

Radiology - Imaging Pregnant Patients Procedure

1. Guiding Principles

The aim of this document is to provide all medical imaging staff employed by the WA Country Health Service (WACHS) with a consistent procedure when conducting a diagnostic imaging radiology procedure on a patient who is pregnant or possibly pregnant.

This procedure is not specific to Aboriginal¹ patients.

2. Procedure

This document does not refer to nuclear medicine procedures.

Imaging is only to be performed when clinically indicated.

For any x-ray procedures that may result in a fetal dose of 1 mSv or higher, a reasonable attempt to establish the pregnancy status of female patients aged 16 to 50 **must** occur immediately before the commencement of the procedure.

It is good practice to ask all women aged 16 to 50, or even outside this age range if considered appropriate by the Imaging Specialist or clinician, if there is any possibility of pregnancy, and the date of their last menstrual period (LMP).

Unless an institution can provide supporting documentation (which must be approved by a credentialed radiology medical physicist), it is to be assumed that the following procedures may result in a fetal dose of 1 mSv or higher:

- Conventional radiographic / fluoroscopic examinations of the abdomen and/or pelvis, or
- CT examinations of the chest and/or abdomen and/or pelvis, or
- Interventional fluoroscopy procedures.

For female patients aged 16 to 50 years, a reasonable attempt to establish pregnancy status must be made prior to the administration of iodine or gadolinium contrast agent.

In situations where pregnancy has not been ruled out, high risk gadolinium-based contrast agents are contraindicated. Iodine-based and low and medium risk gadolinium-based contrast agents are to be restricted to urgent indications following consultation with a radiologist. Information on gadolinium risk can be found on the Diagnostic Imaging Pathways website: <u>Gadolinium contrast for MRI scans</u>.

Checks of pregnancy status are to be recorded in the patient's notes (if available), Radiology Information System (RIS) and imaging request form.

¹ Within Western Australia, the term Aboriginal is used in preference to Aboriginal and Torres Strait Islander, in recognition that Aboriginal people are the original inhabitants of Western Australia. No disrespect is intended to our Torres Strait Islander colleagues and community.

The patient is to be asked in a private and discrete manner; "Is there any possibility you may be pregnant?" Verbal or written assurance by the patient is to be considered sufficient.

If doubt exists regarding the pregnancy status, a blood (serum β -HCG) or urine test should be considered.

Women who are deemed not to be pregnant, and whose last menstrual period was within the past 28 days, may be examined applying appropriate radiation safety precautions.

Women whose last menstrual period was more than 28 days prior, should be considered to be possibly pregnant, unless they fall into one of the following categories:

- Previous tubal ligation or hysterectomy
- Negative pregnancy test during current hospital presentation.

If a patient is conscious and their pregnancy status cannot be confirmed, they may be referred back to the referring clinician.

In the event of an unconscious patient, responsibility for imaging lies with the referring doctor or radiologist.

If a pregnancy test is conducted, the results of the test are to be recorded in the patient's notes, RIS and imaging request form.

It is expected of the imaging specialist to ensure that the ALARA (As Low As Reasonably Achievable) principle is adhered to, and that the minimum exposure settings and minimum number of views are utilised to maintain a low procedural dose while still providing the necessary diagnostic information.

2.1 Procedure if pregnant or possibly pregnant

The decision concerning the degree of urgency of the examination is the responsibility of the requesting doctor.

Where possible, all patients who may be or are pregnant are to be provided with a copy of <u>Inside Radiology – Radiation Risk of Medical Imaging During Pregnancy</u> prior to their exam.

Where possible, all patients who may be or are pregnant should be provided with a copy of <u>Inside Radiology – Gadolinium Contrast Medium (MRI Contrast agents</u>) prior to an exam requiring gadolinium.

A radiologist **must** be consulted prior to all lower abdomen exams being performed on pregnant patients. For all other procedures, lead protection must be used to cover the abdomen and pelvis. In the event that WACHS Medical Imaging Technologists (MIT) do not have access to a radiologist, this is to be documented and options discussed with the referring clinician.

2.2 Non-Urgent

If the examination is non-urgent, for procedures with fetal dose well below 1 mSv (as indicated by ARPANSA, 2008 <u>Safety Guide: Radiation Protection in Diagnostic</u> and Interventional Radiology, Radiation Protection Series Publication No. 14.1), the patient is to be informed the risk of harm to the fetus is negligible. Informed consent can be obtained verbally or in writing, and noted on RIS.

