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Title: Determining the pregnancy status of patients prior to diagnostic nuclear medicine procedures: The Australian experience

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ABSTRACT

Ionising radiation used in diagnostic nuclear medicine procedures has the potential to cause biological effects to a foetus. Nuclear medicine technologists (NMT) therefore have a responsibility to ensure all women of childbearing age are questioned regarding their pregnancy status before commencing any procedure to avoid unnecessary foetal irradiation. In Australia, there are no clearly defined practice guidelines to assist NMT in who to question or how to question their patients.

Methods: Semi-structured interviews were conducted with Chief NMT’s and staff NMT in eight (8) nuclear medicine departments in Australia. Questions were based around five areas: regulations and policy, foetal radiation exposure, questioning of the patient, difficulties in determining pregnancy status, and the impact of the use of hybrid imaging. Audiotapes of the interviews were transcribed and coded using QSR NVivo8.

Results: Topics were coded into five themes based on the areas of questioning: policy and awareness of guidelines, questioning the patient, radiation knowledge, decisions and assumptions made by NMT, and the use of pregnancy testing. There is a wide variation in practice between, and within, departments, in Australia. NMT’s demonstrated a lack of knowledge and awareness of the possible biological effects of radiation.

Conclusion: This study identified a need for a consensus approach to verifying a patient’s pregnancy status in nuclear medicine so that NMT can successfully question patients regarding their pregnancy status. Continuing education programs are also required to keep NMT knowledge up-to-date.
Keywords: ionising radiation, pregnancy status, foetal exposure, qualitative
Determining the pregnancy status of patients prior to diagnostic nuclear medicine procedures: The Australian Experience

INTRODUCTION

Diagnostic nuclear medicine procedures involve the administration of radioactive materials, usually intravenously. These radiopharmaceuticals emit ionising radiation and as such, have the potential to cause biological effects in humans. The injected radiopharmaceutical circulates within the blood stream of the patient and irradiates the entire body of the patient. In Australia, nuclear medicine technologists (NMT) administer the radiopharmaceutical for most nuclear medicine procedures. It is recognised that, although the radiation dose from these procedures is relatively small, there is the potential to cause biological effects in those patients who have been injected (1).

Care must be taken not to administer radiopharmaceuticals to a woman who is pregnant, as this could cause biological damage to the developing foetus (2). The response after exposure to ionising radiation depends on a number of factors including total dose, dose rate, radiation quality, and the stage of foetal development at the time of exposure; together, these factors determine the type and extent of the damage that may occur (3). Developmental consequences can be teratogenic, mutagenic or carcinogenic in nature (3). The most radiosensitive period for the foetus is the period known as organogenesis, which occurs during weeks two to eight after conception (4, 5). At this early stage of the pregnancy, many women are unaware that they are pregnant and therefore, in order to protect the developing
foetus, it is important that the NMT has clear guidelines to follow to ascertain the
pregnancy status of their patients. Several well-recognised published documents
provide guidance regarding the radiologic imaging of pregnant women. These
include documents from international and national organisations such as the
International Commission on Radiation Protection (ICRP) (2), the Society of Nuclear
Medicine (SNM)(6) and the Australian Radiation Protection and Nuclear Safety
Agency (ARPANSA) (7).

In 2008 ARPANSA published the Safety Guide for Radiation Protection in Nuclear
Medicine (7) which provides advice and guidance on radiation practice. Section 5
(p24-28) discusses the protection of the embryo or foetus. The Guide states that
“illustrated signs” advising patients to inform staff if they may be pregnant are to be
placed in prominent places within a nuclear medicine department. It also states that
“staff have a responsibility to enquire about the possibility of pregnancy in all female
patients of childbearing age”. ARPANSA recommends the patient is given an
explanation as to why the question is being asked to ensure full cooperation and a
truthful response. This is identified as a sensitive issue which requires “tact and
discretion”, especially with teenagers and if language barriers exist. When pregnancy
status is deemed uncertain, ARPANSA recommends consulting the nuclear
medicine physician to decide if the procedure should be postponed or whether to
perform a pregnancy test.

