Determination of Pregnancy Status Policy

Introduction

Radiation Safety Regulations (IR(ME)R 2017) requires that the Trust identifies individuals of childbearing potential, to prevent any unintentional exposure of a foetus to the harmful effects of diagnostic/therapeutic ionising radiation.

Any possibility that these patients could be pregnant must be established before a specified examination takes place.

Purpose

This document satisfies the requirements under Schedule 2(c) of IR(ME)R 2017 and describes the policy and procedure used in this Trust to establish whether individuals of childbearing potential may be pregnant or breast feeding.

Procedures

The Trust identifies (using Trust obstetric statistics to establish the local demography) that enquiries need to be made of individuals who have childbearing potential, between the ages of 12-55. Patients described in **Appendix A** may be excluded.

Examinations where pregnancy enquiries are relevant include those where the primary beam is between the diaphragm and the knees, Dexa scans and all radionuclide imaging.

The patient must be asked if there is any chance that they could be pregnant. In the case of radionuclide administrations, it should also be established if the patient is breastfeeding.

This task is the responsibility of the operator undertaking the exposures (Regulation 11.1(f). The patient should have access to an information sheet to read which informs them of the potential effects of having the examination whilst pregnant, when they are asked to complete the pregnancy form **(Appendix E)**. If more than one operator is involved in the procedure, it should not be assumed that pregnancy status has been checked by someone else, and should always be confirmed that checks have been completed.

If the answer to whether they are pregnant is 'No', the radiological examination can be performed.

If the answer is **anything other than a firm 'no'**, the radiographer must check the date of the last menstrual period (LMP). Close attention should be paid to Questions 5-8 on the form. When the period is overdue and the patient cannot be certain that they are not pregnant, consideration should be given to postponing the examination or finding an alternative imaging modality. This will usually require consultation with the responsible radiologist who in turn may need to have a discussion with the referring clinician.

Depending on the nature and urgency of the examination, a pregnancy test could be offered. This could also be considered when an individual has irregular periods. However, there is a larger margin for false negative results in the first couple of weeks after conception compared to later, so this cannot be relied on for accuracy. Pregnancy tests are kept in the screening department. Instructions on the packet should be followed and the results documented on CRIS.

If the IR(ME)R practitioner (in the first instance) or the referrer (if out of hours) agrees to the examination proceeding, the patient should **sign a Trust Consent Form 1** – 'Patient agreement to investigation or treatment' form. The referrer should also sign the form, taking full responsibility for the examination. (Consent forms are **not** required for Chest X-rays.)

If the examination cannot be delayed, i.e. in the case of

- Trauma/emergency surgery
- Medical emergency
- ?Pulmonary embolus
- Where any delay would be detrimental to the patient's health

then the potential foetal dose shall be kept to the minimum consistent with the clinical requirements. An estimation of the radiation risk to the foetus shall be determined by a Trust Medical Physics Expert. This can be done retrospectively and recorded in the patient's notes.

For Nuclear Medicine procedures the patient should also be asked if they are breast feeding. Patients should be advised not to breast feed for 24 hours after the injection. It should be suggested that milk is expressed prior to the injection.

High Dose Procedures

All examinations with a foetal dose of over 10mGy fall into this category. They include CT of the abdomen and pelvis areas, and interventional examinations of the pelvis for example, proctograms and hysterosalpingograms. ('Salps' do not result in doses over 10mGy, however they are classed as High due to the nature of the examination). These examinations should take place within the first 10 days of the patient's cycle and the patient is responsible for changing the appointment so that the examination can be performed within those 10 days. **Appendix B** will be included with the patient's appointment letter for this group of patients. .

If the patient attends outside of this time frame a discussion should be had with the IR(ME)R practitioner and if they can exclude the possibility of pregnancy they can authorise the examination. If pregnancy cannot be excluded, the examination should not be performed and should be rebooked within 10 days of the start of the next period.

Consenting of patients

The responsibility of consenting the patient (or consenting on behalf of the patient) lies with the referrer. In cases of confirmed pregnancy, the justification should be reviewed by the IR(ME)R practitioner. If still justified the referrer is responsible for the completion of Trust consent form 1.

