Please note: **The purpose of this public consultation is to gather feedback on the content of the guidance.**

Following approval of the content, the final document will be professionally proofread, formatted, and designed in accordance with the standard RCR guidance template.

DRAFT RCR Guidance on Intravascular Contrast Media Use in Medical Imaging

1. Introduction

Purpose and scope of the guidance

It has been more than 10 years since the Royal College of Radiologists (RCR) published the third and last edition of its standards for intravascular contrast administration in adults. Since then, evidence and clinical practice have evolved significantly. This document provides updated, evidence-based national guidance on the intravascular use of iodine and gadolinium-based contrast agents in adults and children, supporting safe and effective practice across UK healthcare systems.

The use of medical imaging — including intravascular contrast — has more than doubled in the past decade. While contrast agents play a vital role in diagnosis and endovascular therapy, they carry potential risks that must be balanced against their clinical benefits. These new standards outline best practice to ensure contrast is used as safely, efficiently, and cost-effectively as possible.

The guidance was developed by a multidisciplinary, intercollegiate working group with representatives from:

- Royal College of Radiologists
- Society and College of Radiographers
- UK Kidney Association
- British Society for Allergy & Clinical Immunology
- Association of British Clinical Diabetologists
- British Cardiovascular Intervention Society
- Royal Pharmaceutical Society

The document covers the use of intravenous and intra-arterial iodine-based contrast media and intravenous gadolinium-based contrast agents. It also outlines the regulatory and legal frameworks governing contrast administration, including the use and limitations of Patient Group Directions (PGDs). The document does not cover the extravascular use of contrast media or other intravascular agents such as carbon dioxide used in invasive angiography, or sulphur hexafluoride microbubbles (e.g. SonoVue) used in contrast-enhanced ultrasound.

Two key recommendations mark significant changes from previous UK guidance and common practice, with potential to reduce imaging delays, lower costs, and minimise patient inconvenience:

- **Premedication for patients with prior hypersensitivity reactions:** the group concluded there was no strong evidence for routine premedication, and the guidance recommend it is only used in specific emergency situations.
- **Renal function testing prior to modern gadolinium-based agent administration in approved doses:** the group concluded it's no longer justifiable to perform routine eGFR testing for adult outpatients and inpatients prior to gadolinium enhanced MRI including in known renal impairment.

Bahir Almazedi, Working Group Chair

Glossary and Overview of intravascular iodine and gadolinium based contrast media

Iodine-based contrast media (IBCM): intravascular contrast agents containing iodine. Modern IBCM are non-ionic, low or iso-osmolar molecules with iodine content as the foundation for the mechanism of producing contrast imaging in x-ray-based examinations.

Examples (generic name, brand name, iodine (I) concentration):

- Iohexol, *Omnipaque* – 180/240/300/350 mg I/mL
- Iodixanol, *Visipaque* – 270/320 mg I/mL
- Iopamidol, *Niopam* – 200/250/300/370 mg I/mL
- Iopromide, *Ultravist* – 240/300/370 mg I/mL
- Ioversol, *Opitary* – 160/240/300/320/350 mg I/mL
- Iomeprol, *Iomeron* – 250/300/350/400 mg I/mL

Gadolinium-based contrast agents (GBCA): MRI contrast media in which gadolinium (Gd) is chelated by an organic ligand. Classified by chelate structure (macrocyclic vs. linear). GBCAs are predominantly excreted unchanged by the kidneys (gadoxetate and gadobenate have some hepatobiliary excretion) and leave only tiny Gd traces retained in tissues (whether this Gd is still in its chelated contrast agent form or has been dechelated then bound to another compound is not known).

Examples (generic name, brand name, Gd concentration, standard single dose):

- Gadoteric acid, *Dotarem* – 0.5 mmol/mL, 0.1 mmol/kg = 0.2 mL/kg
- Gadobutrol, *Gadobutrol,* – 1.0 mmol/mL, 0.1 mmol/kg = 0.1 mL/kg
- Gadoteridol, *ProHance* – 0.5 mmol/mL, 0.1 mmol/kg = 0.2 mL/kg
- Gadobenate dimeglumine, *MultiHance* – 0.5 mmol/mL, 0.1 mmol/kg = 0.2 mL/kg
- Gadoxetate disodium, *Primovist* – 0.25 mmol/mL, 0.025 mmol/kg = 0.1 mL/kg
- Gadopiclenol, *Elucirem/Vueway* – 0.5 mmol/mL, 0.05 mmol/kg = 0.1 ml/kg

Overview of intravascular IBCM and GBCA

Iodine-based contrast media (IBCM)

1.1 Be aware that there is no difference in the incidence of contrast associated acute kidney injury (CA-AKI) between low and iso-osmolar agents when used in equimolar amounts in patients with renal impairment

1.2 Warm contrast media in line with manufacturer's guidelines if indicated to reduce viscosity and required injection force, which may lower the risk of extravasation

1.3 Optimise imaging criteria to use the minimum effective iodine dose to achieve diagnostic contrast enhancement and to reduce risk of kidney injury in patients with reduced renal function.

1.4 Perform a risk-benefit assessment and weigh the diagnostic benefit of enhanced imaging against patient specific risks (reduced renal function, allergy history, etc).

1.5 Consider using an iso-osmolar agent (the dimeric iodixanol) during peripheral catheter angiography to reduce burning sensation and pain, particularly in patients with critical limb ischaemia and tissue loss [1] (although this does carry a higher potential risk of delayed hypersensitivity skin reaction).

High-osmolar and ionic IBCM are now avoided for intravascular use, and these old contrast media have been superseded by safer modern options. Modern IBCM are nearly all non-ionic and either low-osmolar or iso-osmolar. Iso-osmolar contrast media (specifically iodixanol) can reduce a burning sensation experienced during peripheral catheter angiography with consequent patient movement and image degradation, particularly in patients with tissue loss. This is because iso-osmolar agents are less likely to cause pain and discomfort compared to low-osmolar agents due to their similar osmolarity to blood, which minimises vascular and nerve irritation. The osmolarity of iodixanol translates to fewer immediate hypersensitivity reactions. However, there is an increased incidence of delayed (2-10 days) skin reactions (Non-Immediate Hypersensitivity Reactions - NIHR) with this compound which patients should be warned about. Successive repeat injections in patients with prior NIHR are associated with earlier subsequent NIHR (1 to 2 days).

