2021 guideline on radiation exposure after radionuclide therapies: implementation in clinical practice in three different hospitals in The Netherlands. Aiming for more uniformity

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Abstract

Introduction

National guidelines on radionuclide therapies have long been based on a 2005 report (*Aanbevelingen 'Het werken met therapeutische doses radionucliden'*), mainly based on iodine-131 ([^{131}I]NaI) therapies. As new therapies were introduced, mainly lutetium-177 ([^{177}Lu]Lu) based - with less radiation burden for the environment – and with the implementation of the 2013 basic safety standards directive in European legislation, an update was necessary. In the meantime, dose rate levels for discharge after [^{177}Lu]Lu were used in the way they were used for [^{131}I]NaI (20 µSv/h at 1m). Guidelines were revised and implemented by the FMS in 2021, in hopes to reach more uniformity between hospitals as well. We investigated this pursued uniformity by the new guideline and provide insights into its implementation.

Methods

Three different hospitals participated: an academic center (UMC Utrecht), a peripheral center (St. Antonius Nieuwegein) and a cancer center (AVL Amsterdam). Each hospital provided their institutional guidelines for comparison. An online meeting was held to seek more information on differences and similarities and to discuss the rationales behind the institutional considerations made. Data collection was focused on the two most used radionuclide therapies today: [^{177}Lu]Lu-PSMA and [^{131}I]NaI.

Results

Some general practical uniformities could easily be adjusted (e.g. the general measure to flush the toilet twice was unanimously considered not useful, and the restrictions on dish washing and intimacy after [^{131}I]NaI therapy could be adapted). A radiation alert pop-up or symbol in the hospital patient file was considered very practical as were travel information letters. For [^{177}Lu]Lu-PSMA, all centers treated patients in a 6 hours admission scheme, and discharged patients without measuring dose rate levels, having patients adhere to instructions and restrictions for three days (i.e. 60 years and older). Most differences were encountered for [^{131}I]NaI therapies, especially dose rate level at discharge (20 µSv/h versus 40 µSv/h at 1 meter versus no measurement at all), and the duration of admission, restrictions after discharge and durations of those restrictions.

Conclusion

The implementation of the FMS guideline in each hospital has been different, based on different assumptions and considerations. For [^{177}Lu]Lu-PSMA the implementation was more uniform than for [^{131}I]NaI. Radionuclide therapies are increasing and becoming more patient tailored. For patients a more uniform approach could be helpful, to prevent confusion between patient information leaflets from different institutions and to prevent 'healthcare shopping' between hospitals. We intend to initiate this discussion and pursue uniformity on a national level in the future.

Introduction

Radionuclide therapies are increasing, both in frequency and in variety of different therapies, encompassing different isotopes. As patients contain radioactivity after treatment, it is important to have them adhere to restrictions for a certain period after each therapy cycle to reduce radiation burden to their environment. National guidelines on radionuclide therapies have long been based on a 2005 report (1), which was mainly based on and applied to iodine-131 ([^{131}I]NaI) therapies. Based on this report, dose rate levels after therapy dictated whether a patient had to be admitted and when to be discharged, 20 µSv/h at 1 meter being the dose rate limit. Based on the actual dose rate level measured at discharge, the duration of restrictions was determined. Meanwhile, new therapies were introduced, mainly lutetium-177 ([^{177}Lu]Lu) based. [^{177}Lu]Lu has less radiation burden due to less gamma abundancy with lower gamma energy (113 and 208 keV versus 364 keV), and a shorter half-life (6.6 versus 8.0 days) (figure 1). As no guidelines on the use of [^{177}Lu]Lu existed, most hospitals implemented the same dose rate limits and contact restrictions. In the meantime, changes in European legislation (implementation of the 2013 basic safety standards directive - Council Directive 2013/59/Euratom) and thus national legislation were implemented: the Nuclear Energy Act (Kernenergiewet; KEW) was adjusted, *and the 'Besluit basisveiligheidsnormen stralingsbescherming (Bbs)'* (2) replaced the *'Besluit stralingsbescherming'*. Therefore an update of the 2005 guideline was necessary. The report was thoroughly revised and an extensive literature review was performed by a committee existing of representatives of the Nederlandse Vereniging voor Nucleaire Geneeskunde (NVNG), Nederlandse Vereniging voor Klinische Fysica (NVKF) and Nederlandse Vereniging voor Stralingshygiëne (NVS) in collaboration with the Autoriteit Nucleaire Veiligheid en Stralingsbescherming (ANVS). This was a huge effort and took several years (3). The new guideline focusses on the moment of discharge from hospital and whether instructions and restrictions - for the patient to adhere to after discharge - are necessary. Of note, radiation exposure to health care professionals and to the environment (e.g. waste water) are not included. The guideline was implemented by the Federatie Medisch Specialisten (FMS) in 2021 (4), in hopes to reach more uniformity between hospitals as well. ANVS formal acceptance is still awaited. We investigated this pursued uniformity by the FMS guideline and provide insights into the implementation of this new guideline in three different centers.

