

**Title:** Development of consensus statements for pregnancy screening in diagnostic nuclear medicine: A Delphi study

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## **ABSTRACT**

Current radiation protection recommendations do not provide clear guidelines or advice on pregnancy screening strategies for diagnostic nuclear medicine procedures. Previous studies have reported on variations in current practice for pregnancy screening prior to diagnostic nuclear medicine procedures. The development of consensus statements aims to provide a consistent approach and assist nuclear medicine personnel to confidently question patients about their pregnancy status.

**Method:** The Delphi technique was chosen for the research design. A panel of “experts” was recruited based on their expertise and experience. Panel members were provided with a summary of existing research. Consensus agreement was pre-defined as 80%. Questionnaires were developed and distributed to the panel members with iterative analysis and feedback between survey rounds. The Round 1 questionnaire was developed from the results of a previous survey. It consisted of 30 questions designed to gather the opinions of the expert panel.

**Results:** An expert panel consisting of ten experienced nuclear medicine personnel from Australia and New Zealand was recruited. Three survey rounds were conducted online using SurveyMonkey between December 2013 and June 2014. Following analysis of the Round 1 responses, consensus statements were developed for Round 2 and revised in Round 3. Consensus was achieved for 16 statements. The statements recommend verbal questioning with patient signature, define age range for questioning as 12-55 years, and provide advice on the

use of pregnancy testing and questioning potentially difficult groups, such as teenagers. A flowchart was included for comment in Round 3.

**Conclusion:** This is the first Australian study to develop consensus statements and a flowchart to assist nuclear medicine personnel in consistently and confidently questioning patients about their pregnancy status prior to diagnostic procedures. Implementation of these statements into clinical practice guidelines should reduce the possibility of inadvertent fetal irradiation.

**Keywords:** ionizing radiation, pregnancy, consensus, Delphi

## INTRODUCTION

Determining the pregnancy status of a female patient prior to a diagnostic nuclear medicine (NM) procedure is potentially problematic. Although the risk to a fetus from the ionizing radiation is relatively small, radiation protection documents recommend all women of childbearing age be questioned regarding their pregnancy status prior to any procedure utilizing ionizing radiation to reduce the possibility of foetal irradiation (1,2). James et al (3,4) have previously shown that, in Australia and New Zealand, a variety of approaches are used by nuclear medicine personnel to question patients about their pregnancy status. The studies revealed that an *ad hoc* method of questioning (whether verbal or in writing) is being used. The types of questions asked, the age range questioned, and circumstances for the use of pregnancy testing varied across nuclear medicine departments. These variations in the approach used to identify women in the early stages of pregnancy may contribute to an increased number of cases of fetal irradiation and therefore the development of a consistent approach was recommended.

Consistency in health care practice is important to ensure all individuals are provided with the same standard of quality care (5). Formal consensus research methods are increasingly used to develop statements and guidelines for a range of health practices when evidence in the literature is lacking or conflicting (6). The Delphi technique is an established method for creating consensus statements or guidelines from expert opinion when there is a lack of evidence on a topic (7,8).

The aim of this study is to gather the opinions of an expert panel of nuclear medicine personnel and develop consensus statements regarding the most appropriate methods to use to question female patients about their pregnancy status prior to diagnostic nuclear medicine procedures. The establishment and implementation of consensus statements into practice will ensure a more consistent approach to assist nuclear medicine personnel to confidently and accurately identify women in the early stages of pregnancy.

## **METHOD**

Ethics approval for the study was provided by the University of Newcastle Human Research and Ethics Committee (Approval number 2009-H-0270). All participants signed a written informed consent.

### *Design*

The Delphi technique was chosen to develop consensus statements on how to determine the pregnancy status of patient's prior to diagnostic nuclear medicine. The technique was first described in the 1950's by the RAND Corporation and since the 1970's, it has been widely used in health to develop consensus statements and guidelines (7). The technique utilizes a panel of experts, selected based on their expertise and experience, to explore important aspects of a topic whilst maintaining participant anonymity. The Delphi process involves a series of questionnaire rounds, each followed by iterative analysis and feedback. The process concludes when a pre-defined level of consensus is reached (6). As the Delphi does not require participants to

physically meet, it can be conducted online making it a cost effective method to enable recruitment of participants from diverse geographical locations.