Importantly, both low- and iso-osmolar agents are safe; some studies suggested iodixanol causes less endothelial injury than low-osmolar agents in theory, but large trials have shown no significant difference in CA-AKI when appropriate hydration is used [2]. Overall, CA-AKI is uncommon with modern IBCM, especially when administered intravenously or when arterial injection is below the level of the renal arteries (i.e. without first pass renal perfusion). For example, the AMACING trial (1120 patients with CKD stage 3) showed no excess need for dialysis or increase in serum creatinine at 1 year when comparing hydration versus no prophylaxis [3]. Nevertheless, for patients with eGFR < 30 ml/min/1.73m^2, appropriate hydration should remain a standard precaution in addition to optimising imaging parameters to minimise contrast dose.

Gadolinium-based contrast agents (GBCA)

1.6 Macrocyclic GBCAs are now the standard for all general intravascular use with the exception of specific liver imaging indications where the remaining linear agents gadobenate and gadoxetate have specialist uses.

1.7 Use the lowest effective gadolinium dose to achieve diagnostic images taking into account patient factors (weight/size) and the proposed MRI protocol.

1.8 Be aware that all GBCAs leave tiny traces of gadolinium in body tissues; this retention was highest with those historical linear agents that are no longer available for use in the UK and Europe.

1.9 GBCAs are safe for use in MRI and often provide essential diagnostic information outweighing the very small potential risk when used at the lowest effective dose.

1.10 Gadolinium-based contrast agents are not licensed for x-ray based angiographic examinations or CT.

Gadolinium chelates differ fundamentally by ligand structure. Macrocyclic agents form cage-like complexes that are very highly stable when compared to the deprecated historic linear GBCAs which can release Gd^{3+} more readily posing higher risk with their use. Macrocyclic GBCAs are now standard for general intravascular use in the UK and Europe. The nephrogenic systemic fibrosis (NSF) literature shows that virtually all cases occurred in association with the older linear GBCAs in patients with end-stage kidney disease. This was especially in patients with suboptimal dialysis status and where the ‘non-ionic’ agent gadodiamide was used in high &/or repeated doses. In contrast, modern macrocyclic GBCAs have an NSF incidence effectively at zero (pooled incidence ≈0% in end-stage CKD). Accordingly, UK/European regulators have largely withdrawn or restricted the older linear GBCAs but never contra-indicated the macrocyclic agents.

Another theoretical safety concern raised has been the phenomenon of gadolinium retention. Multiple studies have demonstrated minute Gd deposits in brain, bone and other organs

after repeated GBCA use, this is higher in bone and other body organs than in the brain for all compounds but disproportionately higher after use of historical linear agents. Occasionally high signal has been observed in deep brain nuclei on native T1W imaging in patients with multiple prior exposures to these linear chelate GBCAs. The status of this retained Gd is unknown, for the macrocyclic agents it is thought likely still chelated as part of the macrocyclic structure but for the linear GBCAs there is some evidence that it may have de-chelated from the contrast compound and be bound to macromolecules. Although the clinical impact of this Gd retention remains unclear with no neurological sequelae found in large population studies, the consensus is to limit cumulative exposure. This is thought most important for younger patients and those likely to require repeated future imaging studies.

In liver imaging, hepatocyte-specific linear chelate agents such as gadoxetate (*Primovist*) and gadobenate (*MultiHance*) may be used because of their uptake into functioning hepatocytes and biliary excretion, this improves hepatic lesion detection and characterisation for certain conditions. Although these agents are linear chelates, the risk of NSF with their use has been proven to be extremely low with few if any unconfounded cases of NSF associated with their use. This is based upon multiple prospective RCTs and large meta-analyses (e.g. Woolen et al. JAMA Intern Med 2020) [4, 5]. Current evidence therefore supports their safe use for liver indications, provided the lowest effective dose is used and dosing intervals are respected.

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2. Legal mechanisms for contrast media administration

2.1 Referrals should adhere to good practice guidelines for clinical imaging (1) referrals in particular adhering to IR(ME)R 24 for examinations using ionising radiation and use of local referral criteria (2 reg 10).

2.2 Referrals must be justified and authorised for a contrast media examination, following the required procedures within the imaging department before the administration is made (2 reg 11) (2 4.10.2)

Local systems should be in place for the entitlement of referrers and the justification and authorisation of contrast agent examinations as supported by iRefer or other clinical support tools. This includes entitling suitably trained and competent radiographers to authorise examinations according to local guidelines for CT(2), MRI (3), and other contrast agent examinations.

2.3 Each Doctor, Registered Practitioner, or associated professional is accountable for their own practice and must be aware of their legal and professional responsibilities relating to their competence in ordering, storing, prescribing, supplying or administering, and recording the administration of contrast media.

The multidisciplinary team within the clinical imaging and radiation oncology environment hold different legal rights and responsibilities for prescribing, supplying, and administering Prescription Only Medicines (POMs)(5). All intravascular contrast media and intravascular saline used in conjunction with the contrast media are POMs. The employing organisation defines how those legal rights and responsibilities can be used taking account of national and professional guidance.(6,7,8,9,10,11,12,13,14,15)

Organisations have a legal duty of care and are responsible for ensuring a Medicines Policy is in place and that the staff they employ are properly trained and competent to undertake only those responsibilities specified in agreed job descriptions.(16)

See appendix 1 and 2 for more information.

2.4 Local arrangements in line with legislation should be made to allow healthcare professionals (HCPs) who are not prescribers to supply or administer contrast media. (17,19,20)

Patient Group Direction (see Appendix 2 for additional considerations)

A PGD allows suitably trained radiographers and registered nurses to administer contrast media to patients without individual prescriptions, provided the conditions outlined in the Patient Group Direction (PGD) are met. They are not a form of prescribing.

- Suitable for pathways where the individual and their medical conditions comply with the inclusion criteria stated in the PGD
- cannot be used where medicines are mixed before administration unless required as a diluent or reconstituting agent specified in the Summary of Product Characteristics
- template PGDs from the Specialist Pharmacy Service should be used across the UK (unless equivalent guidance is available in the devolved nations) (18)

Prescription: Patient Specific Direction (PSD)

While not defined in legislation, a PSD is a written instruction signed by a prescriber for medicines to be supplied and/or administered to a named person/patient. (22)

- where patient flow supports individual prescribing

- must be used for the patients who don't meet PGD criteria

Legal Exemptions

Exemptions are exceptions to the general rules governing administration of medicines for certain groups of healthcare professionals and are listed in the Human Medicines Regulations 2012. E.g. for nuclear medicine procedures (21)

In general, the development of an appropriate PGD enables a wide range of patients to undergo their contrast media studies, although PSDs are still necessary for individual patients who fall outside the PGD criteria.