For procedures with fetal dose \geq 1 mSv, informed consent must be in writing (i.e. patient signature obtained). Prior to the procedure, an estimate must be made and recorded of the fetal dose (should be performed by a medical physicist) and the risks explained to the patient and referrer.

2.3 Medical Emergency / Urgent

If the examination is considered a medical emergency or urgent, and it would normally require a pregnancy check but it is not practical to do so, it may only proceed following consultation with a clinician. Consultation should be with a radiologist, but if this is not possible, it must be with a member of the treating (referring) medical team. A written record of the consultation must be noted on the referral form.

If the situation is immediately life-threatening, the consultation requirement may be waived.

The MIT is to plan the examination using the minimum number of exposures possible applying appropriate radiation safety precautions. After normal working hours, the on-call radiologist must be contacted.

Alternative imaging modalities not requiring the use of ionising radiation (e.g. ultrasound or MRI) should be considered first. If no alternative imaging modalities are applicable to the clinical circumstance, the radiologist and MIT are to plan the examination in order to minimise the degree of radiation exposure.

Note: When an examination proceeds, a complete record of the number of exposures, image sizes and factors used for each exposure, must be retained to allow for subsequent fetal dose assessment.

For further information on Imaging and pregnant patients please refer to:

- Government of Western Australia Radiological Council
- The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

2.4 Justification of Key Points

For any x-ray procedures that may result in a fetal dose of 1 mSv or higher, a reasonable attempt to establish the pregnancy status of female patients aged 16 to 50 must occur immediately before the commencement of the procedure.

The fetal dose limit of 1 mSv is consistent with the requirements of the ARPANSA Code of Practice RPS 14 (ARPANSA 2008a). The age range 16 to 50 was felt to be reasonable given that the majority of births occur in this range (the most recent Australian data available indicate that in 2013, 99.9% of births in Australia occurred in the 16 to 50 range (ABS 2014)).

There is no specific age range that can be clearly defined as "of child bearing capacity". However, advice from the National Association of Testing Authorities (NATA) regarding accreditation requirements (pers. comm. D. Hobday 21/5/2014) is that it is preferable to specify an age limit rather than stating "of child bearing capacity" and leaving the judgement to the MIT.

Unless an institution can provide supporting documentation (which must be approved by a credentialed radiology medical physicist) it is to be assumed that the following procedures may result in a fetal dose of 1 mSv or higher:

- Conventional radiographic / fluoroscopic examinations of the abdomen and/or pelvis, or
- CT examinations of the chest and/or abdomen and/or pelvis, or
- Interventional fluoroscopy procedures.

It is known that these procedures are likely to result in an embryo or fetal dose of greater than (or equal to) 1 mSv (or 1 mGy) (ARPANSA 2008b, Dauer et al. 2012). Note that in this context, 1 mSv and 1 mGy are equivalent.

The main risks to the conceptus from ionising radiation depend on its stage of development and the radiation dose. Immediately post-conception, when the number of cells is small, the most likely effect is death or failure to implant. The main risks to a developing embryo or fetus are increased risk of cancer, and tissue reactions such as organ malformation and retardation (ICRP 2000).

Aside from cancer, the dose necessary to produce these effects is widely accepted to be at least 100 mGy (ICRP 2000, ICRP 2007), and hence doses of 1 mGy or below present negligible risk. With respect to cancer, an embryo or fetal dose of 1 mGy has an associated risk of childhood cancer of below 1 in 10 000 which is considered acceptable compared to the natural risk (approximately 1 in 500) (Wall et al. 2009). Therefore, any x-ray procedure delivering an embryo or fetal doses of 1 mGy or less could be considered effectively safe.

For procedures delivering less than 1 mGy; it is common practice to perform such procedures regardless of the patient's pregnancy status (ACR 2013, RANZCR 2005, Wall et al. 2009). Given that information on pregnancy status will not affect decisions regarding imaging the patient, there is no need to obtain it. This is consistent with the relevant ARPANSA Code of Practice (ARPANSA 2008a) which states:

"3.1.3 The Responsible Person must have protocols in place to ensure that no radiation procedure is carried out unless:

- (c) where a medical procedure may result in a radiation dose of more than 1 mSv to an embryo or fetus, the radiation medical practitioner has taken reasonable steps to determine the pregnancy status of the patient "
- (page 5)

Standard 2.2 of Diagnostic Imaging Accreditation Scheme (DIAS) (DoHA 2010) states:

- "(c) Practice staff obtain and record relevant information about the patient's health status and individual patient risk factors; and
- (d) consent for the diagnostic imaging procedure" (page 24)

In this context, pregnancy would not be regarded as relevant information because it does not affect decision making with respect to diagnostic imaging.