All of the professional and regulatory bodies governing the use of ionising radiation
for diagnostic imaging procedures recommend that the pregnancy status of all
females of child-bearing age should be verified prior to any procedure utilising
ionising radiation (7). NMT are thus required to determine the patient’s pregnancy status prior to any diagnostic imaging procedure that utilises ionising radiation to ensure that unnecessary foetal irradiation does not occur. However, there are no clear guidelines on what constitutes childbearing age, or how to determine the patient’s pregnancy status in the documents.

All NMT are trained to question their female patients, however; it became evident from talking to NMT colleagues around Australia that the methods used vary greatly between department and even staff members within a department. Typically the NMT will verbally question the patient immediately before administering the radiopharmaceutical. Some departments ask women to sign a form stating they are not pregnant and may also require them to provide the date of their last menstrual period. Urine and serum pregnancy tests can be utilised to determine if a patient is pregnant but they are not routinely used.

In recent years, hybrid imaging systems, such as SPECT/CT and PET/CT, have been introduced and rapidly incorporated into general nuclear medicine practice in Australia. The use of CT, combined with SPECT or PET procedures, can increase the patient’s radiation exposure and hence the dose to the foetus by combining the exposure from the radiopharmaceutical with that of computed tomography. Depending on the CT exposure factors used, “the effective dose to the patient from the CT component may be larger than that of the radiopharmaceutical” (7) (p23). If the CT is performed over the abdomen or pelvis of a pregnant woman there will be an increased risk to the foetus.
In 2007, Applegate (8) suggested that the American College of Radiology (ACR) develop a national guideline to address pregnancy screening of patients prior to diagnostic radiology procedures to provide a standardised approach to identifying pregnant patients. The article highlighted the lack of any survey data investigating current practice and an apparent wide variation in departmental procedure. Topics suggested for the proposed guidelines included how the patient should be questioned, age range for screening, use of urine and blood pregnancy testing, and documentation. In 2008, the ACR released “ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation” (9). These guidelines address the possible radiation risks to the foetus and how to screen for pregnancy. The guidelines were developed for diagnostic radiology and specifically state that “it does not address issues for nuclear medicine” (p2).

Schreiner-Karoussou (2009) (10) conducted a preliminary review of European practice concerning ionising radiation and pregnancy and concluded that there was “no harmonisation on this issue at the European level” (p81). The report suggested that there was a lack of consistent practice and thinking in this area among health professionals and that more research is required to give it the merit it deserves.

This paper describes the findings from a qualitative study investigating current practice in Australia for determining the pregnancy status of a patient prior to diagnostic nuclear medicine procedures.

METHOD
Ethics approval for the study was submitted to The University of Newcastle Human Research Ethics committee and approved in September 2009 (Approval number H-2009-0270).

Following a literature review, interview questions were developed to investigate current departmental policies and practice, NMT knowledge of the biological effects of radiation and foetal exposure, and problems NMT associated with determining a patient’s pregnancy status. These questions formed the basis of semi-structured interviews conducted with Chief NMT and members of their staff employed in selected nuclear medicine departments across Australia.

Eighteen nuclear medicine departments were selected and invited to participate in the study. These included departments from each state of Australia covering a variety of metropolitan and rural, and public and private centres. A package sent to the Chief NMT of each department contained an information sheet and consent form for the Chief NMT, as well as a number of letters to be distributed among the NMT working in their department. These letters contained an information sheet, a consent form and a short demographic questionnaire. If the NMT wished to participate, they were asked to return the consent form and questionnaire to the researchers. Interviews were organised to be conducted at a suitable time and place convenient to the participants.

An interview guide was used during all interviews to ensure each interviewee was asked similar questions relating to a series of themes. The themes covered were:

- Regulations and policy
- Foetal radiation exposure
- Questioning of the patient
- Difficulties in determining pregnancy status
- Impact of the use of hybrid imaging

All interviews were recorded using an Olympus DS-50 Digital Voice Recorder. The audiotapes were transcribed using an online transcription service and all data was de-identified during transcription. Transcripts were returned to interviewees for review and editing prior to analysis. After review, each transcript was printed and a paper copy stored for review and analysis. Initial topic coding was performed on each paper transcript and computer coding was conducted on all interview transcripts using QSR NVivo 8.0.