Methods

A nuclear medicine physician and a radiation protection expert/medical physics expert of the three different hospitals participated: an academic hospital (UMC Utrecht - UMCU), a peripheral hospital (St. Antonius Nieuwegein) and a cancer center (Antoni van Leeuwenhoek - AVL). Institutional implementation of the guideline was shared for comparison. An online meeting (13th March 2023) was held to seek more information on differences and similarities and to discuss the rationales behind the institutional considerations made. Data collection on the implementation of the new guideline was focused on [^{177}Lu]Lu-PSMA and [^{131}I]NaI, as [^{177}Lu]Lu-PSMA is one of the most recently implemented therapies that was not included in the original 2005 guideline, and as [^{131}I]NaI is one of the oldest but still most often used therapies in nuclear medicine departments. As the guideline comments on radiation exposure after therapy, *per therapy* - which can be 5 or 6 cycles of [^{177}Lu]Lu-PSMA, but only 1 capsule for [^{131}I]NaI therapy - radiation exposure was compared *per cycle*.

General comments on the FMS guideline

Some important comments on the FMS guideline need to be made:
In 2020, the concept version of the FMS guideline (5) was shared among clinical physicists and radiation experts and some nuclear medicine physicians to comment on. In this concept version, some considerations were explained and discussed, that cannot be found in the final version of the guideline.

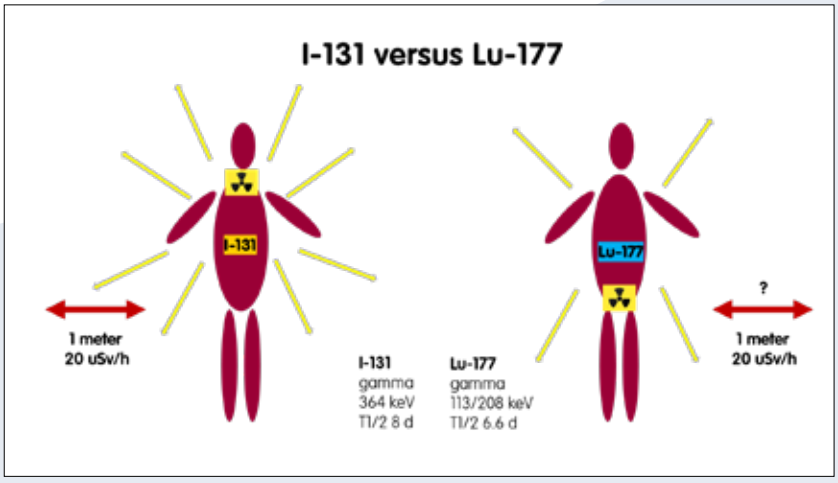

Figure 1. Radiation protection measures

Some important changes were made between the concept version and the final version: e.g. in the concept version, a dose rate limit for discharge after [^{131}I]NaI therapies for malignant thyroid disease was set at 40 µSv/h at 1 meter (20 µSv/h for benign [^{131}I]NaI), which was discarded in the final guideline. Also the duration of hospital admission for [^{177}Lu]Lu-PSMA therapy was changed from 8 to 6 hours and the duration of restrictions was changed from one week to three days.
The FMS guideline is based on dose constraints that apply to persons in direct relation to the patient ('care givers') and to the general population. Based on differences in radiation sensitivity, dose constraints are set on: 1 mSv *per therapy* for children, 3 mSv *per therapy* for adults < 60 years, and 15 mSv *per therapy* for adults > 60 years; for the general population, a dose constraint of 0.3 mSv per 'event' is advised.
The FMS guideline comments on radiation exposure *per therapy*, whereas radiation exposure *per cycle* is more convenient. This is important given the fact that especially for prostate cancer, the number of cycles can differ a lot; some patients starting [^{177}Lu]Lu-PSMA therapy may already have had 6 cycles of radium-223 ([^{223}Ra]$RaCl_2$, Xofigo,®Bayer), and still receive up to 6 cycles [^{177}Lu]Lu-PSMA, whereas others will only receive 1 or 2 cycles of [^{177}Lu]Lu-PSMA due to toxicity or non-response.
Restrictions as described in the FMS guideline for [^{177}Lu]Lu-PSMA and [^{131}I]NaI are quite similar, mainly differing in duration of adherence (table 1).
The FMS guideline refers to a *'Rekentool'* to calculate radiation exposure for the environment after each cycle. Different activities administered and different clinical scenarios can be adjusted. Of note, all *'Blootstellingsscenarios'* were used as were described in the RIVM report by Kloosterman (6).

