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## ORIGINAL ARTICLE

# Are We Adequately Communicating the Potential Radiation Risks to Patients Undergoing Nuclear Medicine Examinations? A Clinical Audit

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## ABSTRACT

***Introduction:*** *We assessed whether the communication of potential radiation risks from nuclear medicine examinations to patients, which is required by law, is adequate.*

***Methods:*** *We performed an audit to assess the adequacy of communication to patients, with two targets: (1) they received sufficient information about the potential radiation risks; and (2) they understood the information before they consented to the examination. We aimed at 100% of patients achieving both targets. If they did not, we planned to implement changes to bring our practice in line with these standards. A total of 53 patients undergoing examinations during a randomly selected week were recruited to fill out a questionnaire.*

***Results:*** *The audit showed that the targets were not achieved, with only 45% of the participants (95% confidence interval = 33-59%) reporting that they both received sufficient information and understood the potential risks. A series of changes were implemented, including distribution of a newly designed one-page information pamphlet to all participants, provision of a newly designed one-page reference sheet to the clinical team, and design of a new workflow for radiographers. Another 53 patients were recruited for re-audit, and the effect of the changes was assessed by comparing the results between the audit and re-audit, using the Chi squared test. These changes were associated with statistically significant improvements in both targets from 45% to 100% ($p < 0.0001$).*

***Conclusion:*** *When patients are provided with an easy-to-understand information pamphlet and the clinical team are instructed to assist patients in understanding the information, the communication targets are achievable.*

***Key Words:*** *Informed consent; Nuclear medicine; Clinical audit; Radiation; Communication*

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# 中文摘要

## 臨床審計：我們有否向接受核子醫學檢查的病人充分說明潛在的輻射風險？

陳德光、歐陽定勤、龔本霆、許殷豪

**簡介：**法律上我們須向接受核子醫學檢查的病人充分說明潛在的輻射風險。本臨床審計旨在評估相關溝通是否足夠。

**方法：**充分的溝通須達致兩個目標：（一）病人接收到有關潛在輻射風險的充分資訊；（二）他們在同意檢查前充分了解潛在的輻射風險。我們的目標是100%病人接收到並充分了解有關潛在輻射風險的資訊。如果未能實踐目標，我們將推行一系列改善措施並再評估成效。本審計在隨機選擇的一周內共招募了53名接受檢查的病人填寫問卷。

**結果：**審計結果顯示我們未能實踐目標，只有45%的審計參與者（95%置信區間 = 33-59%）表示他們收到並了解有關潛在輻射風險的資訊。因此，我們推行一系列改善措施，包括向所有檢查參與者派發新設計的一頁輻射風險資訊小冊子，向臨床團隊提供新設計的一頁參考資訊，以及為放射技師設計新的工作流程。其後，我們招募了另外53名接受檢查的病人填寫問卷，並透過卡方檢驗比較審計和改善後重新審計之間的差異。結果顯示我們的改善措施將審計達標率從45%提升至100%（統計學上顯著差異$p < 0.0001$）。

**結論：**向病人提供易於理解的資訊小冊子，並指導臨床團隊幫助病人理解資訊，審計目標將可得以實踐。

## INTRODUCTION

Every nuclear medicine examination involves the administration of a radioactive tracer. There exists direct epidemiologic evidence of excess cancer risks in a number of groups exposed to low-dose radiation.[1] A risk of death of one in one million can be reasonably considered negligible, since we are exposed to many risks of such magnitude every day, such as from travelling by car.[2] On the other hand, it may not be prudent to ignore a risk of death of about one in one thousand, which may correspond to potential additional life-long risk of cancer for an adult patient undergoing thallium scintigraphy.[3]

The Royal Society of the UK stated that a risk of death of one in one thousand can be acceptable so long as an individual patient knows the risk, receives commensurable benefit, and understands that efforts are made to minimise the risk.[4] In *Montgomery v Lanarkshire Health Board*, the Supreme Court of the UK affirmed the doctors' duty to disclose material risks related to medical treatments.[5] The common law duty for doctors to disclose risk-related information was further affirmed in *Hii Chii Kok v Ooi Peng Jin London Lucien and National Cancer Centre of Singapore Pte Ltd*. by the Singaporean Court of Appeal.[6] Such legal duty is explicitly promulgated in the Code of Professional Conduct published by the Medical Council of Hong Kong (MCHK), which states that informed consent must be obtained for all diagnostic procedures: '*The explanation should cover not only significant risks, but also risks of serious consequence even though the probability is low (i.e., low probability serious consequence risks)*.'[7]