2.5 Before administering a contrast agent and/or saline*, health care professionals who are not prescribers must ensure that they

a. **have a Patient Group Direction which they have been trained and authorised to use, (26, 29, 30)**
   or
b. **have a valid Patient Specific Direction which they are authorised to follow**
   or
c. **are entitled to follow a protocol as part of an authorised nuclear medicine examination (26,27,28,)**

* *Saline supplied in a prefilled syringe for flushing a cannula may be classified as a medical device and may be administered according to a local protocol, provided it is within the employer's policy; all other injectable presentations are Prescription Only Medicines (POMs).*

Healthcare professionals must have authorisation to administer contrast agents and saline, adhering to legislation as it pertains to their profession.

2.6 Services must ensure that staff are appropriately trained and authorised to administer contrast agents and adjunct Prescription Only Medicines (POMs) in accordance with legislation, national guidance (31, 32, 33), and local policies and procedures.

A senior individual, such as the professional lead, should be responsible for ensuring that only fully competent and qualified health professionals are authorised to administer contrast agents and use the latest approved version of any PGD (35). Authorised health professionals must understand their legal and professional responsibilities before using PGDs or administering contrast agents under a PSD (36). Relevant training should be completed to assess practitioners' competency, which can be provided locally or through national resources.

2.7 Departments should have systems in place to ensure senior clinical decision makers have been involved in the decision to request **Radiological studies involving the use of contrast agents (iodine or gadolinium) for emergency patients.**
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a. **In emergencies, the referrer should prescribe the contrast media according to local procedures and the radiographer should administer according to the local imaging and contrast protocol**
b. **In rare circumstances PGDs can include radiographers making 'best interest' decisions where the local PGD development group and the employer support this (37/templates/inclusion criteria)**

Recommendations for Emergency scans

Patients requiring emergency contrast enhanced imaging with intravascular contrast media should proceed without delay. Specifically:

- Measurement of renal function should not be considered a pre-requisite prior to scanning (the electronic requesting system should reflect this).
- Pre-existing renal disease, diabetes mellitus or medication such as metformin should not delay scanning (the electronic requesting system should reflect this).
- Age is not an independent risk factor for CA-AKI and should not delay scanning
- Intravenous fluid administration should not be considered a pre-requisite prior to scanning.
- Protocols for the use of central venous catheters (38) for the administration of radiological contrast media should be in place
- Where a 'best interest decision' is included, this is supported by organisational policy on consent and best interest decisions.

A system that ensures there is no delay is required for emergency imaging e.g. emergency imaging and role of requester as per RCR/ RCEM join statement 2023: Joint Advisory Statement between The Royal College of Radiologists & Royal College Emergency Medicine regarding Emergency Computed Tomography scans and the use of Intravenous Iodinated Contrast Agents | The Royal College of Radiologists

Record keeping

2.8 All staff members are responsible for maintaining full, clear, and accurate records of their contrast media use.(39,40)

2.9 Radiologists, radiographers, nurses and associated professionals performing interventional procedures should consider how records of prescribing and administration are recorded in line with regulatory and professional requirements to include:

Cannulation

- In line with organisational requirements

PGDs (42 1.5.7)

- the clinical assessment and decision to administer the contrast agent(s):
  - date and time of supply and/or administration
  - patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD
  - details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration (record the batch number and expiry date)
  - a statement that administration is by using a PGD
  - name and signature (which may be an electronic signature) of the health professional assessing the patient and administering the medicine
  - relevant information that was provided to the patient or their carer
  - whether patient consent to treatment was obtained, in line with the Department of Health and Social Care's advice on consent (2009).

PSDs

  - patient details

- details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration (record the batch number and expiry date)
- name and signature (which may be an electronic signature) of the health professional administering the medicine
- relevant information that was provided to the patient or their carer
- whether patient consent to treatment was obtained, in line with the Department of Health and Social Care's advice on consent (2009) (41).

Adverse events, reactions, extravasations and near misses

- Patient record
- Incident reporting systems
- National reporting systems

Radiologists should follow professional and regulatory guidance on recording their prescribing decisions and administration records. Radiographers, nurses, and associate professionals should meet their regulatory requirements and adhere to their local policies.

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3. Patient Consent for the administration of intravascular contrast media

3.1 Hospitals and radiology departments should provide patients with adequate information about the benefits and risks including side effects of contrast media in advance of the radiological examination (e.g. patient information leaflets).

Patients should be informed about possible common or serious side-effects and risks associated with the administration of intravascular contrast media (e.g. allergic reaction, kidney impairment), and what to do if they have a history of previous allergic reaction to contrast media and/or kidney disease [3].The risk of death following contrast media administration is ~1:170,000.

3.2 The referring clinician should provide information on the overall clinical context and the need for the contrast-enhanced radiological examination, and whether there are any alternatives.

Providing information to the patient is a shared responsibility between the referring clinician and the radiology department. The referring clinician is best placed to provide information on the overall clinical context and need for the contrast enhanced radiological examination and if there are any alternatives.

3.3 The radiology department should provide information so that the patient can make an informed choice regarding consent to the administration of intravascular contrast media as part of their examination.

3.4 Patient information should be given in plain language, avoiding medical jargon, which, if used, should be explained in layman's terms.

3.5 Services should ensure that patients, service users, families, and carers can access information, translation, and interpretation services if needed to give informed consent [1]. The level of information given depends on the complexity and risks associated with the examination and individual patient factors.

3.6 In pregnancy, patients must be informed about the risks to the unborn child of receiving intravascular contrast media for their radiological examination.

3.7 Information on eating and fasting should be included in the patient information. Fasting is not required before the administration of intravascular contrast media. [2] This excludes patients who are undergoing conscious sedation or general anaesthesia for their contrast-enhanced radiological examination.

3.8 All staff administering contrast media should, before administration, ensure patients understand that they are receiving intravascular contrast media for their radiological examination and that they are aware of associated side-effects.

3.9 The referral process should include details of any medications or medical conditions that can interact with or be exacerbated by the administration of IV contrast medium and be discussed with the patient.

Example screening questions as part of the referral process before IV contrast media administration:

- Ask patients if they have a history of allergy to contrast media, asthma or any known allergy.

There is approximately a ten fold increase in reactions to intravascular contrast media following a previous hypersensitivity reaction. There is approximately a six fold increase in risk of hypersensitivity reaction to intravascular contrast media with a history of asthma with the risk highest in patients with poorly controlled asthma symptoms.

- Ask patients if they have diabetes and if they take metformin (IBCM only).

Certain precautions need to be considered in these patients. See Metformin section for explanation.

- Ask patients if they have thyroid disease or receiving treatment for thyroid disease (IBCM only).

Certain precautions need to be considered in these patients. See other medical conditions and medications section for explanation.

