

Trust Headquarters Russell's Hall Hospital Dudley West Midlands DY1 2HQ

Ref: FOI-102024-0001214

Date: 31/10/2024

Address / Email:

Dear

Request Under Freedom of Information Act 2000

Thank you for requesting information under the Freedom of Information Act 2000.

Request

What is your radiology department's standard operating procedure for making pregnancy enquiries prior to ionising radiation exposure? Please attach current SOP/SOPs with relevant physical/digital enquiry form that the department uses to make these enquiries.

Response

Please find attached our Standard Operating Procedure in relation to ionising radiation exposure.

If you are dissatisfied with our response, you have the right to appeal in line with guidance from the Information Commissioner. In the first instance you may contact the Information Governance Manager of the Trust.

Information Governance Manager Trust Headquarters Russell's Hall Hospital Dudley West Midlands DY1 2HQ Email: <u>dgft.dpo@nhs.net</u>

Should you disagree with the contents of our response to your appeal, you have the right to appeal to the Information Commissioners Office at.

Information Commissioners Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF Tel: 0303 123 1113 www.ico.org.uk

If you require further clarification, please do not hesitate to contact us.

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Yours sincerely

Freedom of Information Team The Dudley Group NHS Foundation Trust



IR(ME)R EMPLOYER PROCEDURE C - MAKING ENQUIRIESOF PATIENTS OF CHIDBEARING CAPACITY TO ESTABLISHWHETHER AN INDIVIDUAL IS OR MAYBE PREGNANCT OR BREAST FEEDING STANDARD OPERATING PROCEDURE	DOCUMENT TITLE:	IR(ME)R EMPLOYER PROCEDURE C – MAKING ENQUIRIES OF PATIENTS OF CHILDBEARING CAPACITY TO ESTABLISH WHETHER AN INDIVIDUAL IS OR MAY BE PREGNANT OR BREASTFEEDING STANDARD OPERATING PROCEDURE	
	Name of Originator/Author /Designation & Specialty:	Radiation Assurance Manager	
	Local / Trust wide	Anywhere throughout the Trust using lonising Radiation	
	Statement of Intent:	To ensure staff have a detailed process for undertaking the procedure detailed above.	
	Target Audience:	Staff using Ionising Radiation	
	Version:	4.0	
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	Contributors:	Designation: All members of the Radiation Protection Group	
	The electronic version of this	s document is the definitive version	

CHANGE HISTORY

Version	Date	Full Review or Minor Amendment	Reason
2.0	07/02/19	Full Review	Updates to Legislation
3.0	07/02/22	Full Review	Full Review
4.0	June 2024	Full Review	Full Review

A translation service is available for this document. The Interpretation/TranslationPolicy, Guidance for Staff is located on the intranet under Trust-wide Policies.

THE DUDLEY GROUP NHS FOUNDATION TRUST

IR(ME)R EMPLOYER PROCEDURE C – MAKING ENQUIRIES OF PATIENTS OF CHILDBEARING CAPACITY TO ESTABLISH WHETHER AN INDIVIDUAL IS OR MAY BE PREGNANT OR BREASTFEEDING STANDARD OPERATING PROCEDURE

1. SOP SUMMARY

This procedure is to be followed at Dudley Group NHS Foundation Trust to make enquiries of all patients of childbearing potential to establish if the individual is or maybe pregnant or breast-feeding prior to making a radiation exposure. This is to comply with IR(ME)R regulation 11(f) and schedule 2(c). This procedure applies across all ionising radiation modalities within the

DudleyGroup NHS Foundation Trust (DGFT).

2. SOP DETAIL

2.1 Scope

This procedure should follow immediately after patient identification for every individual between the age of 12 and 55, this refers to dates from the 12th birthday up to and including 55 years and 364 days.

The following applies:

Pregnancy enquiries:

This procedure should be followed for all Nuclear Medicine examinations and for Xray exams where the primary beam covers the pelvic area (from the diaphragm to the knees). The relevant examination procedure will identify if an enquiry is needed.

Breast Feeding enquiries:

This procedure should be followed for all nuclear medicine examinations.