A literature review showed that 87% of patients were of the view that potential radiation risks should be discussed with them before imaging.[8] Only 29% of patients in four different studies reported being informed about the potential radiation risks of the computed tomography (CT) they underwent.[8] Only 22% of physicians reported providing this information to their patients.[8] In a survey of radiology department chairs, 15% reported that their departments regularly informed patients about potential radiation risks.[8] In fact, many medical doctors requesting radiological examinations do not have adequate understanding about the potential radiation risks. A survey showed that only 22% of emergency department physicians estimated the dose from CT correctly.[9] Another study showed only 34% of

non-radiologist medical doctors correctly estimated the effective radiation dose from a thoracic CT.[10]

In our institute, we inform patients on a notice board that in general the radiation dose of the radiotracer used in our examinations is very low and will reduce to zero over time very quickly. Patients are informed that the radiation dose is so low that it does not cause harm to them and is near that of a chest radiograph. The same message is also delivered to patients through a one-page pamphlet for patients undergoing bone scintigraphy.

This audit was a quality assurance project intended to assess the adequacy of communication to patients in our institute undergoing examinations (excluding positron emission tomography) about the potential radiation risks to comply with the legal and professional standards that they should all (1) receive sufficient information about the radiation risks, and (2) understand the information before they consent to examinations. If necessary, we aimed to take action to bring our practice in line with these standards so as to safeguard patients' right to autonomy.

## METHODS

All patients aged 18 to 70 years undergoing examinations in our institute during a randomly selected week were consecutively recruited to fill out a questionnaire (online supplementary Appendix 1). The data items to be collected included patient demographics, type of nuclear medicine examination, and whether they agreed that they had (1) received and (2) understood the information about potential radiation risks. We also enquired of the participants whether they considered information about the potential radiation risks of the examination important.

### Standards

The targets were that 100% of participants agreed that they had (1) received and (2) understood the information. Indicators to be measured were the proportion of patients who agreed that they received sufficient information about the potential radiation risk of the examination they were to undergo, and that they understood the information before they consented to undergo the nuclear medicine examination. If either one of the targets was not achieved, a re-audit would be performed following implementation of a series of changes.

### Statistical Analyses

The sample size was calculated using Power Analysis and Sample Size 2021 (PASS 21.0.3, LLC, Kaysville [UT], US). A total of 82 subjects were needed, using the Chi squared test for independence, with one degree of freedom, type 1 error = 0.05, power = 0.95, for detection of 20% of difference after implementation of changes (assuming a proportion of 50% under the null hypothesis). The Chi squared test was performed using Number Cruncher Statistical Systems (NCSS 21.0.3, LLC, Kaysville [UT], US).

## RESULTS

The audit was conducted from 15 February 2021 to 19 February 2021. A total of 54 participants fulfilled the inclusion criteria. One participant, who had impaired cognitive function, was excluded. Fifty-three of them completed the survey (Table 1). Only 45% of the participants (95% confidence interval = 33-59%) considered that they received sufficient/very sufficient information regarding the potential radiation risks of the examination they underwent. Also, only 45%

**Table 1.** Characteristics of audit participants (n = 53).

| | No. (%) |
|---|---|
| Age | |
| 18-30 | 1 (2%) |
| 31-40 | 2 (4%) |
| 41-50 | 7 (13%) |
| 51-60 | 22 (42%) |
| 61-70 | 21 (40%) |
| Gender | |
| Male | 12 (23%) |
| Female | 41 (77%) |
| Types of examinations | |
| Cardiac | 33 (62%) |
| Musculoskeletal | 8 (15%) |
| Renal | 9 (17%) |
| Others | 3 (6%) |

**Table 2.** Compliance with audit standards (n = 53).

| | No. (%) | 95% confidence interval |
|---|---|---|
| Audit target 1: receival of information about potential radiation risks | | |
| Received sufficient/very sufficient information | 24 (45%) | 33-59% |
| Received insufficient/very insufficient information | 29 (55%) | 41-67% |
| Audit target 2: understanding of information about potential radiation risks | | |
| Understood well/very well the information | 24 (45%) | 33-59% |
| Understood not well/very not well the information | 29 (55%) | 41-67% |