*Expert panel members:*

The participants were nuclear medicine technologists, nuclear medicine physicians and medical physicists in Australia and New Zealand and who had at least 5 years of experience working in nuclear medicine. Potential participants were purposively selected from members of Special Interest Group committees of the Australian and New Zealand Society of Nuclear Medicine; the medical physicist register of the Australasian College of Physical Scientists and Engineers in Medicine; and the nuclear medicine clinical supervisors database from the School of Health Sciences at the University of Newcastle. A low response for participation was anticipated due to the on-going nature of the Delphi method and the time commitment required for the study. Hence, a total of 35 potential participants were invited to participate in the study via email with the aim of achieving a panel of at least 10 experts. A participant information sheet and consent form was attached to the invitation email.

*Survey Rounds:*

Panelists were asked to participate in up to three rounds of web-based questionnaires. All questionnaires were conducted online using SurveyMonkey. To ensure all panel members began the process with an equivalent knowledge base, each member received an email containing published articles summarizing issues surrounding the topic. The email also included a web link to the first round online survey. The questionnaire for Round 1 was

developed from the results of a previous cross-sectional study conducted by the authors (4). The Round 1 questionnaire consisted of 30 questions with both closed and open responses to allow the participants to give their rationale for any answers. The questions covered a range of issues, including demographic information, method of questioning, and use of pregnancy testing. Round 2 and 3 provided panel members with a report on the analysis and feedback from the previous round, including quotes from participant responses and the level of agreement for each question. A series of statements were developed for each round and panel members were asked to agree or disagree with each one. A free text comment box was included after each statement. Consensus was pre-defined as achieving more than an 80% agreement on any statement. Areas of non-consensus were redeveloped according to the feedback and panel members were given the opportunity to revise their responses. Statements achieving consensus were reiterated in the following round and panel members asked to confirm their agreement and comment if needed.

## **RESULTS**

### *Expert panel members*

Ten people agreed to participate in the study: 8 nuclear medicine technologists, 1 medical physicist and 1 nuclear medicine physician. There were seven female participants. Nine participants worked in Australia and one in New Zealand. All participants had at least 5 years of experience working in nuclear medicine. All ten completed Round 1 however only 9 participants completed the Round 2 and 3 surveys. As all ten participants were emailed the

links to Round 2 and 3 and their responses were anonymous, it is not known if the same participant was the non-responder for both rounds.

### *Survey rounds*

Three survey rounds were conducted between December 2013 and June 2014. Following Round 1 the results of the survey, including comments from the panel members, were tabulated and used to develop 12 statements for the Round 2 questionnaire. Ten of these 12 statements achieved consensus agreement in Round 2 (Table 1). Areas of non-consensus in Round 2 included questioning of teenage girls and women with “cultural barriers”, standard questions to ask, and use of pregnancy testing. These areas were further developed into 9 new statements for the Round 3 questionnaire. In Round 3, panel members were also asked to review and comment on the Round 2 consensus statements. The responses and comments from Round 3 resulted in 7 new statements achieving consensus and one statement from Round 2 being revoked (Table 1). Panel members disagreed (62.5%) with asking women about hysterectomy and commented that asking about hysterectomy was not necessary if LMP was asked first, as this would “prompt them to say that they have had a hysterectomy”.

### *Consensus Statements*

All panel members agreed that the development of guidelines for pregnancy screening prior to diagnostic nuclear medicine procedures were needed to provide a consistent approach. Verbal questioning was agreed to be the most appropriate method prior to all diagnostic procedures, regardless of the potential radiation risk to the fetus. However the patient should be required to

provide their signature to document that the procedure and risks had been explained and to verify their pregnancy status. All panel members agreed that standard questions should include date of last menstrual period (LMP). Childbearing age range was defined as 12-55 years.

For patients with cognitive impairment, the caregiver, medical records or medical personnel should be consulted to determine the possibility of pregnancy and whether a pregnancy test is required. An interpreter should be used to question women with language barriers. The term “under normal circumstances” was included in these two statements to allow for flexibility and individual patient situations. Teenagers aged 12-17 years of age should be asked if they have started menstruation first and if yes, questioned regarding pregnancy. Therefore, if possible, and under normal circumstances, teenagers should be questioned away from accompanying parents or other adults. The term “culturally and linguistically diverse” should be used to describe women from different religious, spiritual, racial or ethnic backgrounds and where possible, under normal circumstances, they should be questioned by female personnel.

All panel members agreed that pregnancy testing should be used whenever there is any uncertainty regarding the patient’s pregnancy status and that if available in a reasonable time, serum human chorionic gonadotropin (HCG) test should be used. If urine HCG testing is used prior to the date of missed menses and the result is negative, the procedure should be postponed until menstruation begins. Retesting with serum HCG test was also provided as an option however this statement only achieved 75% agreement.