In the **event of theatre cases**, "Routine preoperative tests for elective surgery" (NICE Guideline NG45, paragraph 1:3) recommends *establishing pregnancy status, providing information relating to risk, documenting conversations and carrying out a pregnancy test, with consent, if there is any doubt*. This should be completed before the patient is anaesthetised or sedated. **The Operator** (usually a radiographer) **should ensure that pregnancy status has been established before x-raying.** (The Operator should be able to find this information by asking the anaesthetist, or filed at the back of the patients' notes, at the bottom of page 2, Section A of the Elective Surgical Patient Pathway form.)

Individuals lacking Capacity or with Communication Difficulties

If at the time of asking the patient is unable to process the information being put to them, due to impairment of, or disturbance in the functioning of the mind or brain, then the Referring Clinician should be consulted, so as to establish the best way forward in the interests of the patient. This should be done in conjunction with the patient's primary carers. If pregnancy status cannot be established and in the unlikely event of there being no Practitioner to discuss the case with, then the Radiographer may go ahead with the examination, keeping to ALARA principles.

Patients with sensory impairment, for example deaf individuals, do not necessarily lack capacity, but may need an interpreter to establish a definite answer. The operator should document their actions taken to determine pregnancy status on CRIS, in the clinical details section. In the case of an individual with language difficulties, an interpreter is required. No procedure should go ahead until the pregnancy status is established. Steps taken should be documented on CRIS in the clinical details section.

In the case of an unconscious patient (this would normally be in an emergency situation) the referring clinicians and the IR(ME)R practitioners should work together in the patient's best interest, and all decisions documented in the patient's notes and on CRIS in the clinical details section.

Consulting Patients under 16 years of age

All questions should be made discretely, if possible without the parent present.

Children under 13 are legally unable to give consent to sexual activity and therefore, if the possibility of pregnancy is reported, follow local safeguarding procedures. The named nurse for Children's safeguarding can be reached on Ext 2272, email **sft.namedprof@nhs.net**

Trans male or gender-nonconforming individuals

The policy of the Trust is to try to make it as easy as possible for trans and intersex patients to let the operator know if there is a possibility of pregnancy. It is therefore essential to provide adequate and welcoming information e.g. in the form of posters in waiting rooms, and information in appointment letters, to allow every individual the opportunity to ask questions and to declare any possibility of pregnancy. If a patient feels unable to disclose their status, the possibility of a 'never event' is greater. Where the operator is aware that the patient's gender expression differs from their biological sex, they can sensitively ask the patient to fill in the pregnancy form which should then be scanned on to CRIS.

Where a referrer, practitioner or operator is unaware of the possibility of pregnancy due to the individual being unidentified/undeclared as a trans male, or where the individual has not consented to the sharing of their gender identity or their childbearing potential, **the individual to be exposed to radiation has the sole responsibility for safeguarding the foetus**. The referrer may not be able to provide information on pregnancy status when there is a need to protect the confidentiality of a person's transitional status. (The Gender Recognition Act 2004 prohibits disclosure without consent).

If an unintended foetal exposure occurs

This may require notification to the relevant enforcing authority in accordance with published guidance. IR(ME)R 2017 guidance 'Significant accidental and unintended exposures; Guidance for Employers and Duty Holders' says that an unintended foetal exposure where there has been **no** procedural failure does not require notification (p8). However, these may be notifiable as a clinically significant event. The Royal College of Radiologists have published guidance on what constitutes a 'clinically significant event'. A Datix must be completed if an unintended foetal exposure occurs.

APPENDIX A: Exceptions

It can be considered an irrelevant question if a patient is **known** to have had a hysterectomy or bilateral oophorectomy, is post-menopausal, has a known pre-existing medical condition which prohibits conception, or is undergoing treatment resulting in infertility or arrested ovulation.

N.B. If a biological female is transitioning to live as a male, it may still be possible to conceive during transition and therefore a pregnancy form should be offered, if their transitional status is known.

APPENDIX B: Message to Patients Undergoing High Dose Procedures

If you are an individual of childbearing capability, aged between 12 and 55, your examination MUST be undertaken within **ten** days of the start of your period.