**Table 3.** Implementation of changes before proceeding to the re-audit.

| | Action plan | Action taken | Person(s)-in-charge |
|---|---|---|---|
| 1 | Present the above audit findings to clinical team involved and discuss (i) issues on missing or inadequate information (ii) issues on patient survey | The findings of the audit were communicated to the clinical team verbally and/or by means of a PowerPoint presentation. | TK Chan |
| 2 | Design information pamphlet regarding the radiation risks of all nuclear medicine examinations for the reference of clinical team members | An information pamphlet was designed for radiographers (online supplementary Appendix 2). | TK Chan |
| 3 | Design workflow for radiographers | A workflow was designed for radiographers (online supplementary Appendix 3). | TK Chan |
| 4 | Distribute the information pamphlet regarding the radiation risks of all nuclear medicine examinations and the workflow for the reference of radiographers | The pamphlet and the workflow were distributed to each nuclear medicine imaging control room. | Senior radiographer |
| 5 | Design information pamphlet to patients to provide the information about radiation risk | The pamphlet was designed for patients, adapted from the nuclear medicine patient poster designed by the Clinical Imaging Board of the United Kingdom, with permission granted (online supplementary Appendix 4). | TK Chan |
| 6 | Distribute information pamphlet to patients to provide the information about radiation risks | The pamphlet was distributed to 100% of participants when they registered for the examination in the re-audit period. The auditor also confirmed that 100% of participants understood the information. | Reception colleagues |
| 7 | Ensure that the participants read and understood the pamphlet | Some participants were illiterate. Information on the pamphlet was read to them. Overall, 100% of the participants either read the pamphlet or were told the information on the pamphlet. 100% of the participants confirmed that they understood the material on the pamphlet. | Radiographers and TK Chan |
| 8 | Ensure that the participants know they can ask questions and answer them if any | All participants were asked if they had any questions. If any, they were all answered. | Radiographers and TK Chan |
| 9 | Arrange for training in the medico-legal aspects of consent, consenting technique and the possible consequences resulting from inadequate arrangements | Training was provided to the clinical team by means of verbal communication and/or PowerPoint presentation. | TK Chan |

of participants (95% confidence interval = 33-59%) considered that they understood well/very well the radiation risk of the examination (Table 2). Both fell short of the audit targets. It was therefore necessary to implement changes (Table 3) and proceed to re-audit.

The re-audit was conducted from 22 to 26 February 2021. A total of 54 participants fulfilled the inclusion criteria. One participant, who had impaired cognitive function, was excluded. Fifty-three of them completed the survey, response rate being 100% (Table 4). In the re-audit, subsequent to implementation of the changes described in Table 3, there were significant improvements in the compliance with the audit targets (Tables 5 and 6). The change was found to be statistically significant ($p < 0.0001$). Four of the participants (8%) needed further explanation of the information after reading the information pamphlet. All participants considered that they were provided sufficient or very sufficient information about the radiation risks of the examination they underwent. Also, 100% of participants considered that they understood well or very well about the radiation risks of the examination they underwent. This was in full compliance with the audit standards that 100% of

**Table 4.** Characteristics of re-audit participants (n = 53).

| | No. (%) |
|---|---|
| Age (years) | |
| 18-30 | 0 |
| 31-40 | 4 (8%) |
| 41-50 | 8 (15%) |
| 51-60 | 15 (28%) |
| 61-70 | 26 (49%) |
| Gender | |
| Male | 17 (32%) |
| Female | 36 (68%) |
| Types of examinations | |
| Cardiac | 33 (62%) |
| Musculoskeletal | 11 (21%) |
| Renal | 4 (8%) |
| Others | 5 (9%) |

participants should receive sufficient information and understand it.

Out of a total of 106 participants from the audit and re-audit, 105 participants (99%) considered it important or very important for them to know and understand the radiation risks of their examination.