European Commission guidelines (DGENSCP 1998) state:

"(28) The recommendations in paragraphs §28-48 are intended to be applied for treatment or examination that might cause a considerable dose (above 10 mSv) to the unborn child.

Therefore, they are not to be applied for low dose examinations, i.e. below 1 mSv, equivalent dose to the unborn child. This includes X-ray examinations where the uterus is not in the primary beam.

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(29) Having regard to the exceptions in paragraph 28, the presence of pregnancy should be evaluated when an examination or treatment involving ionising radiation is considered." (Page 12)

The clause "unless an institution can provide documentation (which must be approved by a credentialed radiology medical physicist) it is to be assumed that the following procedures may result in a fetal dose of 1 mSv or higher" is included because some institutions may utilise relatively low dose procedures and deliver fetal doses well below 1 mSv If it can be verified that this is the case, then it seems reasonable to exempt them from the mandatory requirement to ascertain pregnancy status for such procedures. Requiring verification from a credentialed radiology medical physicist ensures that the dose estimate has been performed by an expert in the area (ACPSEM 2013).

Ascertaining of pregnancy status immediately before the commencement of the procedure:

"Immediately" is consistent with the ARPANSA Code of Practice (ARPANSA 2008a), and the necessity of obtaining pregnancy information that is current is regarded as self-evident.

Verbal or written assurance by the patient is to be considered sufficient. If doubt exists regarding the pregnancy status, a blood (serum β -HCG) or urine test should be considered.

This is consistent with the ARPANSA Safety Guide (ARPANSA 2008b) which states

"When asking the patient about the possibility of pregnancy it is also important to indicate to the patient why there is a need to know, to avoid them taking offence and refusing to answer or answering less than truthfully. When language barriers exist, it may be useful to seek the service of an appropriate interpreter.

The Radiation Medical Practitioner should consider the amenorrhea occurring in a patient, who usually has regular periods, is due to pregnancy unless proved otherwise. In any event, when doubt exists about the pregnancy status of an individual woman and moderate or high doses to the lower abdomen are involved, the Radiation Medical Practitioner should consider serum β -HCG testing before medical exposure." (Page 22)

It is also consistent with the European Commission policy (DGENSCP1998):

"The patient should be explicitly asked, orally or in writing, whether she might be pregnant or may have missed a period." (Page 12)

The use of iodine- and low or medium risk gadolinium-based contrast agents should not be used for female patients aged 16 to 50 unless it is clinically indicated or the pregnancy status has been established and the patient is not pregnant. High-risk gadolinium-based contrast agents are contraindicated in pregnancy.

This is consistent with current guidelines e.g. Diagnostic Imaging Pathways (WA Gov't 2015a,b), RANZCR (RANZCR 2009, 2013) and European Society of Urogenital Radiology (ESUR 2012). Note that the ESUR guidelines are referenced by both Diagnostic Imaging Pathways and RANZCR.

For non-urgent exams which may result in a fetal dose of at least 1 mSv, before the procedure is performed, the risks must be fully explained to:

- the referrer; and
- the pregnant patient

before the procedure is approved, an estimate of the expected radiation dose to the embryo or fetus must be made and recorded. This should be performed by a medical physicist.

This is closely based on Schedule B of the ARPANSA Code of Practice (ARPANSA 2008a). The only addition is the reference to a Medical Physicist. It is felt that since this is a medical physicist's area of expertise, ideally it would be a physicist performing the dose calculation. The word "should" has been used to acknowledge the fact that sometimes it will not be possible to have a physicist perform the calculation e.g. in an out-of-hours emergency.