This will be supplemented by Advisory posters (Appendix D), Pregnancy posters which must be upon all patients waiting areas or cubicles. In the case of breast feeding this must up in the waiting area or cubicle of nuclear medicine. Leaflets must be given to patients for breast feeding prior to the Examination.

2.2 Procedure for Pregnancy enquiries

The operator undertaking the exposure is responsible for carrying out the pregnancy enquiries in this procedure and for recording the results of the enquiry on the request card, nuclear medicine/Interventional form or on Mobile CRIS.

When a patient attends for an X-ray/ Nuclear Medicine examination within the scope listed above, the Operator should first explain "That to comply with legislation we need to ask every individual of their pregnancy status.". The Operator should ask the patient "Are you or might you, be pregnant?" and whether the answer is "yes", "no" or "I'm not sure", the operator should follow the procedure below:

If the patient replies "NO" definitely not pregnant.

The No box must be ticked under the pregnancy part of the IRMER Operator stamp, the patient must then sign under patient signature in the pregnancy box. If Mobile CRIS or the Nuclear Medicine form is used the same checks must be followed and the patient sign on the mobile touch screen after understanding the declaration.

If the patient replies "YES" definitely pregnant.

The Yes box must be ticked under the pregnancy part of the of the IRMER Operator stamp, the patient must then sign under patient signature in the pregnancy box. If Mobile CRIS or the Nuclear Medicine form is used the same checks must be followed and the patient sign on the mode touch screen.

The Operator should then consult the duty radiologist who will act as a Practitioner and review the justification of the examination, taking into consideration the pregnancy and associated risks to the foetus.

The Practitioner, in consultation with the Referrer, will consider deferring a non- urgent examination until after delivery, bearing in mind that a procedure of clinical benefit to the patient may also be of indirect benefit to the foetus and that delaying an essential procedure until later in pregnancy may present a greater risk to the foetus.

The Radiologist will consider the use of a different modality or of a modified examination protocol and should the examination proceed, the risk to the foetus must be explained to the patient together with the risk of not having the examination and informed consent should be obtained and recorded using (Appendix A).

Appendix A must be signed by both the IR(ME)R practitioner unless documented in another way documented in this procedure.

If the patient replies "UNSURE whether pregnant"

Where the patient is unsure if they may be pregnant then enquiries should be made as to the date of LMP, and the date should be recorded on the request card along with the patient's signature.

• If the patient is within 10 days of the first day of LMP and the examination is a high dose procedure, then proceed with the examination.

• If the patient is within 28 days of the first day of LMP and the examination is a low dose procedure, then proceed with the examination.

High and low dose procedures are detailed in the definitions section below. Where the first day of LMP is outside 10 days or 28 days as appropriate, then the Operator can proceed with the examination if pregnancy can be excluded. by any of the following:

- The patient confirms that they are not sexually active.
- The patient confirms that they have an implantable contraceptive.

The operator should record the reason by which pregnancy is excluded on the request card or on CRIS.

Where pregnancy cannot be excluded then the Duty Radiologist should be consulted. (Appendix A) should be used for this purpose

2.3 Special considerations for pregnancy/breastfeeding enquiries

2.3.1 Patients cannot sign due to physical disability or barrier.

If the patient is unable to sign the declaration due to a physical disability or Physical Barrier (such has highly infectious patients), an Operator can sign on their behalf. All due diligence must be done to follow procedure **2.2**, this should only be used if the patient is conscious and understands the procedure taking place.

2.3.2 Responsibility where several operators are involved in a medical exposure.

If two or more persons act as Operators by initiating the medical exposure of individual (e.g., two radiographers performing a CT scan or Radiologist working with a Radiographer) both/all must be satisfied that the appropriate enquiries have been made regarding pregnancy and/or breast feeding. They should check the documented replies to the enquiries and follow procedure **2.2** and where applicable the consent for the examinations form (see below) before proceeding with the examinations.

2.3.3 Theaters procedures who are anesthetised

Pregnancy status should be established in advance for any patient aged12-55 which comply with the above scope and all due diligence must be done to follow procedure **2.2**

There may be circumstances where a patient may need radiological exposure after being anaesthetized. Pregnancy status is not usually considered by the Anesthetist; however, theatre procedures require pregnancy tests are offered as part of the pre op procedure for consent.

