funded by healthcare providers, and lack of suppliers. ^{68}Ga generator supply in particular has been identified as restricted in many countries and likely to have increased demand in the future with more widespread clinical use of ^{68}Ga-peptide studies.

Many therapeutic tracers were not available due to their high cost, as well as no available supplier or distributor, and lack of regulatory approval. Over the past 10 y there have been significant changes and increases in the regulatory burden regarding production, handling, and transportation of radiopharmaceuticals (*17*). Most countries did not use or have access to ^{123}I, ^{123}I-MIBG, and ^{131}I-MIBG mainly due to cost. This is especially true for low- and middle-income countries. Peptide receptor radionuclide and peptide radionuclide ligand therapeutics including ^{177}Lu-Lutathera (Advanced Accelerator Applications) had limited use across all countries, although it should be mentioned that this field is rapidly changing, and many more sites and countries will have access to these therapeutic radiopharmaceuticals since the survey was completed.

The data obtained in this survey project clearly show that all countries have issues of radiopharmaceutical access and availability,

TABLE 6
Commercial Radiopharmaceutical Kit Suppliers: Part 2

Supplier	Total no. of countries	United States and Canada	Europe	Asia-Pacific	Africa
Lantheus	2	1		1	
Pharmalucence	2	1		1	
Bracco	1	1			
Ayto Pharma	1	1			
Spectrum	2	1	1		
Radpharm	1			1	
Ansto	1			1	
Sirtex	2			2	
Perkin Elmer	1			1	
BAEC	1			1	
Institute of Isotope Co. Ltd.	1			1	
China Isotope Co.	1			1	
Gipharma	2			1	1
Sanofi	1				1
NTP	1				1
Ithema Labs	1				1
Shin Jin (Indonesia)	1			1	
Kimia Farma (Indonesia)	1			1	
Parsisotope (Iran)	1			1	
IPEN	1	1			

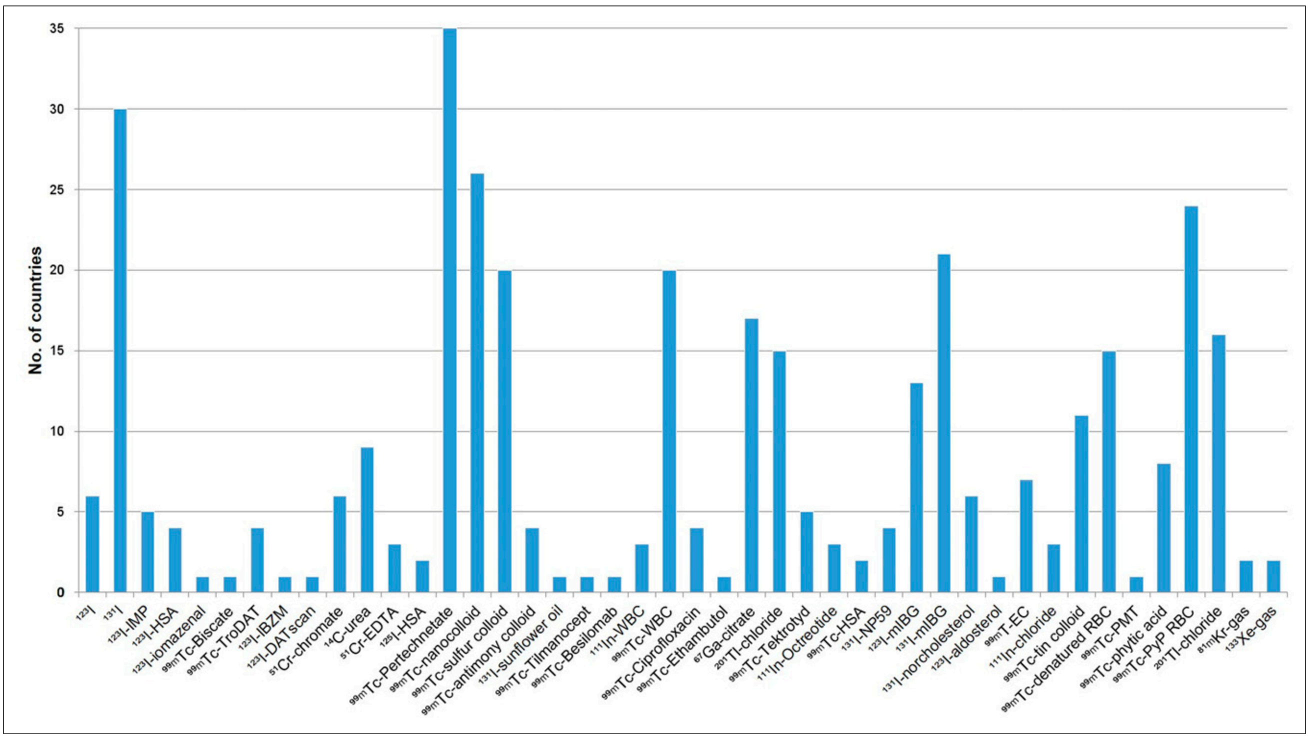

FIGURE 2. SPECT radionuclides and radiopharmaceuticals available in countries surveyed.

