Review of Ethics of Nuclear Medicine: Observations from a Tertiary Nigerian Centre

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ABSTRACT

Nuclear Medicine (NM) is a newly emerging branch of Medicine in Nigeria that entails the use of radioisotopes and radiolabelled compounds in diagnosing and treating disease. Ethics may be defined as "the study of morality careful and systematic reflection on and analysis of moral decisions and behaviour, whether past, present or future." The article seeks to review ethical scenarios encountered in the practice of NM. Issues of medical ethics peculiar to NM are presented in a bid to educate the NM physician, non-NM medical personnel as well as the general public. Examples are justification and beneficence of NM procedures, adequacy of informed consent, need for contraception even in infertile patients, care of the radioactive NM patient, and radioactive waste disposal. Ethical solutions are also proffered.

Keywords: Medical Ethics, Nuclear Medicine, Radiation Exposure, Occupational Health, Nigeria

INTRODUCTION

Nuclear Medicine (NM) is a newly emerging branch of Medicine in West Africa that entails the use of radioisotopes and radiolabelled compounds in diagnosing and treating diseases. The specialty has since expanded to include bone, thyroid, renal, liver, parathyroid, and lung imaging. Therapy at the NM centre presently consists of radioactive iodine therapy (RAIT) of toxic and euthyroid goitre, as well as thyroid cancer of follicular origin. Efforts are being made to expand the scope of our practice, including prospects of hybrid positron-emission tomography/computed tomography (PET/CT) imaging and peptide receptor radionudide therapy (PRRT).

Ethics may be defined as "the study of morality and careful-careful and systematic reflection on and analysis of moral decisions and behaviour, whether past, present or future." Morality itself being "the value dimension of human decision-making and behavior," involving *right* and *wrong*, *good* and *bad*. "Medical ethics focuses primarily on issues arising out of the practice of medicine."[1]

Clinical ethics similarly deals with "provider-patient relationships".[2]Ethical medical behaviour may be defined as "matters of moral principles or practices and matters of social policy involving issues of morality in the practice of medicine. The term 'unethical' is used to refer to professional conduct which fails to conform to these moral standards or policies[3]."

The basic tenets of ethics are respect for persons, beneficence, and justice[4]. These principles are involved in the daily practice of NM, and will be discussed in the following scenarios[5].

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JUSTIFICATION OF NM PROCEDURES

Prior to performing a NM procedure, whether diagnostic or therapeutic, the nuclear physician decides whether it is justified. Does this patient need this exposure to radiation? The indication for the referral is considered; this is important especially in radiation therapy, where the histological type of the disease to be treated must be of the type susceptible to the treatment requested for. In the instance of self- or friend-referred patients, efforts are made to obtain medical documentation supporting their requests, including histology reports as mentioned above. Thus, no NM procedure should be performed unless it's prescribed by the NM physician[6,7].

INFORMED CONSENT

Typically, a patient is informed about the nature of the procedure to be carried out on them, and then gives written consent. It has been previously stated that obtaining consent has little meaning unless patients can understand what is to be done and all hazards made clear[8]. The relaying of information about precautions, and the possible side-effects of the procedure is a balancing act performed on a case-by-case basis. This does not

infer an omission of information, but rather to a sensitive delivery of said information. For instance, the possibility of iatrogenic hypothyroidism and lifelong thyroxine replacement therapy should be explained to the patient while counseling for RAIT, and not after he/she has become hypothyroid.

After RAIT for goitre, our patients are required to observe some temporary (week-long) precautions regarding eating, sleeping, toilet and laundry arrangements. If not well understood, the patient's family or caregivers receive this information (usually third-hand through the patient) with what I term *radiophobia*. (As an extreme case, a patient was once banished from her home for that period after informing her family about some of these precautions.)

PATIENT BIAS/FINANCIAL DISCRIMINATION

There is a preset bias in patient selection based on the cost of our procedures they are not really for the 'common man'. This bias is even more pronounced now due to the nation's recent economic challenges. Prior publications have made appeals for insurance schemes such as the National Health Insurance Scheme (NHIS), and government subsidization of the costs of these procedures, as is practiced in most other countries[9,10]. The relatively high cost of NM procedures is due to the fact that practically all materials and equipment used in performing the procedures are obtained from overseas subject to the prevailing foreign exchange rates.