The FMS guideline refers to a *'Rekentool'* of the 'Nederlandse Commissie voor Stralingsdosimetrie (NCS)' to determine whether a radiation travel information letter is necessary to supply when a patient is traveling after radionuclide therapy (7). Importantly, this tool does not account for biological decay (e.g. excretion). As most of administered radioactivity is excreted within the first 24 hours, this tool largely overestimates the remaining radioactivity in the patient. With care and knowledge of the individual patient, the tool can be used for this purpose.

Instructions and restrictions (table 1) were discussed. The general advise to flush the toilet twice after radionuclide therapies was unanimously considered not useful, as the little amount of radioactive urine that could potentially remain in the toilet would not cause any radiation burden, also considering the duration of toilet stay.

Missing items in the FMS guideline

Restrictions not mentioned in the FMS guideline included limitations on sharing of dishes (commonly recommended after [^{131}I]NaI) and intimacy (asked frequently by patients, but no guidance is provided and thus restrictions are often applied). All centers agreed that the stay in a hotel/ hostel during the restricted period after each cycle was not allowed.
Patients that are treated with [^{177}Lu]Lu-PSMA are, in contrast to most patients receiving [^{131}I]NaI therapy, frequently more heavily metastasized, have no other therapy options, and have a worse prognosis. Due to the local prostate cancer or previous prostate directed therapies, patients often have problems with micturition like hematuria, incontinence and/ or nephrostomies. As most radioactivity is excreted in the urine (after 4 hours, 50% of administered activity is excreted mainly in urine (8), urine incontinence is a contra-indication for therapy if not specifically taken care of by the patient. In AVL, at the start of [^{177}Lu]Lu-therapies, a bladder catheter (catheter-a-demure, CAD) was inserted to prevent contamination. However, as this resulted in even more problems (leakage, pain, possible urine retention after removal) this was discarded. When already in situ, a CAD or NSK (bladder catheter or nephrostomy catheter) is no contra-indication, if the patient is self-sufficient (UMCU/AVL). St. Antonius hospital did not encounter such cases yet.

[^{177}Lu]Lu-PSMA

[^{177}Lu]Lu-PSMA was clinically implemented in UMCU already in 2016, in AVL in 2021; in St. Antonius hospital so far only study patients were treated. All three centers eventually treated patients in a 6 hours admission (9), and discharged patients without measuring dose rate levels (table 2).
In the AVL (conform FMS guideline), the duration of contact instructions and restrictions was 3 days for all care givers including children, as dose constraints were not exceeded. UMCU used a longer duration of restrictions (UMCU institutional guidelines): 3 days for care givers > 60 years old, versus 7 days for children and adults < 60 years old, as these restrictions were already shorter than used before. Restriction on using public transport and flying was 3 days (AVL) and a radiation information letter was supplied until 3 weeks after therapy; in UMCU these restrictions were 7 days, and a travel information letter was provided on request.
For patients treated with [^{177}Lu]Lu-PSMA, frequent visits to other health care professionals can be necessary; the need to report radionuclide therapy was 3 days in the UMCU (conform FMS guideline) whereas in the AVL a longer duration of 14 days was implemented, because of the possible radioactive waste material.

Table 1. Instructions and restrictions according to the FMS guideline.