# DISCUSSION

## Approaches to Radiation Risks Disclosure

There are three current strategies of risk disclosure for examinations: no mention, understatement, and full disclosure. One philosophy is not to mention potential radiation risks. The basic argument is that radiologists are too busy to lose time in obtaining informed consent and too wise to undertake inappropriate examinations. The long-term nature of the risk and/or its minimal to mild magnitude appear to provide an excuse for overlooking the issue of informed consent.[1]

Another approach is to understate the potential risks. We commonly read statements such as 'a nuclear medicine examination is safe, with an irradiation corresponding to a simple radiograph' or 'almost always less than a common radiological examination'. Both patients and clinicians might believe that a simple radiograph would be a chest radiograph. In reality, however, the radiation dose ranges from 50 chest radiographs for thyroid scintigraphy to 4000 chest radiographs for a cortical adrenal gland scintigraphy.[1]

In the alternative, the potential radiation risks can be fully disclosed. This approach was more strictly required in the research setting.[11] This is the approach we used in our implementation of change. We mentioned in our newly designed patient pamphlet that 'The amount of radiation in a nuclear medicine examination varies, but is less than 5 years' duration of your natural exposure. The radiation risks are negligible to low.' We made it clear in a remark that 'There is a 20% life time chance of developing a fatal cancer in the general population. A nuclear medicine examination may expose an adult patient to less than or much less than 0.1% extra chance' (online supplementary Appendix 4).

**Table 5.** Results of re-audit (n = 53).

| | No. (%) | 95% confidence interval |
|---|---|---|
| Audit standard 1: receival of information about potential radiation risks | | |
| Received sufficient/very sufficient information | 53 (100%) | 93-100% |
| Received insufficient/very insufficient information | 0 | 0-7% |
| Audit standard 2: understanding of information about potential radiation risks | | |
| Understood well/very well the information | 53 (100%) | 93-100% |
| Understood not well/very not well the information | 0 | 0-7% |

## International Ethical Principles

The World Medical Association's Medical Ethics Manual provides that informed consent is one of the central concepts of present-day medical ethics: *'The patient has the right to … make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions.'*[12]

## Prevailing Legal Paradigm

In law, a medical professional must serve a patient's best interests. It was established in the UK case *Airedale NHS Trust v Bland* that *'the best interests of the patient are served by respecting the patient's wishes.'*[13] In order for patients to make informed decisions, the *Montgomery* case affirmed doctors' duty to disclose material risks related to medical treatments,[5] citing Lord Woolf MR as saying in another UK case *Pearce v United Bristol Healthcare NHS Trust: '[I]f there is a significant risk which would affect the judgment of a reasonable patient, it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.'*[14] Insofar as what amounts to a significant risk, it was said in the UK case *Wyatt v Curtis* that *'a risk which … doubles, or*

**Table 6.** Chi squared test for the differences between audit and re-audit.

| Subgroup | Audit | Re-audit | Chi squared test |
|---|---|---|---|
| Compliance of either one audit standard | 24 | 53 | Difference 55% (95% confidence interval = 40-67%) |
| Non-compliance of both audit standards | 29 | 0 | Chi squared = 40 |
| | | | degree of freedom = 1 |
| Total No. of participants | 53 | 53 | $p < 0.0001$ |

*at least enhances, the background risk of a potentially catastrophic abnormality may well be both substantial and grave, or at least sufficiently real'* for a patient to be told about.[15]

It was further established in the *Hii Chii Kok* case that *'material information should not be limited to risk-related information'*. This should include all information that *'may be needed to enable patients to make informed decision about their health ... [A]s to what exactly it is about the various types of information that would be considered relevant or material, in our judgment, this is largely a matter of common sense*.'[6]

The International Covenant on Economic, Social and Cultural Rights of the United Nations provides that the right to health is an inclusive right, in which the entitlement includes provision of health-related information.[16] Such right and entitlement is also protected in Article 39 of the Basic Law of Hong Kong.[17]

## Local Professional and Corporate Guidelines

Locally, the Code of Professional Conduct published by the MCHK provides that informed consent must be obtained for all diagnostic procedures.[7] Consent may be either implied or expressed, and is valid only if the doctor has provided proper explanation of the nature, effects, and risks of the proposed procedure and/or treatment.[7] The explanation has to cover *'risks of serious consequence even though the probability is low (i.e., low probability serious consequence risks)'*.[7] The doctor must ensure that the patient understands the explanation.[7] The local Hospital Authority Head Office Operations Circular No. 19/2015 'Update on HA Informed Consent for Operation/Procedure/Treatment' has largely adopted the relevant provisions in the Code of Professional Conduct published by the MCHK.[18]