Table 1 - Approximate Fetal Effective Doses

Approximate fetal effective doses (mSv) arising from common radiological examinations of pregnant patients [†]			
Examination	1st trimester	3rd trimester	
Conventional Radiography*			
Skull	<0.01	<0.01	
Chest	<0.01	<0.01	
Cervical spine	<0.01	<0.01	
Thoracic spine	<0.01	<0.01	
Lumbar spine	2	6	
Abdomen	1.5	2.5	
Pelvis	1	2	
Intravenous pyelogram (IVP)	2	10	
Extremities	<0.01	<0.01	
Mammography	<0.01	<0.01	
Barium meal	1	6	
Barium enema	7	25	
CT**			
Head	<0.005	<0.005	
Neck	<0.005	<0.01	
Chest without portal phase	0.1	0.6	
Chest with portal phase	1	7	
Chest (pulmonary embolism)	0.1	0.4	
Chest/abdomen/pelvis	12	13	
Abdomen/pelvis – single phase	12	12	
Abdomen/pelvis – multi phase	15	30	
Thoracic spine	0.2	1.0	
Lumbar spine	10	25	
Pelvimetry	-	0.2	

* Based on data from Sharp et al. and simulations using PCXMC code.

** Estimates for CT examinations are obtained using the ImPACT dose calculator and typical technique factors.

† Table reproduced from Annex A of 'Safety Guide: Radiation Protection in Diagnostic and Interventional Radiology', Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Radiation Protection Series 14.1 (2008). Note that all doses should be treated as indicative only as individual doses can differ from the tabulated values by as much as a factor of 10, except for those examinations remote from the lower abdomen.

3. Definitions

Credentialed Radiology Medical Physicist	A person who has satisfied the requirements for registration as a Qualified Medical Physics Specialist in Radiology Physics by the ACPSEM. The ACPSEM Register of Medical Physics Specialists can be found on the <u>ACPSEM website</u> .
Imaging Specialist	MIT or clinician who is in control of a fluoroscopic or radiographic procedure and meets the requirements specified in the relevant conditions of registration or licensing as per the Radiation Safety (General) Regulations 1983. For further information please refer to the conditions in your Registration of Premises.
Practice staff	In the context of Standard 2.2 of DIAS (DoHA 2010) this refers to the staff that are normally responsible for obtaining patient information. This may vary between sites but could include MITs, nursing staff, radiologists, booking and clerical clerks.
Radiation Medical practitioner	The practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to ionising radiation. In nuclear medicine, this person will normally be a nuclear medicine specialist, in radiation oncology, this person will normally be a radiation oncologist and in diagnostic or interventional radiology, this person will usually be a radiologist, but might also be, for example, a cardiologist or, for limited procedures, a general practitioner.
Responsible Person	 In relation to any radioactive source, radiation-producing equipment, prescribed radiation facility or premises on which radioactive sources are stored or used, this is the person: (a) having overall management responsibility including responsibility for the security and maintenance of the source, radiation-producing equipment, facility or premises (b) having overall control over who may use the source, radiation-producing equipment, facility or premises (c) in whose name the source, radiation-producing equipment, facility or premises would be registered if this is required. In Western Australia this is the Registrant.

4. Roles and Responsibilities

As described above.

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

5. Compliance

This procedure is a mandatory requirement under the <u>Radiation Safety (General)</u> <u>Regulations 1983</u>.

Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the <u>Employment Policy Framework</u> issued pursuant to section 26 of the <u>Health Services Act 2016</u> (HSA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Evaluation

Evaluation and review of this procedure will occur periodically or as deemed necessary due to changes in standards of practice.

7. Standards

National Safety and Quality Health Care Standards – 1.7.1, 1.8.1 EQuIPNational Standards – 11.4.1, 11.5.1, 15.14.1

8. Legislation

Radiation Safety Act 1975 Radiation Safety (General) Regulations 1983

9. References

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Health Protection Agency, The Royal College of Radiologists and the College of Radiographers.

WA Department of Health, <u>The Correct Patient</u>, <u>Correct Site and Correct Procedure</u> Policy and Guidelines for WA Health Services (2nd Edition)

10. Related Policy Documents

WACHS Medical Imaging – Radiation Safety Plan WACHS Imaging Clinical Practice Standard

11. Related WA Health System Policies

The Correct Patient, Correct Site and Correct Procedure Policy and Guidelines for WA Health Services (2nd Edition)

12. WA Health Policy Framework

Clinical Governance, Safety and Quality Policy Framework

13. Appendix

Appendix 1 - Radiology Procedure for Imaging Pregnant Patients Flowchart

This document can be made available in alternative formats on request for a person with a disability

Contact:	Area Chief Medical Imaging Technologist (M.	Melville)	
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Appendix 1 - Radiology Procedure for Imaging Pregnant Patients