If a negative pregnancy test has been done within the last 24 hours and this is documented on the consent from the examination can proceed

If the patient has signed to refuse the test on the consent form the examination and has been signed the examination can proceed, this will need to be documented on the CRIS system.

If the patient is anaesthetized without appropriate pregnancy checks having been performed, the examination can continue however, the Operator must complete an incident from in line with Trust Policy. This is on the basis of the risks to the foetus from radiation is far lower than the clinical risk of undergoing a second round of anesthesia.

2.3.4 HSGs (Hysterosalpingography) examinations

Routine procedures

The patient phones on the 1st day of their period date and then abstains from sexual intercourse until their appointment time. On the day of the examination the Operator must confirm that the patient has abstained and document this this either on the request form or on the CRIS system, procedure **2.2** must then be followed.

Patients with extreme irregular cycle or do not have a menstrual cycle.

A patient abstains from sexual intercourse for 6 weeks prior the appointment, then on the appointment date a pregnancy test is undertaken. This will be reviewed by the IRMER Practitioner responsible for the examination and documented on the Radiology CRIS system, procedure 2.2 must then be followed.

2.3.5 Where the patient is unconscious

In the case of an unconscious patient where the examination is an emergency, the referring doctor should be asked to declare any known pregnancy and sign the pregnancy form or mobile CRIS. Where the patient is known to be pregnant, the operator should follow procedure as documented in **2.2**.

2.3.6 Children

The sensitive nature of the questions; potential for embarrassment and the pressures on the patient to mislead staff in the presence of their parents must be considered. As such, it is best to speak to the patient without parents present and in the presence of an appropriate chaperone. If a relative objects to questioning, then explain it is a legal requirement and the examination cannot be completed without this information.

There may be a safeguarding concern if an individual under 16 years of age confirms they are pregnant; if an in individual of 13 years or younger suspects or confirms they are pregnant; **this must be escalated to the Lead Nurse in Safeguarding.** Individuals under 16 the Referrer and Practitioner should be informed for review and potentially escalated to the Lead Nurse in Safeguarding.

2.3.7 Language or learning difficulties.

All patients aged 12-55 with language or learning difficulties, or difficulties with hearing or sensory impairment, must have their pregnancy status checked in accordance with the above procedures. However, the use of a family member as an interpreter for non-English speaking patients is not advised. In these circumstances, formal interpreting services should be used in linewith the Interpreter Policy.

In the case of hearing impairment, the difficulty may be overcome by written communication. A British Sign Language Interpreter should be organized, Alternatively, the Operator must gain as much information as possible and contactthe Practitioner.

2.3.8 Practitioner who are not based on site.

When a practitioner is not based on site, there must be a Practitioner contactable to provide support and advice regarding this procedure. All due diligence must be done to follow procedure **2.2**.

In circumstances where there is a risk of pregnancy, but due to the lack of a Practitioner on site prohibits a physical or electronic signature then the Operator must record the Practitioner decision from off-site either on the request card or on CRIS. The risk to the foetus must be explained to the patient by the Operator performing the examination and informed consent should be obtained and recorded using the first part of (Appendix A). Alternately the mobile CRIS pregnancy disclaimer can be used with the patient signing using the mobile touch screen.

2.3.9 Practitioner clinical overrule using CRIS vetting module.

In the case where a patient is known to be pregnant, this can be overruled at the vetting stage of the CRIS process by a Practitioner.

In these circumstances the Practitioner must Write "Patient is pregnant,

examination justified" in the protocol part of the Vetting module.

The risk to the foetus must be explained to the patient by the Operator performing the examination and informed consent should be obtained and recorded using the first part of (Appendix A). Alternately the mobile CRIS pregnancy disclaimer can be used with the patient signing using the mobile touch screen.

2.3.10 Nuclear Medicine

Pregnancy

For all Nuclear medicine scans Procedure **2.2** must be followed for patients who are known to be pregnant. The exception to this is VQ scans for Pulmonary Embolism, due to the clinical risk of the condition pregnancy can be overruled via an Authorisation Guideline. This is part of the Trust Guideline for Investigation of Pulmonary embolism, as it is the preferred investigation for PE in Pregnancy.