*Flowchart*

In Round 3, panel members were provided with a flowchart that could be used by nuclear medicine personnel to assist in questioning women regarding their pregnancy status. The panel members commented that the flowchart would be “helpful” and was “a great idea” to support any guidelines and use as a “quick reference guide”. The flowchart questions initially separated women into three age groups 12-17, 18-49, and 50-55 however; the 2 older age groups were combined in the final version. Questions in the initial flowchart included: whether menstruation had started (12-17 years only), hysterectomy, LMP, if sexually active, and if they thought there was any chance they might be pregnant. Panel members made comments and suggested changes for the flowchart. The question about hysterectomy was considered unnecessary as the information is usually provided when asking LMP. Therefore, the first question for 18-55 years was changed to LMP. Questions regarding sexual activity were also considered unnecessary and removed. The flowchart was revised to reflect this feedback (Figure 1).

## **DISCUSSION**

National and international radiation protection guidelines recognize the increased radiosensitivity of fetal tissue (1,2,9,10). They recommend that all female patients of childbearing age be questioned regarding their pregnancy status prior to any procedure using ionizing radiation to avoid fetal irradiation. However, the radiation protection guidelines do not provide clear instructions on how to question the patient or which patients to question. The age range for questioning has not previously been defined and there is no advice for questioning potentially difficult patient groups, such as teenagers. This study has developed 16 consensus

statements to assist nuclear medicine personnel in Australia and New Zealand in confidently questioning patients and how to accurately assess pregnancy status.

### *Age range*

The consensus statements developed in this study define the age range for questioning as 12-55 years. There are a very small number of cases of females under the age of 12 years or over 55 years becoming pregnant. Australian birth statistics for 2012 show the total number of births at 309,582, with 405 (0.13%) from mothers aged 15 and under, and only 45 (0.01%) from mothers 50 years and over (Table 2) (11). These numbers only include the number of live births and do not include the number of miscarriages or induced abortions. Medicare Australia statistics for Item number 35643 *Evacuation of the contents of the gravid uterus by curettage or suction curettage* show that in 2012 there were over 61500 terminations performed in Australia, with 7145 of these performed in women aged 19 years or less and 15020 in women 35 years or more. The actual number of induced abortions performed is difficult to calculate because Medicare data does not include information on patients admitted to hospital and because it is estimated that approximately 15% of private patients do not claim a Medicare benefit (12). These factors, and the aggregation of data for ages 15 and under, make it difficult to calculate the number of pregnancies in very young teenage girls. However, assuming a worst case scenario where all of the 7145 terminations in the 19 years or less age group were conducted on teenagers under the age of 15, the estimated number of pregnancies in under 15 year olds accounts for less than 2.5% of all pregnancies.

### *Potentially difficult patient groups*

Certain groups of patients, such as teenagers, women with cognitive impairment, or language or cultural barriers, have been identified as potentially problematic to question about their pregnancy status (4). When teenage girls are accompanied by an adult relative, they may be reluctant to provide truthful answers to questions about pregnancy for fear of embarrassment or recrimination (13). Removing the girl to another area under the guise of weighing her provides an opportunity to ask the relevant questions in privacy. This strategy may raise issues about the legality of questioning a minor without a parent or guardian present. The age of consent for medical procedures and treatment varies depending on the country and state. However, in Australia, if the girl is deemed *Gillick* competent, she is entitled to the same confidentiality for medical information as an adult. A *Gillick competent* or *Mature Minor* child is deemed to be old enough, or mature enough, to make their own decisions and understand the issues and consequences regarding medical treatment. (4,13,14).

In Round 2 of the Delphi study, participants commented on the use of the term "cultural barriers" as being "too non-specific". The Multicultural Health curriculum statement within the *Royal Australian College of General Practitioners Curriculum for Australian Practice 2011* (15) uses the term, "culturally and linguistically diverse", to define groups and individuals that differ according to religion and spirituality, racial backgrounds and ethnicity as well as language. They suggest the term "culturally and linguistically diverse background" can be used to reflect intergenerational and contextual issues, not only migrant experience. This term was agreed upon to replace "cultural barriers" by 8 out of the 9 participants in Round 3 of the Delphi study.