3.10 Discuss the benefits and risks of examinations using intravascular contrast media with patients, and their family members/carers/guardians if appropriate. Follow the recommendations in the NICE guideline on shared decision making. [2024]

3.11 The healthcare professional administering the injection, whether a radiologist, radiographer, or other authorised HCP operating under a Prescription (PSD) or Patient Group Direction (PGD), must ensure that the patient has:

- Received and understood all relevant information regarding the procedure.

- Had the opportunity to ask questions and receive satisfactory answers.

- Confirmed their consent for the contrast medium injection prior to administration.

Informed consent can be implied, verbal or written depending on the circumstances and type and complexity of the radiological examination.

3.12 If an adult has the capacity to make a voluntary and informed decision to consent to or refuse a particular treatment, their decision must be respected.

Patients can refuse to give consent and can withdraw consent at any time. This should be documented in the medical notes including details of the reasons for refusal and discussions which took place.

3.13 Consent for medical treatment in children and young people should follow established standards of care and law. Typically, the patient provides consent if capable. For those under 16 who are not deemed capable of consenting, consent is generally obtained from an individual with parental responsibility.[5]

3.14 Where patient capacity is compromised, e.g. the patient is unconscious, do not delay the use of intravascular contrast media in an emergency if the risk of delaying the contrast media is likely to be clinically significant. In less time-critical emergencies, informed consent should be obtained and, whenever

possible, management decisions should be discussed with the next of kin or legal guardian.

If a person does not have the capacity to decide on their treatment and they have not appointed a lasting power of attorney (LPA), the healthcare professionals treating them can go ahead and give treatment (including IV contrast medium) if they believe it's in the person's best interests, for example patient needs emergency treatment to save their life, but they are incapacitated or unconscious. The reasons why emergency treatment was necessary should be fully explained to the patient if and when they have recovered.

3.15 Record patient consent as required by local policy or legal obligation, for example formally in the medical notes during complex radiological examinations involving intravascular contrast media such as vascular interventional procedures.

3.16 When using a Patient Group Direction (PGD), Radiographers must assess and consent individuals to receive contrast media following the requirements of the PGD, the organisation's consent processes and their local policy. In certain situations, such as after major trauma, making the assessment and obtaining consent may not be possible. In these cases, it is the employing organisation's responsibility to decide whether radiographers working under Patient Group Directions (PGDs) can administer contrast based on patients' best interests. [6]

The responsibility for administering contrast, whether with or without consent, lies with the radiographer working under the Patient Group Direction (PGD). If the radiographer has any concerns about administering contrast under a PGD, they should refrain from proceeding and escalate the case to the appropriate clinician, such as a radiologist or the referrer.

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4. Extravasation and general principles of safe use

4.1 Ensure that all local and organisational policies and procedures support the prevention, recognition, and management of contrast media extravasation in line with local, national and international guidance.

Contrast media extravasation (CMEX) refers to the unintended leakage of intravascularly administered contrast media from the intravascular compartment into surrounding soft tissues. CMEX is a recognised complication of contrast-enhanced imaging and can result in serious sequelae. CMEX during MRI does not usually lead to serious complications, probably given the low volumes and injection rates used.

Occasionally, CMEX also occurs during fluoroscopy assisted procedures (angiography) but due to the combination of often manual injections, small boluses and real-time visualisation of the contrast administered, it is rarely an issue.

While CT contrast media extravasation occurs relatively infrequently it is thought to be the commonest adverse event in radiology. Research suggests anywhere from 0.1 to 1.2% of CT scan injections result in extravasation although less than 1% of these extravasations have severe side effects associated with skin changes, compartment syndrome or possible skin necrosis. However, even what may be clinically regarded as a minor extravasation incident will be perceived as important by the patient and contribute to feelings of dissatisfaction at a stressful time since “something has gone wrong” with their care.

Extravasation of GBCAs for MRI occurs much less often with one paper indicating a rate of 0.06% with no serious sequelae.

From 1 April 2011 until 31 March 2021, NHS Resolution received 444 claims relating to extravasation injuries across all specialities. Of those 444 claims, 138 remain open, 197 have settled with damages paid and 109 have closed with nil damages. 9% of settled claims were from CT contrast. Placement of the cannula outside of the radiology department and arm position during imaging are considered contributory factors to this. This in total has cost the National Health Service (NHS) 15.6 million pounds. This includes payment for claimant legal costs, NHS legal costs and damages.

4.2 Ensure that all protocols for administering contrast media also adhere to manufacturers' guidelines regarding pressure and flow rates for specific vascular access devices.

CVCs, PICCs and power injectable ports are increasingly used for patients in critical care, on chemotherapy or long-term antibiotics. Contrast injection via power injector compatible versions of these devices have been shown to be safe when manufacturer guidance is followed with a low 1% reported risk of adverse incident. Although rare, extravasation from central catheters can lead to significant morbidity, i.e. mediastinal extravasation, haematoma and cardiac arrhythmias. Consider a post-contrast CT topogram as a method to quickly evaluate catheter tip position in these patients.

4.3 Ensure all staff involved in the administration of intravenous contrast media are trained in the prevention, recognition and management of extravasation, relevant to their role and the environment in which they work

Actions and levels of responsibility differ depending on the job role; however, all staff caring for patients who receive contrast media injections should be able to recognise risk factors, understand and implement necessary prevention strategies (which may include referral to a vascular access team or expert), identify issues during or immediately after the contrast

administration and take immediate action including managing any subsequent complications from extravasation.

4.4 Where canulation is performed outside the scan room, or the patient arrives from a ward with a cannula in place:

- **a. Test flush the cannula with saline in line with organisational policies**
- **b. Ensure the cannula is securely located using a device or dressing designed to secure the cannula**
- **c. Advise the patient not to flex the arm (if cannula sited at antecubital fossa or below) nor pull on the cannula**

4.5 Recheck the cannula and flush with saline while the arms are in the scan position to confirm correct placement.

CMEX can happen when the vein is not robust enough to handle the pressure of the injection, or if the cannula dislodges or fractures during the injection. Patients may experience burning, stinging & or swelling at the injection site. Most CMEX incidents are minor and resolve. There is an increased incidence with automated power injection because higher pressures can be attained and large volumes can extravasate in a short period of time (with manual injections, extravasation is less likely as there is direct supervision of contrast administration). Gauge of cannula can have a bearing and there is a higher risk of CMEX when smaller cannulas are used, probably reflecting patient factors with difficulties in accessing large calibre veins.