ARSAC Notes for Guidance stipulates that "Where foetal doses exceed 1 mGy the Practitioner should pay particular attention to the justification of these exposures". The overall dose to the uterus from a VQ scan is 0.6 mGy far below the stipulated level by ARSAC Guidelines.

In these circumstances (Appendix A) will still need to be signed by the patient to obtain informed consent for the procedure or using Mobile CRIS

Breastfeeding

Patients between the ages of 12 and 55 years presenting for nuclear medicine examinations/treatment should be asked to state whether they are breastfeeding.

When a patient attends for a Nuclear Medicine examination within the scope listed above, the Operator should first explain "That to comply with legislation we need to ask every individual of their breastfeeding status.". The Operator should ask the patient "Areyou or might you, be pregnant?" and whether the answer is "yes", "no" the operator should follow the procedure below:

Prior to the examination, patients will be informed if the examination will have any effect on breastfeeding. Advice will be given to express in advance of the appointment, and to breastfeed directly before administration. This advice will come in the form of Patient Information Leaflets, (see Employer Procedure H Appendix A)

Leaflets/Posters on display in the waiting room provide advisory material, encouraging patients to inform the operator if they are breastfeeding and detailing the risks of the procedure. These can be seen in (Employer Procedure H Appendix C)

If the patient replies NO not breastfeeding.

The response will be recorded in mobile CRIS or on the request form/Nuclear Medicine form.

If the patient replies YES to breastfeeding.

If a patient responds that they are breastfeeding, the IR(ME)R Practitioner will consider:

- Delaying the test until they are no longer breastfeeding (in this scenario, the risk provided by the radiopharmaceutical will be weighed against the importance and urgency of the examination)
- Choosing an alternative radiopharmaceutical that is not secreted in breast milk.

This will be recorded on the CRIS system.

Following the appointment, the patient will be provided with advice on how they should proceed, based on the examination and dose they receive. This information is given via the letter seen in (Appendix C) and uses the interruption times provided by ARSAC guidance (seen in Appendix B).

The provision of these instructions will be recorded in the CRIS system.

3. DEFINITIONS

For the purposes of this IR(ME)R Employer's Procedure:

ARSAC- Administration of Radioactive substances advisory committee.

CRIS- Computerised Radiology Information system

VQ- Ventilation/Perfusion scintigraphy

High dose procedures:

- CT Abdomens, Pelvis (including Hips) and Lumbar Spine
- Hysterosalpingograms, Small bowel enemas, Barium Follow Throughs and Herniograms
- Abdomen and Pelvis Interventional procedures.
- GI Investigations of the Abdomen, ERCPs (Endoscopic Retrograde Cholangio-Pancreatography) and Stents of the Abdomen.
- High dose Nuclear Medicine procedures None currently performed unless in conjunction with CT Abdomen, Pelvis and Lumbar spine.

Low dose procedures:

All examinations not listed under high dose procedures.

4. **REFERENCES**

Health Protection Agency, Royal College of Radiologists and the College of Radiographers. Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising radiation.

https://www.sor.org/learning/document-library/protection-pregnant-

patients during-diagnostic-medical-exposures-ionising-radiationadvice-health [accessed 17/06/24]

Association of Paediatric Radiographers with the Society and College of Radiographers. Practice Standards for Imaging of Children and Young People. http://www.sor.org/learning/document-library/practice-standards- imagingchildren-and-young-people [accessed 17/06/24]

Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation. RCR Guidance 2009.

https://www.rcr.ac.uk/publication/protection-pregnant-patients-duringdiagnostic-medical-exposures-ionising-radiation[accessed 17/06/24]

Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources (publishing.service.gov.uk) https://www.gov.uk/government/publications/arsac-notes-for-guidance [accessed 17/06/24]

implications-for-clinical-practice-in-diagnostic-imaging-interventional-radiology-and-nuclear-medicine.

https://www.rcr.ac.uk/system/files/publication/field_publication_files/irmerimplications-for-clinical-practice-in-diagnostic-imaging-interventionalradiology-and-nuclear-medicine.pdf [accessed 17/06/24]

Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources. <u>Notes for guidance on the clinical administration of</u> <u>radiopharmaceuticals and use of sealed radioactive sources</u> (<u>publishing.service.gov.uk</u>) (accessed 12/06/2024)

Appendix A: Radiology Department – Dudley Group of Hospitals NHS Trust

CONSENT FOR RADIOLOGICAL EXAMINATION

Patient who is or may be pregnant.