*Pregnancy testing*

In the early stages of pregnancy, especially prior to the date of missed menses, a serum HCG pregnancy test is the most accurate method to determine if a female is pregnant. Although the minimum detection limits for urine HCG pregnancy tests have decreased over the past 20 years to 10-20 IU/L, their performance in the lower range of HCG concentration is poor and false-negative results are common when used prior to the date of missed menses (16-18). This may be due to user error, urine sample dilution, variations in menstrual cycle duration and calculation of the date of missed menses, and variations in the timing of implantation and therefore the concentration of HCG in urine (16-18)

A systematic review published in 2013 reported on the accuracy of pregnancy checklists to rule out pregnancy (19). The checklists were based on criteria defined by the World Health Organisation (WHO) Selected Practice Recommendations for Contraceptive Use (20,21). The review reported on three studies of diagnostic accuracy assessing the validity of a pregnancy checklist when compared to a urine pregnancy test representing 2650 women. The review revealed a consistent 99-100% negative predictive value across the included studies which mean that the checklists were able to confidently rule out pregnancy in women who are not pregnant. A number of other studies have reported on the ability of women to self-assess their pregnancy status (22,23). These studies also report excellent negative predictive value (99% & 100%) for questioning a woman if she "might be" pregnant.

Performing serum pregnancy tests on all females prior to diagnostic nuclear medicine procedures would be costly, time consuming, and unnecessary. The consensus guidelines and associated flowchart provide a simple, consistent process for pregnancy screening which should

identify the majority of pregnancies and limit the number of pregnancy tests required. The current study demonstrates ongoing support for the development of consensus guidelines and reinforces the results from previous studies by the authors (3,4,24).

## **CONCLUSION**

The consensus statements and flowchart developed in this study cover a range of issues which have not previously been discussed in radiation protection documentation for diagnostic nuclear medicine procedures. They provide a clear and consistent approach for nuclear medicine personnel to follow when questioning patients about their pregnancy status. The statements recommend the use of verbal questioning with documentation via the patient signature, define the age range to question, provide strategies for teenagers and other potentially difficult groups, and provide advice regarding the use of pregnancy testing.

In future research the results from this study will be used as a framework for the creation of “best practice” guidelines for pregnancy screening prior to diagnostic nuclear medicine procedures. Implementation of the guidelines into clinical practice will provide advice and a consistent approach for questioning patients which will assist nuclear medicine personnel to confidently and accurately determine pregnancy status and reduce the possibility of inadvertent fetal irradiation.

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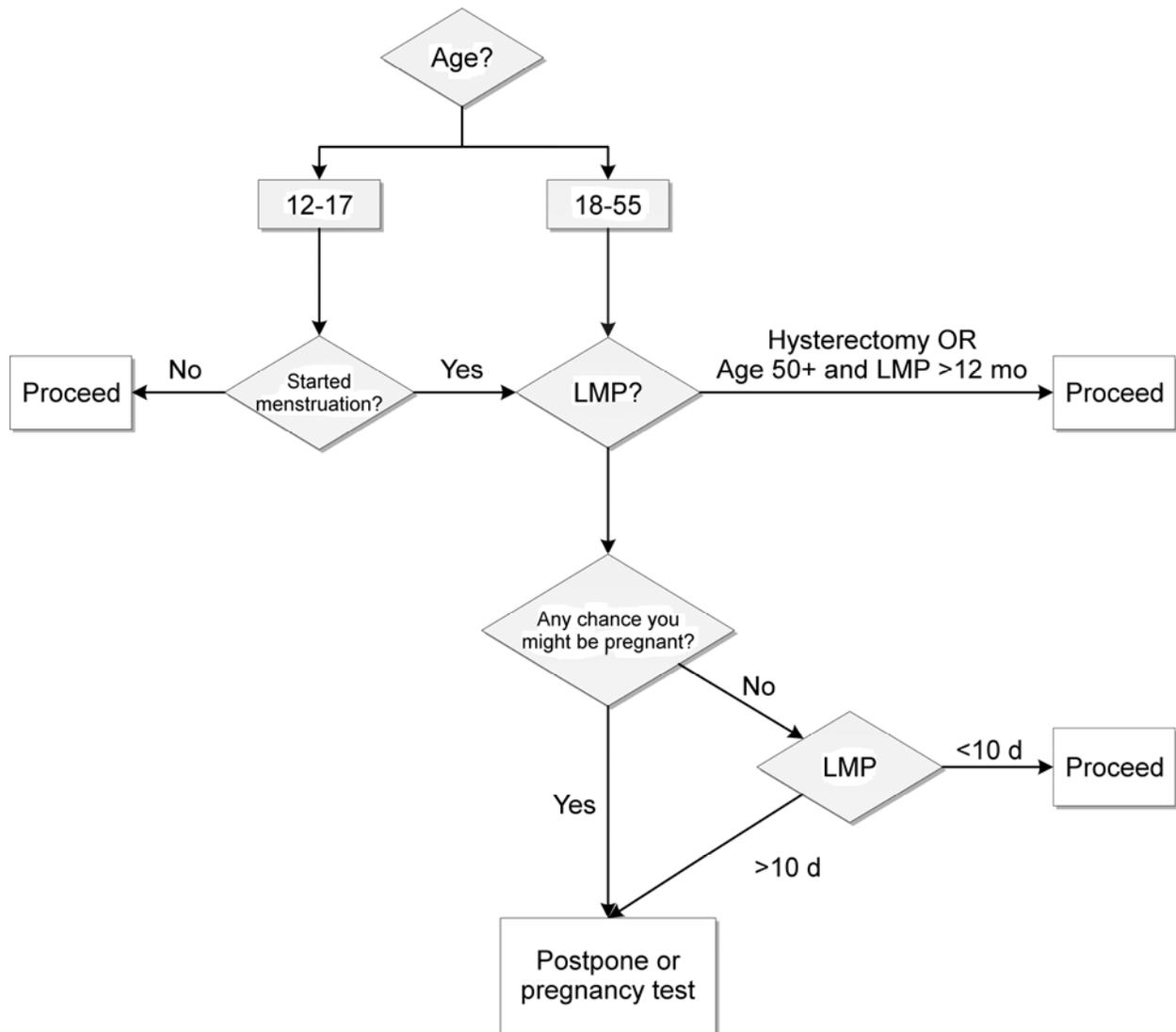