a. Recognise patients in whom extravasation risk is higher:
   - i. Oncology patients: previous history of radiation to the limb or chemotherapy via peripheral veins.
   - ii. Less optimal injection sites such as small distal veins (e.g. back of hand) and the lower limbs (likely related to a smaller amount of subcutaneous tissue and the fact that veins can be more fragile in these regions).
   - iii. Elderly patients.
   - iv. Oedema, obesity or deep veins.
   - v. Paediatric patients.
   - vi. Patients with altered levels of consciousness and sensation.
   - vii. IV drug users and those with impaired venous &/or lymphatic drainage.
   - viii. Patients with dementia and delirium.
   - ix. Patients with learning disabilities.

b. Where appropriate use a twenty-gauge or larger cannula in the antecubital fossa:
   - i. Ensure the cannula is firmly secured.
   - ii. Perform a saline test flush by hand or power injector.
   - iii. Warm contrast media in line with manufacturers guidance to reduce viscosity.
   - iv. Directly monitor the site during injection if feasible.
   - v. For more peripheral cannula sites consider reducing flow rates to minimise the risk of extravasation.
   - vi. Ensure the elbow is not flexed or the cannula kinked when positioning the patient in the scanner with the arms above the head.
   - vii. Ensure the power injector and tubing are positioned to allow adequate table movement without tension on the cannula.
   - viii. Ensure two-way communication is possible at all times during the scan and injection.

ix. Instruct patients to raise an alert should pain, stinging or swelling occur during the injection.

4.6 Ensure all patients receive information about the benefits and risks of having contrast media including the risk of extravasation. Confirm and document consent to proceed in accordance with local policy.

4.7 Ensure there is a process in place to manage situations where informed consent cannot be given.

4.8 Observe the patient, any real-time images and pump injector parameters during the administration of contrast media using visual oversight and remote monitoring where appropriate.

4.9 Provide appropriate communication systems for patients to alert to any untoward pain or swelling during injection.

4.10 If extravasation is suspected, then stop contrast administration immediately and complete imaging if possible before attending to the patient.

4.11 Extravasation kits, including management flow charts, patient information leaflets and material with which to provide cold compresses should be readily available in the imaging suite.

4.12 Consider imaging in cases of suspected severe extravasation to assess the extent and compartmentalisation of the extravasate (subfascial versus subcutaneous).

a. Where imaging is undertaken, perform cross-sectional imaging (CT or MRI) or 2-plane CT topogram before removing the patient from the scanner.

b. Where cross sectional imaging cannot be performed undertake plain radiographs with two orthogonal views.

c. Recognise that imaging performed following contrast media extravasation constitutes a new medical exposure under IR(ME)R and such regulations should be followed.

d. Ensure justification for imaging is undertaken by an entitled IR(ME)R practitioner or, where permitted by local employer's procedures, by a radiographer acting under approved written authorisation guidelines.

4.13 Document all contrast media extravasations in the patient record and relevant organisation incident reporting system (e.g. Datix) as per local and national requirements.

Records of extravasation incidents should include:

a) Type and volume of contrast injected.
b) Outcome of the patient assessment including extent and depth of extravasate (best assessed by cross-sectional imaging where CMEX is severe).
c) Type of advice and guidance given to patient.
d) Any onward referral or management information.

4.14 Monitor extravasation rates and compliance with local protocol for the prevention and management of contrast media extravasation through regular audit. (Example: https://www.rcr.ac.uk/career-development/audit-quality-improvement/auditlive-radiology-templates/contrast-extravasation-in-ct-qsi-ref-xr-513/)

4.15 Consider appointing an organisation contrast extravasation lead.

4.16 On identification of extravasation, advise the patient to elevate the affected limb, and apply ice packs according to manufacturer's guidance: do not discharge home until assessed by a trained healthcare professional.

Where symptoms do not resolve rapidly, a healthcare professional trained in extravasation should:

a) Provide a physical examination including assessment of tenderness, swelling, erythema, paraesthesia, active and passive range of finger motion and perfusion.
b) Refer for immediate surgical review in severe cases.
c) Not use extravasation volume as the threshold to trigger surgical consultation.
d) Be alert to assessing for different skin signs on damaged, diseased or darker skin.
e) Discharge home if no immediate concerns with clear advice including instructions for where and when to seek additional medical care and a clear description of signs and symptoms to look out for.
f) Consider follow-up with a phone call the day after discharge.

4.17 Services should ensure that radiographers have access to clear escalation pathways and timely senior clinical support, including remote advice where appropriate.

4.18 Seek urgent surgical review when skin blistering, paraesthesia, altered tissue perfusion or persistent pain for more than four hours following contrast extravasation which suggest severe injury.

4.19 Ensure there is a local arrangement for rapid access to the plastic surgery services in cases of severe extravasation.

4.20 Notify the referrer following any symptomatic extravasation.

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5. Identifying Patients at Risk of Contrast Hypersensitivity Reactions

5.1 Referrers should ascertain whether patients have had prior hypersensitivity reactions (HR) to intravascular contrast media (CM) when requesting scans likely to or intended to be performed with contrast and provide all other relevant information (e.g. history of severe asthma and allergic reaction requiring medical intervention) with the request.

5.2 Imaging staff should ask patients/carers about previous HR to intravascular CM prior to their administration.

5.3 Patients/carers should also be asked about a history of asthma and previous significant allergic reaction requiring medical treatment prior to administering intravascular CM.

Definitions & Classification of Hypersensitivity Reactions [1,2,3]

Immediate hypersensitivity reactions (IHR) are defined as occurring within 1 hour of CM administration (rarely up to 6 hours) and are either allergic (activation of mast cells and basophils mediated by IgE) or non-allergic. Anaphylaxis following administration of intravascular contrast media is a multifactorial response with potentially multiple immunologic mechanisms involved but typically including IgE-mediated activation of mast cells and basophils.

IHR should be classified as per the American College of Radiology (ACR) guidelines [3] into those that are mild, moderate or severe as this practical grading informs treatment decisions and future management. Patients experiencing severe IHR following administration of intravascular CM should be referred to a drug allergy specialist.

Non-Immediate hypersensitivity reactions (NIHR) occur between 1 hour to 1 week of IV contrast agent administration (rarely up to 8 weeks) usually with a non-allergic mechanism occurring through cell mediated and other mechanisms. NIHR are manifest most frequently in the skin (>90% skin only) as rashes (macular or maculopapular exanthemas), redness and/or skin swelling with headache also often reported. Most NIHR are mild or moderate in severity, but rarely severe cutaneous adverse reactions (SCAR) can develop - such patients should be referred to a dermatologist for treatment and advice on future use of CM.