	[^{177}Lu]Lu PSMA	[^{131}I]NaI benign	[^{131}I]NaI malignant
The patient needs to take care of good toilet hygiene:	**3d**	**3d**	**7d**
-If possible, use a separate toilet.			
-When using the toilet: in a sedentary position.			
-Flush the toilet twice.			
-Wash hands after using the toilet.			
-In case of contamination (urine, other body fluids): clean them yourself.			
-House mates and guests need to take care of toilet hygiene:			
-Wash hands after using the toilet.			
-Use disposable gloves when cleaning the toilet.			
At least the following should be mentioned, to adhere to after therapy administration (distance):	**3d**	**7d**	**7d**
The patient needs to stay away from house mates:			
-Sleeping together is not allowed			
-Keeping a distance (social activities)			
The patient needs to prevent situations in which keeping a distance of more than 1 meter for more than 1 hour is not be possible:			
-Visiting sport competitions/ restaurants/ theaters etc.			
-Using public transport/ taxi etc.			
-Office hours/ work/ school etc.			
Instruct the patient about a travel information letter	***rekentool**	***rekentool**	***rekentool**
Instruct the patient to report the radionuclide therapy when visiting a health care professional.	**3d**	**3d**	**7d**
In case of death after therapy, restrictions may be required; the radiation protection expert should be contacted if death occurs within a certain period of time after therapy.	**13d**	**45d**	**58d**
Before therapy, have the patient empty his/her bladder; after therapy, have the patient void at the toilet of the Nuclear Medicine department before leaving the hospital.	**NA**	**Y**	**NA**

d: days; FMS: Federatie Medisch Specialisten; NA not applicable; Y: yes. * The FMS guideline refers to a *'Rekentool'* of the 'Nederlandse Commissie voor Stralingsdosimetrie (NCS)' to determine whether a radiation travel information letter is necessary when a patient is traveling after radionuclide therapy (7).

[^{131}I]NaI for malignant thyroid diseases (1.1-7.4 GBq)

All centers performed [^{131}I]NaI therapy for thyroid cancer (table 2). The FMS guideline discarded the need to measure dose rate levels, whereas the concept guideline set the dose rate level for discharge at 40 µSv/h. In the final guideline, a 24 hours admission is mentioned.

In St. Antonius hospital, radiation exposure per category (child, adult care giver and general population) was calculated based on a general scenario, using the FMS '*rekentool*'. Based on these assumptions, two options were possible: a 48 hours hospital admission (standard), or, if predefined criteria were met, a 24 hours admission plus a 24 hours isolation period at home was possible. These criteria were:
1. No children < 18 years at home;
2. Sleeping separately at, at least 3 meter is possible; 3. A separate toilet is

Table 2. Instructions and restrictions according to three different hospitals.

	[^{177}Lu]Lu-PSMA	[^{131}I]NaI benign	[^{131}I]NaI malignant
Administered dose (GBq)			
AVL	*7.4*	*NA*	*1.1-7.4*
St. Antonius Ziekenhuis	*6.8 (study)*	*≤ 2.0*	*1.1-7.4*
UMCU	*7.4*	*≤ 1.0*	*1.1-7.4*
Hospital admission	**6h**	**NN**	**24h**
AVL	*6h*	*dose rate dependent*	*≥ 24h, dose rate dependent*
St. Antonius Ziekenhuis	*6h*	*- <0.4 GBq: no - ≥0.4 GBq: 48h or 48h isolation at home**	*- 48h or - 24h + 24h isolation at home**
UMCU	*6h*	*dose rate dependent (max 3d)*	*≥ 24h, dose rate dependent (max 5d)*
Dose rate level at discharge (µSv/h at 1m)	**NA**	**NA**	**NA**
AVL	*NA*	*<20*	*<40*
St. Antonius Ziekenhuis	*NA*	*N/A*	*N/A*
UMCU	*NA*	*<20*	*<20*
Instruct the patient to adhere to good toilet hygiene	**3d**	**3d**	**7d**
AVL	*3d*	*3d*	*7d*
St. Antonius Ziekenhuis	*3d*	*- ≤1.0: 7d - >1.0: 14d*	*7d*
UMCU	*3d (>60y) 7d (<60y)*	*dose rate dependent (20/ 10/ 5)*	*dose rate dependent (20/ 10/ 5)*
Instruct the patients to keep a distance	**3d**	**7d**	**7d**
AVL	*3d*	*7d*	*7d*
St. Antonius Ziekenhuis	*3d*	*- ≤1.0 GBq: 7d - >1.0 GBq: 14d*	*7d*
UMCU	*- 3d (>60y) - 7d (<60y)*	*dose rate dependent (20/10/5 µSv/h)*	*dose rate dependent (20/10/5 µSv/h)*
Instruct the patient to ask for a travel information letter	**rekentool#**	**rekentool#**	**rekentool#**
AVL	*3 weeks*	*3 weeks*	*3 weeks*
St. Antonius Ziekenhuis	*NS*	*3 months*	*3 months*
UMCU	*NS*	*on patient request*	*on patient request*
Instruct the patient to report the radionuclide therapy when visiting a health care professional	**3d**	**3d**	**7d**
AVL	*14d*	*14d*	*14d*
St. Antonius Ziekenhuis	*NS*	*7d*	*7d*
UMCU	*3d*	*7d*	*7d*
Before therapy, have the patient empty his/her bladder; after therapy, have the patient void at the toilet of the Nuclear Medicine department before leaving the hospital	**NA**	**Y**	**NA**
AVL	*NA*	*Y*	*NA*
St. Antonius Ziekenhuis	*NA*	*Y*	*NA*
UMCU	*NA*	*Y*	*NA*