<u>Please write details or affix hospital sticker</u> Patient's Surname (Block Capitals):
Forename(s):
Patient Registration Number:
Examination requested:

PART 1

PATIENT:

A doctor or specialist has asked that you have a test that involves exposing you to ionising radiation. You have told us that you either know yourself to be pregnant or you cannot be certain that you are not pregnant. If the test involves exposing your abdomen and pelvis to radiation, there may be some small risk to the baby.

The Doctors are aware that you are or may be pregnant. They feel that the benefit to you of having this test today outweighs any risk to the unborn baby from the radiation exposure.

You may prefer not to have the examination today. It is your decision. You may ask if there is any alternative test that does not involve ionising radiation. You may ask if there is any chance that the test could be postponed until a time when you are not pregnant. If you do not wish to have the examination today, do not sign the form.

If you are willing to have the test performed today, please complete the declaration below:

Patient's Declaration:

- 1. I am definitely pregnant or I may be pregnant.
- 2. I understand that there may be risks to an unborn child from exposure to radiation.
- 3. I consent to the examination being performed.

Signature of patient: Date:

Signature of staff acting as witness:

Print name of staff member:

PART 2

IRMER PRACTITIONER should complete section below if examination involves direct radiation exposure to abdomen & pelvis:

I confirm that acting as a Practitioner under the *Ionising Radiation (Medical Exposure) Regulations 2017*, I have reviewed the justification for this examination. I confirm that in my opinion this examination is justified and should be performed.

Signature of IRMER Practitioner:..... Date......

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APPENDIX B: BREASTFEEDING INTERRUPTION TIMES FOR ISOTOPES TYPICALLY USED WITHIN NUCLEAR MEDICINE

Breastfeeding interruption times (calculated so baby's dose is less than 1mSv from a single administration, if multiple exposures are expected consideration should be given to limit annual dose to infant to less than 1mSv):

Radioactive substance	Activity administered to	Feeding interruption time
	Patient (MBq)	(hours)
99mTc pertechnetate	80	30
	800	57
99mTc human albumin	100	13
macroaggregates or		
microspheres		
	200	20
99mTc DTPA	300	0
	800	5
99mTc DMSA(III)	80	0
99mTc MAG3	100	0
	200	2
99mTc normal	800	20
erythrocytes [1]		
[for labelled normal		
erythrocytes the figures		
will be sensitive to		
changes in the labelling		
efficiency, which can vary		
substantially]		
99mT colloid [2]	80	0
99mTc sestamibi	400	0
	900	3
99mTc phosphates and	800	0
phosphonates		
123I iodide	20	42
123I mIBG	400	25

For any isotopes not listed in the above table, please refer to ARSAC guidance.

Appendix C: Post-examination advice for breastfeeding patient

Breastfeeding patients having nuclear medicine investigations

Nuclear Medicine Department

Name				
Date				
Radiopharmaceutical given				
Activity				

Why do you need to stop feeding?

Your doctor has decided to perform a test which involves the injection of a radiopharmaceutical. The radiopharmaceutical is used to investigate a specific problem you are experiencing, the associated risk with the procedure is very low.

Unfortunately, some of the radioactive particles in the injection can pass into your breast milk. If you continue to feed your baby with your breastmilk, your baby will receive an unnecessary radiation dose.

Feeding your baby during the interruption period

During the time when you are unable to breastfeed, you can continue to give you baby breastmilk that you may have expressed and stored, or you can choose to use formula.

Expressing during the interruption period

In order to reduce the impact of being unable to feed your baby during this period, it is recommended that you express milk whenever your baby would normally feed. You can use a breast pump, or you canhand express to clear as much milk from the breasts as possible. Any milk collected during this time should be thrown away. Expressing milk at regular intervals (e.g., whenever your baby would normally have a feed) will help to minimise any interruption in your milk supply.