5.4 Many other historically proposed risk factors (e.g. allergy to shellfish or topical iodine) have poor discriminatory power in predicting HR to IVCM, are unlikely to influence administration/management and are not recommended for screening purposes.

5.5 Patients with prior Non-Immediate Hypersensitivity Reaction are not at higher risk for Immediate Hypersensitivity Reaction upon re-exposure to intravascular CM.

5.6 Patients with prior HR to iodine based contrast media are not at significantly higher risk for HR to gadolinium based contrast agents and vice versa.

Risks Factors for Contrast Hypersensitivity Reactions [4]

The most important factor predicting a future hypersensitivity reaction to CM is a history of previous HR to CM (moderate to high risk). HR are less commonly encountered with gadolinium based contrast agents (GBCAs) used for MRI than with iodine based contrast media (IBCM). It should be noted however that the current non-ionic low/iso osmolar iodinated contrast media are in the order of 5 to 10 times safer than the older high osmolar ionic media no longer in use.

Patients with acute/active or poorly controlled asthma, and those with severe or multiple allergies requiring medical intervention, are also at increased risk of HR to intravascular contrast media (moderate to high risk).

Many other previously proposed risk factors such as age less than 50 years, history of (controlled) asthma or chronic urticaria etc. are less consistent risk factors being low or very low risk and have poor discriminatory power in predicting HR to an intravascular contrast agent. Similarly, simply a history of allergy (e.g. atopy, asthma, drug/food allergies) is not a significant risk factor to predict HR to contrast agents. Thus, ascertainment of these previously cited factors is not recommended for screening individuals prior to contrast enhanced examinations. An additional point of note is that humans cannot be allergic to iodine which is vital to body functions and the term 'iodine allergy' is to be deprecated. Patients with prior NIHR are not at higher risk for an IHR (which are mediated by IgE or other mechanisms) upon re-exposure to CM since these NIHRs are produced through unrelated mechanisms (cell mediated etc.) and vice versa.

Similarly, hypersensitivity reactions to IBCM are not a significant risk factor for predicting reactions to GBCAs, and vice versa.

5.7 When HR relating to intravascular contrast do occur, they should be fully documented in accessible form in the patient record (and ideally in the report of the examination), informing the patient what that means as well as reporting it to the MHRA.

Documentation of Hypersensitivity Reactions [1,2,3]
Given that the strongest risk factor for future HR to contrast agents is prior reaction it is crucial that when these do occur the reaction incident is documented in detail. Documentation should include the contrast agent involved (trade and generic names), the date and time of the injection and subsequent reaction, the nature of the reaction (IHR versus NIHR), the severity of the reaction and the results of serial tryptase evaluations (for moderate and severe IHR). Patients and/or carers should be informed and future implications of HR explained. All suspected acute or delayed hypersensitivity reactions to contrast agents should be reported electronically via the MHRA website (https://yellowcard.mhra.gov.uk).

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6. Management of adverse reactions

Background

- Adverse drug reactions are a broad group of unintended effects that arise due to a drug's pharmacological properties and include hypersensitivity reactions.
- In this section we discuss the recognition and management of immediate and delayed hypersensitivity reactions following intravascular administration of iodine-based contrast media and gadolinium-based contrast agents, (IBCM and GBCA, respectively).
- There is an overlap between the features of hypersensitivity reactions and adverse effects due to other mechanisms, such as physiological reactions. We briefly discuss the features of physiological reactions for context and to aid in discrimination between the two types of reactions.

Classification of adverse reactions

Hypersensitivity reactions

- Hypersensitivity reactions to IBCM and GBCAs include immune-mediated adverse events. [1,2]
- Hypersensitivity reactions can be defined as immediate or delayed reactions, occurring within or more than an hour after contrast administration, respectively.

IBCM

- Hypersensitivity reactions to IBCM have decreased in incidence with the wider use of non-ionic low-osmolar and iso-osmolar contrast media over the historic ionic high-osmolar media, and with the use of lower doses. [1,20]
- The incidence of severe hypersensitivity reactions is particularly low with non-ionic monomeric low-osmolar agents; up to 0.02% following intravenous administration. [18]
- Reported rates of immediate reactions to low and iso-osmolar contrast media range between 0.3% to 1.4% of injections, and are most commonly mild or moderate reactions. Severe reactions are uncommon, occurring in up to 0.6% of injections. [1,9]
    - ***Optimise imaging parameters to minimise contrast dose. [1,10]***

- Fewer studies exist that exclusively assess the rate of hypersensitivity reactions after intra-arterial administration of IBCM. A systematic review [19] concluded that a difference in risk of hypersensitivity reactions between intravenous and intra-arterial route of administration was unclear.

GBCAs

- Hypersensitivity reactions to GBCAs are less common than reactions to IBCM and are usually mild when they do occur. [8,20]
- The incidence of acute hypersensitivity reactions of any severity was up to 0.4% in a large cohort study. [12] The incidence of delayed reactions was 0.04%.
- The incidence of hypersensitivity reactions varies with the type of GBCA used. Nonionic linear agents have the lowest rate of immediate hypersensitivity reaction compared to other classes. [11]

Immediate onset hypersensitivity reactions

The following signs and symptoms apply to both IBCM and GBCAs. [1,2]

- *Mild: signs and symptoms are self-limiting and non-progressive.*
    - Localised urticaria, pruritus, scattered hives.
    - Cutaneous oedema.

- Sensation of itchy or scratchy throat.
- Nasal congestion, sneezing, conjunctivitis, rhinorrhoea.

- *Moderate: signs and symptoms are more pronounced than for mild reactions, but vital signs are unaltered. Often require medical treatment and may become severe if untreated.*
  - Diffuse, rapidly-spreading urticaria, pruritus, erythema (>50% body surface area).
  - Facial angioedema without dyspnoea.
  - Throat tightness or hoarseness without dyspnoea.
  - Wheezing/bronchospasm, without hypoxia.

- *Severe: signs and symptoms are often life-threatening and can result in permanent morbidity or death without appropriate management; this includes anaphylaxis.*
  - Facial angioedema with dyspnoea.
  - Diffuse erythema with hypotension.
  - Throat tightness or hoarseness (laryngeal oedema) with stridor and/or hypoxia.
  - Wheezing or bronchospasm, with hypoxia.
  - Hypotension and tachycardia.
  - Systemic reaction involving two or more of above moderate symptoms (with or without altered vital signs).
  - Anaphylaxis. Most cases occur within 15 to 30 minutes; a shorter interval is associated with more severe reactions.[1,2] The presentation can be heterogenous, multisystemic and rapidly progressive.[4] Skin or mucosal involvement is not always present [20,4]. Consider this diagnosis if two or more of the following features are present [1,2]:
    - Involvement of skin or mucosal tissue or both (angioedema, urticaria, pruritus, flush).
    - Respiratory compromise.
    - Hypotension or symptoms of end-organ dysfunction.
    - Significant or persistent vomiting and/or severe diarrhoea.