In bold the duration as described in FMS guideline. AVL: Antoni van Leeuwenhoek; d: days; FMS: Federatie Medisch Specialisten; NA not applicable; NN not necessarily; Y: yes; UMCU: UMC Utrecht. *Only if predefined criteria are met. # The FMS guideline refers to a '*Rekentool*' of the 'Nederlandse Commissie voor Stralingsdosimetrie (NCS)' to determine whether a radiation travel information letter is necessary when a patient is traveling after radionuclide therapy (7).

available, which has to be cleaned by the patient him/herself; 4. The patient is totally self-dependent; 5. The patient has to be able to go to and from the hospital by himself (not using public transport); 6. The patient and his/her environment are totally aware of all risks of not sticking to the instructions and restrictions; 7. The patient agrees with the shorter admission duration. In all other cases, a 48 hours admission is necessary. Restrictions were 7 days after therapy for all patients, including restrictions to children nearby (more strict).
In AVL, radiation exposure per category (child, adult caretaker, and general population) was calculated based on a general scenario, using the FMS '*rekentool*'; some slight differences were seen. AVL used an admission of at least 24 hours, and a dose rate level for discharge of 40 µSv/h, as was used in the concept guideline. Based on some of the patients treated in AVL, an admission of only 24 hours is not considered enough to guarantee dose constraints for the environment. Some patients had a high iodine uptake and/or had several cycles of treatment (NB the standard calculations account for just one cycle); using a dose rate level of 40 µSv/h in a worst-case scenario was still considered safe. In specific cases, less strict limits could be used. Restrictions were 7 days for all patients, including children nearby.

In UMCU, radiation exposure per category (child, adult care giver < 60 years old, adult care giver > 60 years old and general population) was calculated based on a general scenario, using the FMS '*rekentool*'. Exposures per category were calculated for three different dose rates at discharge: 20, 10 and 5 µSv/h, based on which the duration of instructions and restrictions was adjusted. Of note, dose rate levels were measured on a daily base, and discharge was possible when dose rates decreased to below 20 µSv/h at 1 meter (according to the 2005 guideline).
AVL used the instructions and restrictions as mentioned in the FMS guideline (table 1). UMCU used previously developed institutional instructions and restrictions. St. Antonius hospital used the contact instructions and restrictions as mentioned in the FMS guideline, specifically adding a restriction on intimacy. St. Antonius hospital in addition implemented a complete list with items considered relevant during the duration of restrictions (like attending a library or cinema).
The restriction on using public transport and flying was 7 days (all centers). The need for the previous iodine treatment to be reported by the patient when visiting a healthcare professional differed slightly (table 2).

[^{131}I]NaI for benign thyroid diseases (≤ 2 GBq)