**FINDINGS**

A total of sixteen (16) interviews were conducted from March to October 2010 at eight (8) nuclear medicine departments in Australia. Four (4) departments were within public hospitals and four (4) departments were private practices. All staff NMT had a minimum of 3 years experience working as an Australian and New Zealand Society of Nuclear Medicine (ANZSNM) accredited NMT. Table 1 shows a summary of the demographic information for all departments and participants.

Topic coding identified thirty seven (37) free nodes (topics) which were further categorised into five (5) tree nodes (themes). The themes identified were:

- Policy and awareness of guidelines
Three of these themes were aligned to those used at interview and the additional themes, decisions and assumptions made by NMT and the use of pregnancy testing, were related to the question theme of difficulties in determining pregnancy status. The impact of the use of hybrid imaging was included in the theme of “radiation knowledge”.

Policy and awareness of guidelines
All interviewees were asked if they knew whether their department had a written policy regarding verifying the patients pregnancy status. Only one participant (C6) said their department had a written policy but it was “not that readily available” to the NMT working in the department. Nine participants thought that their procedure protocol documents, radiation safety manuals or consent forms would have information on this.

“If our protocol manual and I think there is also a blurb written with the Radiation Safety Manual as well.” (S1)

“We don’t have a written policy as such however it is written into all of our consent forms.” (C7)

Fifteen out of the sixteen participants (94%) were not aware of any guidelines or policy statements from the ANZSNM, ARPANSA or other professional bodies that dealt specifically with how to verify a patient’s pregnancy status.
Questioning the patient

Australian policy and guidelines referring to the use of ionising radiation in medical imaging state that all women of child-bearing age must be questioned regarding their pregnancy status. However “child-bearing age” does not have a clearly defined age range. Participants were asked what age range of patients they questioned and how they determined which patients would be considered within “child-bearing age”.

There were varied responses from all departments and between the chief and staff NMT of each department. In six out of the 8 departments, the responses from the chief and staff NMT differed. Eight (50%) NMT specified age ranges from 12, 14 or 16 and up to 50-55 years old. Eight participants (50%) stated that an age range was not specified in their department and thus each NMT made the decision on which patients to question.

“I don’t believe we have guidelines for the age. That’s just up to the tech at the time.” (C2)

“Pretty much from 16 to 50, but anything under that, and depending where you work, we have a lower class area around us that - you have your suspicions when a young girl comes through, we usually ask the parent to leave the room, and we will question them under the age of 15, 16, if we feel it’s necessary” (S6)

“There’s a lot of people doing IVF and things these days and having children in their 40s and even into their late 40s sort of thing.” (C6)

Interviewees were asked to describe how they questioned their female patients regarding pregnancy status. Fourteen participants (87.5%) said that they verbally questioned the patient and two participants (12.5%) said they used a written form which the patient completed and signed. Twelve participants said they required the
patient to sign or initial some type of document which indicated they were not pregnant at the time of administration of the radiopharmaceutical. This was stored as part of the patient referral documents. Verbal questioning only was used by four participants, who all worked in private practice. Only four participants routinely asked the patient when their last menstrual period (LMP) was. There was 100% agreement between the answers of the Chief NMT and the staff NMT in all departments. The method of questioning used in each department is displayed in Table 1.

All participants using verbal questioning, with or without signing a document, were doubtful that there was any legal validity to this if challenged in a court of law. Verbal questioning alone left the NMT open to a possible “he said, she said” scenario. According to ARPANSA (7), the “ultimate decision to perform or reject each individual nuclear medicine procedure” (p6) lies with the Nuclear Medicine Specialist (the radiation medical practitioner). The referring doctor also has a responsibility to alert the nuclear medicine specialist if a patient may be pregnant.

The participants in the study felt that when the patient gave their signature or initials, it was more a case of the patient agreeing to document that they had been asked about their pregnancy status rather than declaring that they were not pregnant.

“I guess we think it adds, like I say, more the evidence that we’ve asked the question because if someone says I don’t remember that question or we’ve got at least proof that we did ask it and they must have read - it’s a simple statement. So it’s more that that gives us confidence that we’ve checked. Whether it will help our case further in a legal setting, I think we would have to wait and see.” (C5)
In most instances the patient would be asked “Is there any chance you could be pregnant?” or similar. If the patient responded “No” and was “100% sure” the NMT would usually go ahead with the procedure with no further questioning. Only when the patient seemed unsure or if they said they were trying to conceive, did the NMT consider asking questions concerning their last menstrual period, contraceptive methods or sexual activity.