Physiologic reactions

Signs and symptoms:

- *Mild:*
  - Limited nausea or vomiting.
  - Isolated flushing, warmth or chills.
  - Headache, light-headedness/dizziness, anxiety, or altered taste.
  - Mild hypertension.
  - Self-limiting vasovagal reaction.

- *Moderate:*
  - Protracted nausea or vomiting.
  - Hypertension.
  - Isolated chest pain.
  - Vasovagal reaction that requires (but is responsive to) treatment.
    - Usually distinguishable from anaphylaxis due to absence of skin or mucosal manifestations.
    - Typically preceded by bradycardia, whereas tachycardia is the typical feature with anaphylaxis.
- *Severe:*
  - Vasovagal reaction resistant to treatment.
  - Arrhythmia.

- Convulsions or seizures.
- Hypertensive emergency and/or symptoms of end-organ ischaemia.

Delayed reactions to intravascular contrast media

- These reactions occur between one hour and one week post-administration of intravascular contrast. [6]
- The incidence is hard to quantify because of delayed symptomatology, variable reporting and difficulty establishing causality. [1] However, delayed reactions are considered to be less common than acute reactions to both IBCM and GBCAs.
- Delayed reactions are estimated to account for up to 23% of all hypersensitivity reactions to IBCM [1] and 10% of reactions to GBCAs [12]
- Skin reactions are the most common manifestation and they are usually mild to moderate and self-limiting; case reports of severe skin reactions exist. [1,6] Skin reactions have an incidence of around 2% to 4% after the administration of IBCM [6]. Delayed skin reactions occur more commonly following the administration of nonionic dimers (e.g. iodixanol*: Visipaque*) compared with nonionic monomers.

Signs and symptoms [6]:

- Skin reactions; typically pruritus, maculopapular rash, erythema, swelling.
- Severe cutaneous reactions (such as Stevens-Johnson syndrome/toxic epidermal necrolysis) are rare. [7]
- Nausea or vomiting.
- Fever.
- Headache.
- Muscular pain.

Treatment

Mild/moderate immediate reactions

- Cease contrast administration.
- Monitor vital signs to assess for potential evolution into a more severe reaction.
- Observe the patient for 30-60 minutes to ensure clinical resolution and no deterioration with the vascular access maintained.
- Consider giving an oral antihistamine for mild urticarial reactions. In most cases, medical treatment is not required.

Severe immediate reactions including anaphylaxis

- Cease contrast administration.
- Give intramuscular adrenaline. Use 1 mg/ml (1:1000) adrenaline.
  - Give 0.5 ml to adults or teenagers over 50 kg.
  - Give 0.3 ml to patients aged 6 - 12 years, or those over 30 kg.
  - 0.15 ml to paediatric patients aged 6 months - 6 years.
  - 0.1 to 0.15 ml to paediatric patients aged less than 6 months.
  - Give 0.01 ml/kg to patients weighing 30 kg or less.
    Autoinjectors are also available *(see explanatory note 1)*.

- In severe cases further administration of adrenaline may be necessary; most guidelines recommend that adrenaline doses can be repeated every 5 to 15 minutes in anaphylaxis.
- Attach monitoring as soon as possible, including pulse oximetry, blood pressure and ECG leads (where possible). [4]

- Measure vital signs (heart rate, blood pressure, respiratory rate and oxygen saturations, level of consciousness) and auscultate for wheeze (where possible) to monitor treatment effect and assess if further adrenaline is required. [4]
- Give other treatment as necessary including fluid resuscitation and appropriate patient positioning (supine or Trendelenberg); supplemental oxygen *(see explanatory note 2)*.
- Monitor the patient until signs and symptoms have fully resolved, typically within an emergency department setting. [1] *(see explanatory note 4)*.
- Inform the patient of the possibility of biphasic reactions, where symptoms recur up to 72 hours after complete resolution of initial symptoms. [1]
- ***Measure serum tryptase levels after a moderate or severe immediate hypersensitivity reaction, ideally within 2 hours of reaction. [11] Compare this with a baseline level taken over 24 hours after full resolution of signs and symptoms (see explanatory note 3). [11, 20]***

Delayed reactions

- Manage late skin reactions symptomatically [6]. For example, with H1 antihistamines, topical corticosteroids and emollients.
- Do not extend monitoring beyond routine practice in patients with a history of prior delayed reaction [1].

Explanatory notes- treatment protocols section:

1. *Adrenaline autoinjectors are available in three doses of adrenaline, depending on the brand: 0.15 mg, 0.3 mg and 0.5 mg. [4] However, adrenaline administration by syringe and needle is preferred in the emergency setting to allow delivery of an age/weight appropriate dose. See UK resus council anaphylaxis guidance (https://www.resus.org.uk/library/additional-guidance/guidance-anaphylaxis) Antihistamines are commonly administered but there is only indirect evidence supporting this practice. Glucocorticoids have a slow onset of action and play no role in the acute treatment of anaphylaxis. [1,3] There is also no clear evidence that they prevent biphasic reactions. [5]*
2. *Serum tryptase levels are ideally taken immediately following a hypersensitivity reaction once patient stabilised, within 1-2 hours post onset, and then more than 24 hours later. [11] Comparison between post-reaction levels and the baseline level (after at least 24 hours) is used to support a diagnosis of anaphylaxis. A transient increase in tryptase levels is the most effective way for confirming an immediate hypersensitivity reaction.*
3. *Treat symptoms as a hypersensitivity reaction in the acute setting if there is uncertainty, and regularly reassess and respond to any changes in the clinical picture in all patients with hypersensitivity reactions.*

Post-reaction management

Documentation

- Document hypersensitivity reactions to contrast media in the electronic medical record and the radiology report.
- Ensure that the patient's GP is notified and, where feasible, that their NHS app (in England only), or equivalent digital health platform if residing outside England, is updated.
- Include the following details when documenting a hypersensitivity reaction to contrast media [1, 20]:
    - Location, time and date of administration.
    - Specific details of the inciting contrast agent, including name, dose (volume and concentration).

- Type (immediate versus delayed) and severity of the reaction.
- Signs and symptoms; what systems were involved, time of onset, evolution, duration.
- Reaction treatment, patient response and monitoring time.
- Which clinical staff were involved and what their roles were.
- Further steps, including clinical follow-up and advice regarding allergy specialist referral.