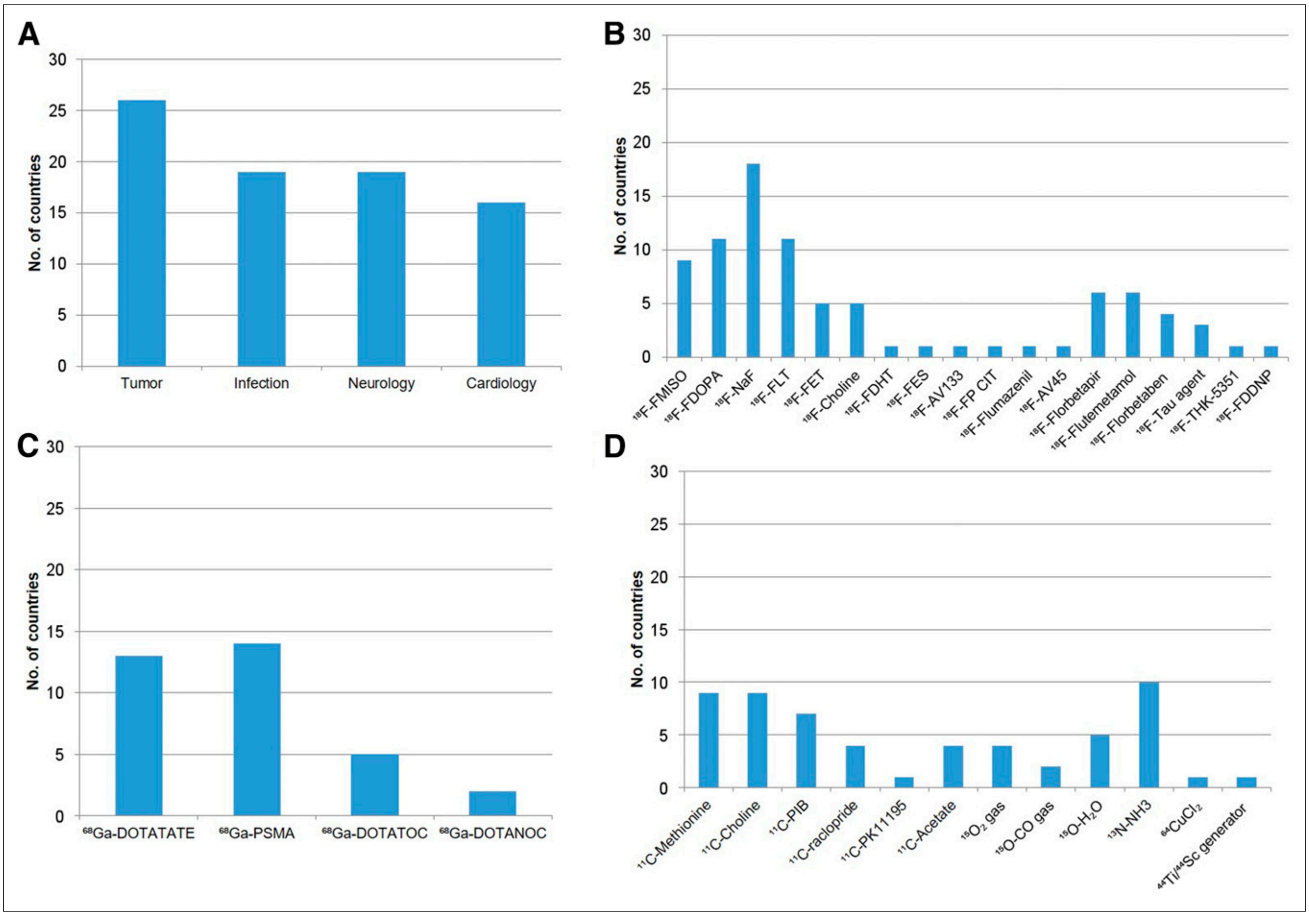

FIGURE 3. Number of countries with access to PET radiopharmaceuticals: ^{18}F-FDG clinical use (A), available ^{18}F-labeled PET tracers (B), commonly used ^{68}Ga-labeled tracers (C), and other PET tracers (D).