Several types of patients were identified as potentially problematic. Teenagers were the main group discussed, with most NMT stating it was difficult not only to decide which young girls to question, but also to get a reliable, truthful answer from a girl especially if she was accompanied by her parents. In some departments they attempt to take the girl to a private area without the parent and question them there.

“The difficulties obviously are young females with parents in attendance. If they’re around the age of 13/14 you try to separate them from the parents so you can actually get them to answer truthfully.” (C2)

“If the father is standing right next to you when you’re asking quite a young girl, I find that quite difficult. I also find it difficult because it’s very uncomfortable for the young girl as well because the father’s standing there looking at them going, I’m hoping you’re not sexually active. But I do find that quite difficult.” (S3)

Other potentially difficult patients identified were patients with language barriers, different cultural backgrounds, mentally disabled patients and inpatients on certain medications. In these patients the NMT was not always sure the patient understood the question being asked or the reasons for it.

“The other group I guess would be the ones who come in who don’t speak English, maybe from a different cultural background” (C7)
“I suppose if you’ve got a patient of childbearing age who’s got any sort of mental or -
mental retardation - they’re always difficult to ascertain. Just because they’ve got a
disability, you can’t rule them out from being pregnant.” (C2)

“We have so many inpatients we get a lot of people that are on morphine and all sorts of analgesia and are not aware that they’ve actually signed something, or that we’ve given them something or why we’ve given it to them, even though we have described why.” (S5)

Radiation knowledge

The interviews included direct questions aimed at ascertaining the NMT knowledge of, and attitudes towards, ionising radiation and in particular foetal radiation exposure. The majority of participants (81%) thought that the most radiosensitive time during gestation was in the first trimester and only one participant could narrow that down to a more discreet time frame. When questioned about the possible consequences of foetal irradiation, only one NMT (S8) could give specific information on the biological effects that may occur. Four participants said they did not know the possible consequences and eleven participants gave vague responses.

“I guess it could lead to some sort of congenital defect” (C1)

“Deformities in the foetus and developmental problems and stuff like that.” (S2)

“I guess there would be increased chances of childhood cancers and what not like that, but outside of that I don’t know.” (S7)

The NMT were asked whether they would be concerned if they or their partner were irradiated whilst unknowingly pregnant. Eight participants (50%) said they would be concerned and one of these said they would terminate the pregnancy. The reasons given for their concern were the same as the reasons the other NMT gave for not being concerned. Almost all of them said that their knowledge of radiation was
sufficient to make them believe that either the foetus would be safe, or that possible biological damage could ensue.

“I’d be concerned. It’s the sort of thing that because you sort of work in radiation safety and radiation you’re a bit more sort of switched on about it”. (S1)

“I don’t think I would, and I don’t know whether that meant I’m too blasé about radiation or just informed enough to not be concerned about the risk.” (C6)

Decisions and assumptions made by NMT
There were many comments made suggesting that NMT’s rely on the patient’s word when they say that they are not pregnant. The NMT has a professional responsibility to question the patient regarding their pregnancy status however the patient also has a responsibility to answer truthfully to the best of their knowledge. If a patient confidently answers that they do not think they could be pregnant, most NMT said they would accept that response and proceed with the procedure without any further questioning.

“It’s not a direct written formal questionnaire; it’s purely just based on someone’s word.” (S1)

“As a rule the patient’s word is usually enough and then they sign that form” (C6)

Use of pregnancy testing
Accurate determination of the pregnancy status of female patients prior to diagnostic imaging is vital to avoid any unnecessary foetal irradiation. The routine use of serum pregnancy testing on all female patients would be time consuming, expensive and impractical. This would require sending patients to a pathology service to have blood withdrawn. In a hospital department which provided this service, it could take approximately one hour for a result. This delay would be inconvenient for the patient and disrupt department work flow schedules. Urine pregnancy tests are a quick way
to check if a patient is pregnant or not, however the results may be unreliable if performed prior to the date of missed menses and hence are only appropriate in certain cases (11).