INFERTILITY AND CONTRACEPTION

The two terms seem contradictory. The scenario is one in which a patient with a delay in achieving conception presents for RAIT 'for primary hyperthyroidism'. Understandably, one of the contraindications to radiation therapy is pregnancy. RAIT, in particular, if performed on a pregnant woman, crosses the placenta and may cause hypothyroidism. The solution is to explain the reason for this to the lady in question, preferably along with her partner. Patients are advised to avoid conception for at least six months after RAIT. 'Furthermore, the date of the last normal menstrual period is elicited, and pregnancy tests are performed on the day of RAIT prior to administering radioactivity.' When the risk to the foetus is understood, patients have always agreed to this. Patients are also counseled about other therapy options for treating goitres, such as thyroidectomy.

Another ethical issue with contraception is that birth control may be incompatible with some patients' religious beliefs. In this scenario, one of such couples opted for abstinence for the required period.

BENEFICENCE

Radiation Therapy

Regarding RAIT and other therapy, the need for justification has been mentioned previously. In addition, the benefits of therapy must outweigh its risks. In a patient with a medullary thyroid cancer, for instance, RAIT would be superfluous, as the metabolism of parafollicular cells from which the tumour originates, do not utilize iodine. In this scenario, therefore, the referral for RAIT would be declined. Rather, the more appropriate I-131 metaiodobenzylguanidine (MIBG) therapy may be considered.

In another scenario, the NM doctor must decide how much therapy is enough therapy. In Ibadan, we have set the limit at a cumulative total of one Curie, i.e. 37000 MBq . Beyond this, the fulcrum tilts the balance toward more dangerous side-effects of therapy than benefits.

Care during therapy

Paralyzed, immobilized patients are not suitable for NM treatment that involves isolation. This scenario again refers to RAIT with large doses of radioactive iodine (RAI), but could also easily allude to other radioactive treatment requiring isolation. In life-threatening cases, should NM personnel care for the patient? The ethics of minimizing radiation exposure caution against this, in the interests of the ALARA (As Low As Reasonably Achievable) principle applied to radiation safety of staff[11-13]. However, as medical professionals, NM personnel are first to care for patients and save lives. To be sure, in emergencies, NM personnel at our Centre have been known to hazard themselves to resuscitate radioactive patients on admission. However, it is not advisable to deliberately risk further radiation exposure. It is recommended that local standard operating procedures (SOPs) should be developed to guide professionals in the handling resuscitation of radioactive patients.

Public exposure from NM patients

At Ibadan, patients are discharged home after radiation therapy involving dose rates that translate to less than or equal to 555 MBq at one metre from the patient. 'However, it is not advisable to deliberately risk further radiation exposure. It is recommended that local standard operating procedures (SOPs) should be developed to guide professionals in the handling resuscitation of radioactive patients.'This is done to safeguard the general public from unnecessary exposure, keeping in mind the recommended annual radiation exposure limit of 1 mSv[14,15]. Care-givers and relatives of patients scheduled for radiation therapy at NM are also counseled adequately.

After undergoing routine NM procedures, the radiation risk to the public from such patients has been adjudged minimal and within the recommended ICRP limits[16,17]. Such patients would have excreted most of the radioactivity administered to them by the time they leave the facility. Moreover, physical decay of the radioactivity administered would have occurred. The most common of the latter are Tc-99m based compounds, with half-lives of six hours[18].

Radioactive waste disposal

Another aspect of radiation protection of the public entails the safe disposal of radioactive waste generated as a result of NM procedures. Radioactive waste may be defined as "material, whatever its physical form, remaining from practices and interventions, and for which no further use is foreseen, that contains or is contaminated with radioactive substances, and has activity concentrations higher than level for clearance or exemption from regulatory requirements[15-19]." Waste disposal is the responsibility of the supplier of radioactivity[20,21]. NM deals with unsealed sources of radioactivity, and most of the radioactive waste from NM procedures is relatively short-lived and classified as Category I; thus it may be discarded as normal waste after allowing for radioactive decay. Categories II-IV waste disposal require more stringent disposal[19]. It is noteworthy that Nigeria has only one radioactive waste management facility in the Centre of Energy Research and Training (CERT), Zaria, Kaduna State.