Figure 1: Final Flowchart

## TABLES

Table 1: Final consensus statements from Round 2 and 3

Round	Consensus Statements
Two	Guidelines offering advice for pregnancy screening prior to DIAGNOSTIC nuclear medicine procedures would provide a more consistent approach.
	The procedure and any potential risks associated with it should be explained and female patients should be VERBALLY questioned regarding their pregnancy status AND required to provide their SIGNATURE to indicate the procedure and any radiation risks have been explained and indicate their pregnancy status.
	Childbearing age should be defined as 12-55 years for the purposes of questioning patients about their pregnancy status prior to diagnostic nuclear medicine procedures.
	Women up to 55 years of age should be questioned about their pregnancy status using the standard approach.
	Under normal circumstances, consultation with a carer, medical records or medical personnel should be initiated to determine the possibility of pregnancy for women with a cognitive impairment and to help decide if a pregnancy test is required.
	Under normal circumstances, an interpreter should be used to question women with a language barrier about their pregnancy status.
	Standard questions should include last menstrual period (LMP).
	<i>Standard questions should include both LMP and hysterectomy.</i> Revoked in Round 3
	Pregnancy testing should be used prior to diagnostic nuclear medicine procedures whenever there is uncertainty as to the patient's pregnancy status.
	Standard verbal questioning with patient signature is required to verify pregnancy status for all diagnostic nuclear medicine procedures regardless of the potential level of radiation risk to the foetus.
Three	If possible, when a teenage girl is accompanied by a parent or other adult, they should be taken to another room, without the parent, to be weighed for radiopharmaceutical dose calculation and questioned then.
	Teenage girls from age 12 to 17 years should be asked if they have begun menstruating and if yes, then questioned regarding pregnancy status.
	For girls aged 12-17 years: 1. Ask if they have begun menstruating. If no, proceed with examination. 2. If yes, continue with standard questioning
	The term "culturally and linguistically diverse" can be used to describe women who differ according to religion and spirituality, racial backgrounds and ethnicity as well as language.
	Whenever possible, a female staff member should question women from culturally and linguistically diverse backgrounds about their pregnancy status.
	If available in a reasonable time, serum pregnancy testing should be used in preference to urine pregnancy testing.
	If urine pregnancy testing is used PRIOR to the date of missed menses and the result is NEGATIVE, postpone the examination until menstruation begins

Table 2: Births and age of mother - Australia 2012 (11)

<b>Age of mother (years)</b>	<b>Number of births</b>
15 and under	405
16	887
17	2037
18	3255
20	6123
25	12685
30	21696
35	15545
40	5164
45	328
50 and over	45
<b>Total Births</b>	<b>309852</b>