If your appointment falls outside of this window, please contact the booking team on 01722 336262 Ext 4282 to rearrange it.

APPENDIX C: Explanation Sheet for Patients & Signature Forms

"**Could you be pregnant?**

You may have heard that it's not good to have x-rays whilst pregnant, but maybe you don't understand why.

Here is a brief explanation to help it make sense.

Cells which are growing and dividing rapidly are more vulnerable to damage if exposed to radiation. An unborn baby is doing lots of growing!

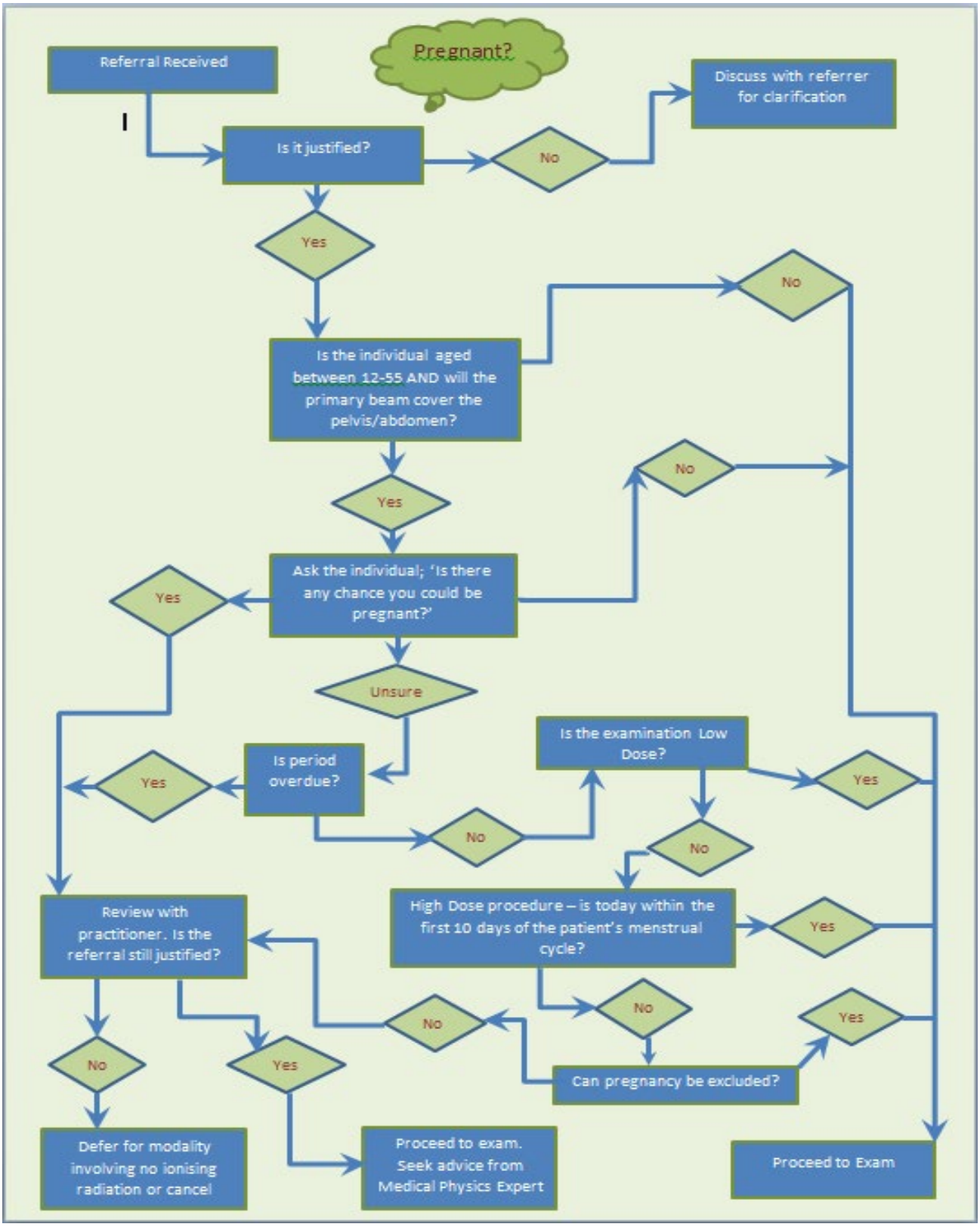
There are two types of effect which radiation can cause; those which need a minimum dose, and those that don't.