An example of unethical waste disposal is that of the Koko dump in 1987 a foreign company. Twenty-six workers who handled the waste developed macrocytic anaemia and leucopaenia attributed to radiation injuries[22].

THE SAFE PRACTICE OF NUCLEAR MEDICINE

Radiation monitoring of NM personnel/Radiation workers

NM personnel need to have their radiation exposure monitored. The yearly limit of exposure for NM staff is 20 μSv/year over five years, not exceeding 50 μSv in any single year[14]. If this limit is exceeded by any NM member of staff, the staff member needs to be re-allocated to work in a non-radioactive zone. For pregnant NM personnel, the International Commission on Radiological Protection (ICRP) recommends the same dose limit of 1 mSv for the duration of the pregnancy as for the general public, as the embryo/foetus is also regarded as being a member of the public (i.e. a non-radiation worker)[14,23,24].

In the same vein, NM personnel are entitled to appropriate and accurate monitoring of their radiation exposure. Dosimeters for NM personnel should be sensitive to radiation from as little as μSv. Also, timeous medical tests such as the full blood count should be performed to monitor the health status of these workers. (Marie Curie, who discovered radium and polonium, died of aplastic anaemia due to radioactive exposure in the course of her work)[25,26]. Furthermore, the results of these tests should be promptly disseminated to personnel whether normal or not.

Non-radiation medical personnel exposed to NM patients

Medical personnel exposed to 'radioactive patients' who have had administered radioactivity to them should be assured of their safety. Thus, NM patients are discharged home only at radiation levels safe for the public. As for those non-NM personnel (surgical teams) exposed to radioactive patients in the course of surgery, the radiation dose to them as been assessed[27-29]. Such procedures include sentinel lymph node mapping (SLNM), radio guided occult lesion localization (ROLL),

radiosynovectomy or radioactive synoviorthesis. Other occasions of exposure include the care of a NM patient after their scan. The level of radiation exposure from NM patients following SLNM has been calculated as being quite low and within recommended ICRP limits. Whole-body doses received ranged from 0.05-0.45 mSv[27].

CONCLUSION

The practice of NM will always involve the practice of medical ethics, as with other arms of Medicine. Issues of medical ethics which are peculiar to NM have been presented above in a bid to educate the NM physician, non-NM medical personnel as well as the general public, in order to develop a better relationship among all three.

DECLARATIONS

The author declares that she has no competing interests.

List of abbreviations

ALARA	- As Low As Reasonably Achievable
CERT	- Centre for Energy Research and Training
ICRP	- International Committee on Radiological Protection
MIBG	metaiodiobenzylguanidine
NM	Nuclear Medicine
NHIS	National Health Insurance Scheme
PET/CT	Positron Emission Tomography/ Computed Tomography
PRRT	Peptide Receptor Radionudide Therapy
RAI	radioactive iodine
RAIT	radioactive iodine therapy
ROLL	radioguided occult lesion localization
SLNM	sentinel lymph node mapping

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REFERENCES

1. Williams JR. Medical Ethics Manual. 3rd ed. World Medical Association 2015. Available from: www.wma.net/en/70education/30print/10medical_ethics/. [Accessed April 16 2017].
2. Rosenthal MS. Ethical issues in the management of thyroid disease. *Endocrinol Metab Clin North Am.* 2014;43(2):545-64.
3. American Medical Association. Council on Ethical and Judicial Affairs 1996. Available from: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion101.page. [Accessed April 17 2017].
4. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission). Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Washington, DC: Federal Register Document; April 18, 1978:79-12065. Available from: http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf. [Accessed April 16 2017].
5. Corrao S, Arnone G, Arnone S, Baldari S. Medical ethics, clinical research, and special aspects in nuclear medicine. *Q J Nucl Med.* 2004;48(3):175-80.
6. Kim BI. Radiological Justification for and Optimization of Nuclear Medicine Practices in Korea. *J Korean Med Sci.* 2016;(31):Suppl 1:S59-68.
7. Beecher HK. Ethics and clinical research. *N Engl J Med.*1966(274);24:367-72.
8. Adedapo KS, Fadiji IO, Orunmuyi AT, Ejeh JE, Osifo BO. Public health in Nigeria. *Hell J Nucl Med.*2011;14(1)**:**85.
9. Adedapo KS, Onimode YA, Ejeh JE, Adepoju OA. Avoidable challenges of a nuclear medicine facility in a developing nation. *Indian J Nucl Med.* 2013;28 (4):195-9.
10. Greaves C, Tindale W. Radioiodine therapy: care of the helpless patient and management of the radioactive corpse. *J Radiol Protect.*2001;21(4):381-92.
11. Reyher P (1912). Das röntgenverfahren in der kinderheilkunde. Berlin: Hermann Meusser.
12. National Council on radiation protection