## Is Potential Radiation Risk Material?

Since the 1970s, the potential risk of radiation has been estimated using the linear non-threshold (LNT) model, which assumes a linear relationship between radiation dose and cancer risk. Much of the evidence on radiation-induced cancer risks came from a Japanese atomic bomb survivors' lifespan study and studies of medically exposed populations.[19] As the LNT model implies that even the smallest dose may trigger carcinogenesis, there have been many challenges to its scientific basis in the last two decades.[20-22] Some studies even demonstrated health benefits of low-dose radiation exposure, including reduced cancer incidence and increased longevity.[23] The prudent use of radiation by means of ALARA (as low as reasonably achievable) approach is further criticised as being radiophobic.[21] A model suggesting protective effects at imaging radiation levels (radiation hormesis) was proposed to counter the LNT model (harm at any dose).[21]

This said, there exists direct epidemiologic evidence of excess cancer risks in a number of groups exposed to low radiation doses.[1,19,24] The controversy remains unresolved. The French Academy of Sciences report concluded that the use of LNT model is not based on scientific evidence.[25] In contrast, the Biological Effects of Ionizing Radiation VII report and that of the International Commission on Radiological Protection endorsed the use of the LNT model.[26,27] After all, prevailing radiology and nuclear medicine professional guidelines still embrace the principle of ALARA inherited from the LNT model.

While some criticised the use of LNT model as ignoring the huge benefits of imaging, promoting fear and imaging avoidance,[21] patients are entitled to be informed of the potential radiation risks estimated by the LNT model. A medical doctor cannot be faulted for overcaution so far as patients are told of the potential nature of the risk and also the substantial benefits of the examination. The law has made it clear that the best interests of a patient are served by respecting his or her wishes.[13] In law, a doctor is allowed to withhold from a patient a material risk *'only if he reasonably considers that its disclosure would be seriously detrimental to the patient's health...'*. However, this does not enable a *'doctor to prevent the patient from making an informed choice where [he/] she is liable to make a choice which the doctor considers to be contrary to [his/] her best interests*.'[5]

All of our participants except one considered information about potential radiation risks of examinations important or very important. We fully concur with the Court of Appeal in Singapore that the judgement is *'a matter of common sense'*.[6] Any possible increased risk of getting a fatal cancer, the controversy granted, must still be *'both substantial and grave'* for a reasonable patient.[15] In short, the ethical and legal authorities, local professional code and corporate guideline unequivocally require that nuclear medicine physicians should adopt the approach of full disclosure regarding potential radiation risks. Our results indicate that such standard is achievable through changes.

### Should Patients be Asked to Sign a Consent Form?

The law does not require that consent has to be in writing. A valid consent can even be implied. In many minor examinations or procedures patients give implied consent. For example, the patient lies on the examination couch when the doctor proceeds to conduct a physical examination; or the patient may roll up a sleeve and offer an arm when the doctor proceeds to take a blood sample.

Mandatory written informed consent may result in undue anxiety and occasional refusal of examinations that may be lifesaving when in fact the radiation risk is minimal. So far as a patient understands the information about the radiation risk, given the large volume of workload in the nuclear medicine centre, it is reasonable and fair to proceed with the examination on the basis of implied consent. It is relevant to note that the MCHK's Code of Professional Conduct also stipulates that for non-invasive treatments, consent can usually be implied.[7]

### Limitations

The clinical team was not blinded to the participant group. Reporting bias may have been introduced when the informed consent process took place during the audit period and when some less educated patients needed prompts in answering the questions.

Also, the audit was conducted based on subjective answers from the participants. What the participants subjectively consider sufficient may not be sufficient from legal and professional perspectives. What the participants thought they understood also may not represent actual and complete understanding of the information.

## CONCLUSIONS

Despite the target that patients know and understand the potential radiation risks of their examination, our previous practice fell short of it frequently. Our audit results demonstrate that once a patient is provided sufficient information in the form of a pamphlet and the clinical team is given instructions to assist patients in understanding the information, the standard is achievable.

Future research can be conducted amongst the stakeholders to investigate how much information to give, how best to provide it, when to provide it, whom to provide it to, with a view to perfecting the informed consent process.

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