For further information, please contact Nuclear Medicine by calling 01384 456111, ext.; For a need additional information regarding expressing your milk, you can contact the National Breastfeeding helpline on 0300 100 0212.

Please STOP breastfeeding between			
on			
And			
on			

Appendix D: Advisory poster (Pregnancy and Breastfeeding)

PREGNANT? OR THINK THAT YOU COULD BE? PLEASE INFORM YOUR RADIOGRAPHER BEFORE YOUR X-RAY, SCAN OR TREATMENT

Os ydych chi'n feichiog neu'n meddwl y gallech fod, siaradwch â'ch radiograffydd CYN i chi gael pelydr-X, sgan neu driniaeth.

Veuillez informer le manipulateur en radiologie AWANT votre radiographie, échographie ou traitement si vous pensez être escelute

Falls Sie schwanger sind oder schwanger sein könnten, sprechen Sie bitte VOR der Röntgenaufnahme, dem Scan oder der Behandlung mit ihrem röntgenologischen Untersucher.

Se è incinta o pensa di esserio, consulti il Suo radiologo PRIMA di fare una radiografia, un'ecografia o un trattamento.

Jeśli jestel lub podejrzewasz, że możesz być w ciąży, prosimy porozmawiaj ze swoim elektroradiologiem PRZED przetwietleniem, badaniem USG lub leczeniem.

Se está ou suspeita estar grávida, consulte o seu médico radiologista ANTES de fazer o exame de raio-X, scan ou tratamento

Dacă sunteți însărcinată sau credeți că ați putea fi, vă rugăm să discutați cu radiologul ÎNAINTE de radiografie, scanare sau tratament.

Если Вы беременны или допускаете такую возможность, пожалуйста, проконсультируйтесь с Вашим радиографом ПЕРЕД ректтенограммой, сканированием или лечением.

如果您已怀孕或认为自己有机会怀孕,请在进行 X 光、 扫描或治疗前向放射治疗师查询

यद्वि आप गर्भवती है या आपको लगता है को आप गर्भवती हो सकती है तो एक्सरे, सुवैन या इलाज से पहले अपने रेडपिंग्राफर से बात करे।

আপনযিদ গির্ভবর্তী হন বা আপনা মনং করনে যা, আপনা গির্ভবর্তী হতে পারনে, আপনার একস-রা, সৃক্ষান বা চার্কিংসা করান**োর আগ**ে অনুগৃরহ করা, আপনার রাডেঙিগুরাফারকতে তা বনুন।

إذا كنت حاملاً أو تعتقدين أنك ربما تكونين حاملاً، تحتلي من فضلك بشأن ذلك مع فني الأشعة. الذي يقوم بفحصك قبل إجراء فحص الأشعة السينية أو المسح أو العلاج الخاص بك.

FUJ:FILM Value from Innovation



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Nuclear Medicine Tests

Your health

- Nuclear medicine tests help with making diagnoses and monitoring treatment.
- They involve the use of ionising radiation which will have been approved by a specialist.





Radiation

- Everyone receives some ionising radiation every day from radioactivity in the air, food that we eat and even from spacel
- The amount of radiation in a nuclear medicine test is similar to your natural exposure over about one to four years so the risks associated with it are low.
- The main benefit of the test is making the correct diagnosis, so you can get the treatment that's right for you. This benefit is far greater than the small risk from radiation.

Our staff and equipment

- Staff are trained to take the best possible images of you or readings using the lowest amount of radiation.
- Equipment is regularly checked to make sure the test is safe and effective.





Your test

- Before your test, you will be given a small amount of a radioactive substance. We normally inject it, but sometimes you can eat, drink or even breathe it depending on the test.
- If you are pregnant or think you may be pregnant, or are breastfeeding, please inform a member of staff immediately.
- After your test you will still have some radioactivity in your body which will leave over time. You will emit a small amount of radiation which will be insignificant for most people around you, but we may ask you to limit your contact with children and pregnant women for a time.
- Your test may also include a computed tomography (CT) scan. This uses a beam of X-rays to make 3-D pictures.

We are here to make sure your test is right for you, so let's talk!

Produced by the Clinical Imaging Board, a collaboration between the Institute of Physics and Engineering in Medicine, the Royal College of Radiologists and the Society and College of Radiographers.







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