although the capability to address these issues varies according to the size of the country, funding, and nuclear medicine infrastructure (including workforce). Interestingly, the problems of limited suppliers of cold kits, and many diagnostic SPECT radiopharmaceuticals, were seen in low-, middle- and high-income countries globally, indicating the problem is not restricted just to countries with challenges in funding of nuclear medicine studies. Many of the workforce issues can be addressed in part by coordinated efforts to enhance training of physicians, technologists, and scientists in nuclear medicine; regional (e.g., SNMMI, European Association of Nuclear Medicine, and Asia

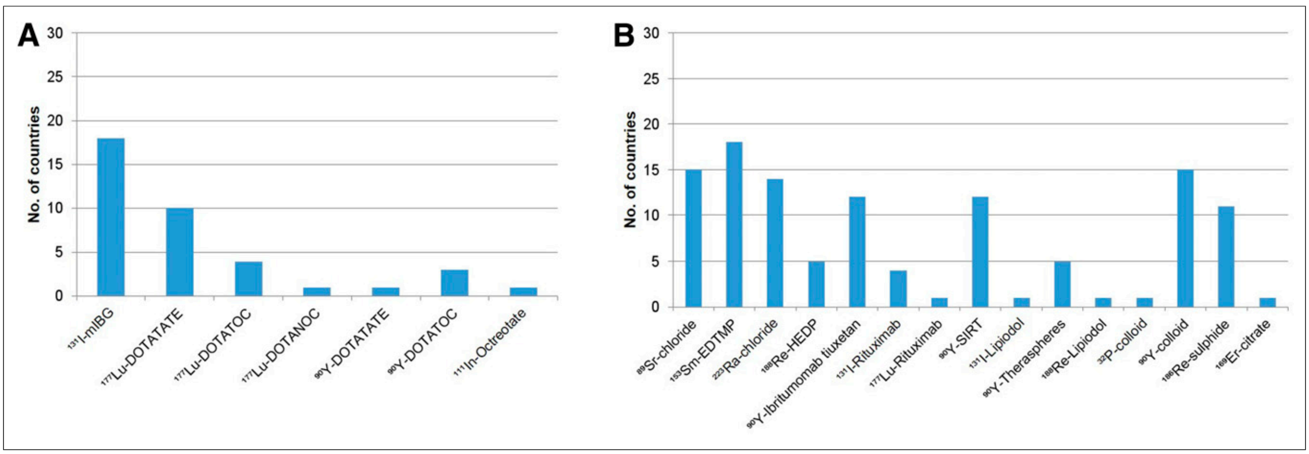

FIGURE 4. Number of countries with access to range of radionuclide therapies: targeted therapy (A) and radionuclide therapies currently used other than ^{131}I (B).

Oceania Federation of Nuclear Medicine and Biology) as well as IAEA programs all play a part in supporting direct training, as well as documentation and position papers on protocols and infrastructure requirements. The ability of nuclear medicine societies to identify access issues and work with regional societies/associations to identify sources of radioisotopes and kits and facilitate local regulatory approvals may play a role. It is also important for companies and professional organizations (e.g., Nuclear Medicine Europe) to be involved in provision of supplies and stability of supply chains. Regional initiatives through IAEA and the World Health Organization may have a role in supporting access programs, particularly in low- and middle-income countries. In the context of personalized medicine and targeted therapies, and particularly in theranostics, strategic initiatives aimed at promoting the use and funding of SPECT and PET radiopharmaceuticals should align with drug development and approvals in countries. This would also benefit from cooperation and sharing of health technology assessments between countries, thus improving time to approvals and economic justification of new studies. Although global efforts to enhance access and availability of radiopharmaceuticals will also be subject to major industrywide events such as ^{99}Mo–^{99m}Tc shortages, and more recently the COVID-19 pandemic which is impacting on global supply chains (*13–16*, *18*), the importance of nuclear medicine in routine patient care should be a key driver of any approach.

CONCLUSION

This NMGI has revealed an interesting portrayal of the issues related to the supply, availability, cost, regulatory barriers, and other factors related to the use of radiopharmaceuticals internationally. Particularly surprising was the limited availability of standard diagnostic radiopharmaceuticals in many countries, particularly low- and middle-income countries. There are several strategic initiatives required to address the varied causes of reduced supply, ideally linking major industry and health organizations. Nuclear medicine is widely used and is expanding worldwide, and addressing the issues of access and availability of radiopharmaceuticals is a key strategy for ensuring patients can benefit from these vital imaging and therapeutic procedures.

DISCLOSURE

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KEY POINTS

QUESTION: What are the issues impacting access and availability of radiopharmaceuticals at a global level?

PERTINENT FINDINGS: Limited sources of radiopharmaceuticals and kits, supply chains, regulatory and reimbursement issues, and workforce are limitations to access.

IMPLICATIONS FOR PATIENT CARE: Strategic action to address these issues is required to ensure optimal availability of radiopharmaceuticals for patients in all countries.

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