Participants were asked whether they used pregnancy testing, in which circumstances, and which type of tests were used. All except one NMT said they had used pregnancy tests but not routinely. Most used the tests when a patient expressed uncertainty about their pregnancy status. Seven participants said they had only used serum βHCG tests while six only used urine testing kits. One participant could not recall ever using a pregnancy test on a patient. In three departments the chief and staff NMT gave differing answers as to the type of testing they used.

**DISCUSSION**

Nuclear medicine procedures use ionising radiation which has the potential to cause biological effects in a foetus. The various organisations that provide radiation protection information and guidance recommend, but do not regulate, how NMT question women of childbearing age about their pregnancy status. This preliminary study investigating NMT practice regarding pregnancy status has highlighted the need for re-education and an Australian wide consensus approach to questioning female patients.

This study has shown that a variety of methods of questioning is used across Australia and that NMT show a lack of awareness of departmental and national policy. Verbal questioning is still widely used however this is not usually documented
and hence may lead to possible legal complications in the event a patient is irradiated in the early phases of pregnancy.

Although it is recommended to question all women of “childbearing age”, this age range has not been clearly defined. There appears to be no set age limits that NMT adhere to and the lower age limit varies within and between departments. Patients from 12-16 years of age may be questioned depending on the NMT and their assessment of the patient. Women delaying pregnancy until later in life and the increasing number of older women having IVF pregnancies are seen as a reason to ask women up until the age of 55 or 60. However, it may be more prudent to question patients regarding the date of their last menstrual period. In younger patients this would ascertain if they have begun menstruation and in the older patients it would identify women who have completed menopause.

NMT’s identified teenagers as one of the most difficult patient groups to question about their pregnancy status. It requires tact and sensitivity by the NMT to ensure a truthful response to questions about pregnancy, especially if the parents are present. Removing the girl to another area, often under the guise of weighing them, is a common tactic used to allow the question to be asked in private without the parent. NMT’s in this study reported using visual assessment of the patient and their discretion to decide which young girls to question. Teenage pregnancy rates are declining across the industrialised world (12). However both the age at menarche and age of first sexual experience are also reported to be declining (13) making it imperative for NMT’s to ensure that all their younger patients are adequately informed of the risks of radiation and questioned about possible pregnancy.
In Australia, NMT’s are required to complete radiation protection and radiation biology education as part of their training courses (14). This study identified a lack of knowledge of the possible biological effects of foetal irradiation. All participants had completed their training more than two years prior to the study which indicates a need for an emphasis for ongoing education in this area.

Pregnancy testing is not routinely used in Australia to screen for pregnancy prior to diagnostic imaging. Human chorionic gonadotrophin (hCG) is produced after implantation of the conceptus. Detecting hCG levels in early pregnancy is made difficult due to variability in the timing of implantation (6 to 12 days after ovulation) and in the timing of ovulation after the onset of the last menstrual period (11). Urine pregnancy test kits are widely available and relatively cheap. However they have a high rate of false-negative results when used prior to the date of missed menses (15, 16) and hence may fail to identify a pregnant patient if the test is performed too early. Serum hCG tests are able to detect smaller concentrations of hCG than urine tests (17) and therefore are more accurate when used before the date of missed menses. Nuclear medicine practices should carefully assess their use of pregnancy testing and to ensure patients in the early stages of pregnancy are identified prior to commencing a procedure using ionising radiation.

CONCLUSION

There appears to be a wide variation in the approaches NMT use to determining a patient’s pregnancy status in nuclear medicine departments in Australia. Verbal questioning is the most common approach used; with or without the addition of a
patient signature to document their response. The age range for “child-bearing” needs to be clearly defined and NMT should ensure all patients in this range are questioned. A surprising finding of the study was that NMT often visually assess patients and use their discretion when deciding who to question. NMT also place a great deal of reliance on the patient’s word when they say they are not pregnant. The use of pregnancy testing before the date of missed menses should be carefully assessed to determine the most accurate test to detect early pregnancy. This study has identified a lack of a consistent approach by NMT in Australia when questioning women about their pregnancy status prior to diagnostic nuclear medicine procedures. There is a need for re-education and a consensus approach to ensure pregnant women are not irradiated unnecessarily.

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REFERENCES


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