- The effects which need a minimum dose include birth defects or death. No procedure in a hospital is likely to give you anywhere near the amount of radiation needed to do this.
- Those effects which do not need a minimum dose include the development of cancer in the child, once it has been born. There is evidence that a child may develop cancer, if it was exposed to radiation in the weeks immediately after conception. The risk of this from an x-ray or scan is small, but significant.

It is our job as Radiographers to try to prevent this if possible. The benefit of you having a procedure must outweigh the risk to an unborn baby, and this is always carefully thought about before we image you.

Hopefully you understand why we take our own precautions by asking you if there is any chance that you could be pregnant."

Appendix D: Pregnancy Procedure Flowchart



Diagnostic imaging and nuclear medicine
Inclusive Pregnancy Status (IPS) form

SoR 100

1. What is your preferred name? _____

2. What are your pronouns? He/Him, She/Her, They/Them, Other _____

Your doctor/healthcare professional has requested an X-ray or other similar investigation that requires an exposure to radiation. As radiographers, it is our professional duty and legal responsibility to ensure that we protect individuals from unnecessary exposures to radiation. This is particularly relevant when considering any potential risk to pregnancy where there is greater risk from the harmful effects of radiation.

As you are **aged between 12 and 55 years old**, please answer the following questions.

3. Which sex were you registered as at birth? Female / Male (please circle)

If you are aware that you were born with a physical variation in your sex characteristics (VSC), also known by the terms diverse sex development (DSD) or intersex, please let the radiographer know.
This can be discussed privately if you wish.

Only answer the following if you have answered Female above, and/or have a VSC with the potential of pregnancy:

4. Have you had any previous surgery, treatment or medical conditions that resulted in you being unable to become pregnant? YES / NO

If YES, please move on to patient signature. If NO, please continue:

5. When was the 1st day of your last menstrual period? _____

6. Are you or might you be pregnant? YES / NO

Only continue with the following questions if you are unsure of the response to Question 5 or answered YES to Question 6:

7. Is your period overdue? YES / NO / UNSURE

8. Are you using any form of contraception? YES / NO

Patient signature _____ Date _____

Staff signature _____ Date _____

Making enquiries about pregnancy is a legal requirement. With your permission, a copy of this document will be stored electronically in your radiology notes. All your personal data is managed in line with data protection regulations. Please inform a radiographer if you do not consent, or consent to only part of this information being stored. Please note, we might not be able to continue, or it could delay your examination, if we are unable to confirm your pregnancy status

Staff to complete:

Patient NHS number: _____ **DOB:** _____

Clinical need overrides LMP status ☐ Date _____

IR(ME)R practitioner's name _____ Signature _____

Document History/Review

Document Control			
Document Name:	Determination of Pregnancy Status Policy		
Author:	Helen Russell	**First published:**	July 2021
Reference No:		**Current Version Published:**	July 2021
Current Version:	0.2	**Review Date:**	July 2024
Document Managed by Name:	Tom Beaumont	**Authorising Committee:**	Radiology SMT
Document Managed by Title:	Operational Lead Radiographer	**Ratification Committee:**	
Date Authorised:	July 2021	**Date Ratified:**	

Consultation Process
Radiology SMT, MPE, Operational Lead Radiographer

Relevant Legislation
Ionising Radiation (Medical Exposure) Regulations 2017
Employer's Procedures for Salisbury NHS Foundation Trust as required under IR(ME)R 2017

Version Control				
Version	**Date**	**Author/Reviewer**	**Action**	**Revision description**
0.1	July 2021	Helen Russell	Creation	Rewrite to include recommendations in Schedule 2 Employer's Procedures 1(c) and to reflect the requirements of the Equality Act 2010 and the Gender Recognition Act 2004
0.2	June 2022	Tom Beaumont	Revision	Addition of SoR Inclusive Pregnancy Status form