St. Antonius hospital and UMCU use [^{131}I]NaI for the treatment of benign thyroid diseases, using maximum doses of 2 GBq. In AVL no treatments for benign thyroid diseases were performed since 2018; the guideline was implemented anyway. The FMS guideline discarded the need to measure dose rate levels, whereas the concept guideline set the dose rate level for discharge at 20 µSv/h.
In St. Antonius hospital, a flow chart was designed, based on administered dose (< 400 MBq/ 400-1000 MBq / > 1000 MBq); a dose < 400 MBq was given on an outpatient base plus 7 days restrictions. For the higher doses, the previously mentioned criteria were used to determine whether strict isolation at home was possible for a 48 hours duration; if not possible, admission for 48 hours was necessary. This was followed by a period of contact restriction of 7 days (400-1000 MBq), or 14 days (> 1000 MBq).
In UMCU, radiation exposure per category (child, adult care giver < 60 years old, adult care giver > 60 years old and general population) was calculated based on a general scenario, using the FMS '*rekentool*'. Exposure per category was calculated for three different dose rates at discharge: 20, 10 and 5 µSv/h, based on which the duration of instructions and restrictions was adjusted. Of note, dose rate levels were measured on a daily base, and discharge was possible when dose rates decreased to below 20 µSv/h at 1 meter (according to the 2005 guideline and according to the concept FMS guideline).
In AVL, although no therapies for benign thyroid diseases are performed since 2018, radiation exposure per category (child, adult care giver, and general population) was calculated based on a general scenario, using the FMS '*rekentool*'. Dose rate levels were measured on a daily base, and discharge was possible when dose rates decreased to below 20 µSv/h at 1 meter (according to the 2005 guideline and according to the concept FMS guideline).

Discussion

The implementation of the FMS guideline in each hospital was different, based on different assumptions, prior experiences, considerations and choices. As [^{177}Lu]Lu-based therapies were not included in the original 2005 report, hospitals that implemented this therapy developed their own guidelines. Uniform use of dose rate limits for discharge of 20 µSv/h at 1 meter made implementation in the clinic relatively straightforward, even though this was more strict than absolutely necessary for [^{177}Lu]Lu due to less gamma radiation. This also fitted with the ALARA-principle to try to keep exposure as low as reasonably achievable. As most patients prefer to sleep in their own bed at home, the 6 hours admission period is very practical and allows room for more therapies per week per hospital (10). Differences in implementation of the new guideline between hospitals for [^{177}Lu]Lu-PSMA therapies were small.

Since the incidence of prostate cancer and indications for therapy are still increasing, the implementation of [^{177}Lu]Lu-PSMA therapy in different hospitals will be growing. The FMS guideline will help to standardize hospital protocols.
For [^{131}I]NaI therapies, the FMS guideline is less strict when compared to the former dose rate level for discharge (20 µSv/h at 1 meter). The results of the standardized scenarios in the FMS '*rekentool*' showed that a less strict regime did not lead to exposures of care givers or the general population that exceeded the applicable dose constraints. In the past, discussions could be encountered when patients > 60 years old could not be discharged because of measured dose rate levels of e.g. 22 µSv/h at 1 meter even though they lived alone or with a housemate of > 60 years old, not causing any radiation protection problem. The FMS guideline allows for elderly patients to be discharged with dose rate levels over 20 µSv/h at 1 meter and aims at a new balance in risk based assessment of discharge and outpatient treatment. Concerning the duration of hospital admission, differences between hospitals were seen for [^{131}I]NaI therapies, all based on clear considerations; radiation burden to the environment can be decreased by increasing duration of hospital admission. However, on a national base, this could be more expensive and most patients prefer their own bed. Of note, the '*ANVS handelingsperspectief bij overlijden*' (11) was implemented only after the implementation of the FMS guideline and gives more specific guidance on the topic of death after radionuclide therapies; considerations on a per case base can be made.
The dose rate level of 20 µSv/h at 1 meter for discharge used to be a standard condition in hospital radiation licenses. Violation of this, or any, condition is an offence. Hospitals try their best to adhere to license conditions and inspection is regularly performed. Thus, although guidelines have changed, not all hospitals feel free to change their protocols. It should be noted that the ANVS is aware of this problem. However, at the moment it seems that the new FMS guideline perhaps increased differences between hospitals. This can be confusing for patients and patient associations. Ideally, a new guideline would lead to more uniformity also in patient information leaflets and thus prevent healthcare shopping between centers in the Netherlands.

Conclusion

The implementation of the new FMS guideline in each hospital has been very different, based on different assumptions, prior experiences, considerations and choices. For [^{177}Lu]Lu-PSMA the implementation was more uniform than for [^{131}I]NaI. Radionuclide therapies are increasing and becoming more patient tailored. For patients, a more uniform approach could be helpful, to prevent confusion between patient information leaflets from different institutions and to prevent 'healthcare shopping' between hospitals. We intend to initiate this discussion and pursue uniformity on a national level in the future.

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