and measurements. Implementation of the principle of as low as reasonably achievable (ALARA) for medical and dental personnel. NCRP report no. 107. Bethesda, Md: NCRP, 1990.

13. Oudiz A, Croft J, Fleishman A, Lochard J, Lombard J, Webb G. What is ALARA? (Centre d'étude sur l'évaluation de la protection dans le domaine nucléaire) CEPN report no. 100. Paris, France: CEPN, 1986.
14 ICRP. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. *ICRP*.2007;37(2-4):1-332.
15. ICRP. The International Commission on Radiological Protection. Release of patients after therapy with unsealed radionuclides. ICRP Publication 94. *Ann ICRP.* 2004;34:1-80.
16. Mountford PJ, O'Doherty MJ, Forge NI, Jeffries A, Coakley AJ. Radiation dose rates from adult patients undergoing Nuclear Medicine investigations. *Nucl Med Commun*. 1991;12(9):767-77.
17. Mountford PJ, O'Doherty MJ. Exposure of critical groups to Nuclear Medicine patients. *ApplRadiat Isot.* 1999;50(1)**:**89-111.
18. Nigerian Nuclear Regulatory Authority. Nigeria Radioactive waste management regulations 2006. Available from: http://www.nnra.gov.ng/publications.[Accessed April 16 2017].
19. Nigerian Nuclear Regulatory Agency. Okafor ON. Nigeria's experience with implementing the Code of Conduct and the Joint Convention on the Safety of Radioactive Waste and Spent fuel in relation to Nigeria's management in disused sealed radioactive sources (DSRS). DSRS Workshop, Lisbon, Portugal 11th -15th October 2010. Available from: http://www-ns.iaea.org/downloads/rw/waste-safety/workshops/lisbon2010/monday/nigeria.pdf.[Accessed April 16 2017].
20. International Atomic Energy Agency. Policies and strategy on radioactive waste management. Available from: https://www.iaea.org/sites/default/files/policiesrwm0609.pdf. [Accessed April 16 2016].
21. Ogunranti JO. Haematological indices in Nigerians exposed to radioactive waste. *Lancet.* 1989;16(8664):667-8.
22. ICRP. Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. *Ann ICRP*. 1991;21(1-3)**:**1-201.
23. NRC Enclosure 4, Issue 3. Dose limits to embryo/fetus of a declared pregnant occupational worker. Available from: http://www.nrc.gov/docs/ML1408/ML14084A339.pdf. [Accessed April 30 2017].
24. Langevin-Joliot H. Radium, Marie Curie, and modern science. *Radiation Res*.1998;150(5 Suppl):S3-8.
25. Rockwell S. The Life and Legacy of Marie Curie. *Yale J Biol Med.* 2003;76(4-6):167-80.
26. Brenner W, Ostertag H, Peppert E, Czech N, Kampen WU, Muhle C, Luttges J, Jenze E. Radiation exposure to the personnel in the operating room and in the pathology laboratories due to sentinel lymph node detection with Tc-99m-nanocolloid in breast cancer patients. *Nuklearmedizin*. 2000;39(5):142-5.
27. Law M, Chow LW, Kuong A, Lam CK. Sentinel lymph node technique for breast cancer: radiation safety issues. *Semin Oncol***.** 2004;31(3)**:**298-303.
28. Sattari A, Dadashzadeh S, Nasiroghli G, Firoozbadi H. Radiation dose to the Nuclear Medicine nurses. *Iran J Radiat Res***.**2004;2(2):59-62.