Confirming a reaction

- Evaluation by an allergist with skin prick testing and intradermal testing can facilitate the diagnosis of hypersensitivity reaction to a specific agent and aid in the selection of potential alternative contrast agents [1,21] *(see explanatory notes 1 and 2).*
- Skin testing is more likely to be positive following a severe reaction. [13] This particularly applies to reactions occurring within 6 months prior to skin testing because skin testing has a higher sensitivity within this timeframe. [16]
- Recommendations regarding skin testing in the context of prior immediate reaction vary between Europe and the United States [1]; European guidance [16] typically suggests performing skin testing in patients with a prior hypersensitivity reaction. This practice is not routinely followed in the US [1].
- Discussion around the limitations of skin testing is important, including the potential for a future reaction to a contrast agent, despite a negative skin test [1].
    - ***Consider referral to an allergist for skin testing against the inciting agent and a panel of alternative agents after a severe immediate reaction to IBCM or GBCA.***
- A role for skin testing following a mild or moderate reaction is debatable, particularly if imaging is postponed and there is a diagnostic/treatment delay, whilst awaiting assessment by an allergist.
    - ***Avoidance of the inciting agent in patients with prior mild or moderate immediate reaction is favoured over skin testing.***
- Decision-making around skin testing in the context of prior delayed, non-severe cutaneous reaction should be made on a case-by-case basis. The accuracy and validity of skin testing in this population is unclear. [1]
- Skin testing is potentially unsafe if there is a history of prior severe delayed cutaneous reaction. Joint input from dermatologists and immunologists/allergists is recommended.
- Serum tryptase levels can be assessed to aid in the diagnosis of hypersensitivity reaction after an immediate reaction. This is not generally performed after mild or delayed reactions.

Explanatory notes- Post-reaction management section:

1. *Referral to Allergy or Immunology services is recommended following severe hypersensitivity reactions for assessment and testing. This may aid in selecting an alternative contrast medium, with a low risk of cross-reactivity. Use of an alternative contrast medium is more effective and safer than premedication for preventing a recurrent reaction.*
2. *Skin prick testing is performed initially and intradermal testing used if skin prick testing yields a negative result. Intradermal testing may be less specific because it can have an irritant effect. [17] On the other hand, a negative skin test may be falsely reassuring, with some patients having a reaction after future contrast administration, despite a negative skin test result.*
3. *Serum tryptase levels are ideally taken immediately following a hypersensitivity reaction once patient stabilised, within 1-2 hours post onset, and then more than 24 hours later. [11] Comparison between post-reaction levels and the baseline level (after at least 24 hours) is used to support a diagnosis of anaphylaxis. A transient*

increase in tryptase levels is the most effective way for confirming an immediate hypersensitivity reaction.

Future imaging considerations

- Evaluate the history of prior reaction, including the severity and whether or not the diagnostic criteria for anaphylaxis were met. [1]
- Strongly consider alternative imaging modality; this should be the first line approach where there is a history of severe prior reaction. [1]
- Perform the study in a hospital setting during daytime hours with a rapid response team available, including personnel, equipment, and supplies to treat anaphylaxis (if no alternative imaging modality). [1]

If the inciting agent is known:

- Switch to an alternative IBCM or GBCA, if feasible. [1] This applies where there is a history of any hypersensitivity reaction to an IBCA *(see explanatory note 1)*, or a history of acute hypersensitivity reaction to a GBCA *(see explanatory note 2).*
    - ***Avoid contrast agents that have shown cross-reactivity on skin testing if skin testing has been undertaken. [6]***

If the inciting agent is not known:

- Give IBCM as per formulary where there is a history of mild or moderate hypersensitivity reaction.
- Refer to Allergy services for intradermal testing (IDT) where there is a history of severe reaction and there is no alternative imaging modality. [1]
    - ***Administer the IBCM with a negative IDT.***

- Consider switching agents on a case-by-case basis in patients with a history of mild to moderate delayed skin reactions. [1]
- Consider skin testing on a case-by-case basis in patients with a history of mild to moderate delayed skin reactions. [1]
- Avoid all IBCM in patients with a history of previous severe delayed skin reaction. [1]

Premedication

- Premedication refers to glucocorticoids with or without antihistamines [1]; antihistamines are used variably within premedication regimens in the literature.
- The risks and benefits of premedication need to be considered. There is no strong evidence supporting a role for premedication in preventing recurrent hypersensitivity reactions. [21]
- Premedication will not stop anaphylaxis occurring but may help to control more mild symptoms if they occur.
    - ***Routine premedication is not recommended in patients with a history of hypersensitivity reaction to IBCM and GBCA.***
    - ***Switch to a different IBCM or GBCA if the inciting agent is known and a different imaging study is not possible (see explanatory note 1).***
    - ***Premedication may be considered in specific emergency situations in patients with prior immediate severe hypersensitivity reaction.***

- Premedication is not recommended in the setting of prior delayed skin reaction to IBCM or GBCAs [6] *(see explanatory note 4)*.
- Premedication is **not recommended** in the following settings:
    - Patients receiving IBCM with a history of hypersensitivity reaction to a GBCA

- Prior physiologic reaction to intravascular contrast media (*see explanatory note 5).*
- Patients with a history of prior chemotoxic reaction.
- Patients with a history of shellfish allergy or topical iodine allergy.

Explanatory notes- Future imaging considerations section:

1. *If an alternative imaging study is not possible and the index contrast agent is known, a different contrast agent should be used. [1] This strategy is supported by studies showing that some patients with a history of reaction to a known agent and a positive skin test have a negative skin test result to other IBCAs. [14,15] Switching to a different IBCM is more protective against recurrent reaction than premedication. However, this may be logistically challenging, and the specific inciting agent may not be known. [21]*
2. *Switching to a different GBCA has been shown to have a preventative effect in patients with a history of acute hypersensitivity reaction, but not in patients with a history of delayed reaction.*
3. *There is no strong evidence supporting the use of corticosteroid and H1 antihistamines in the prevention of hypersensitivity reactions to IBCM and GBCAs. There is a low risk of direct harm, associated cost, diagnostic delay and patient inconvenience with arranging premedication. [21]*
4. *There is limited evidence supporting the use of premedication with corticosteroids in patients with prior delayed skin reaction. [6] The risk of harm from use of premedication is considered to be low however this will add cost and delays in addition to patient inconvenience.*
5. *Physiologic reactions do not require premedication because they are non-immune-mediated.*

Staff Training, Competence and Resuscitation Facilities

Services must operate within a safe, well-governed framework where risks are managed, and competent staff are immediately available to respond effectively to adverse events. These standards set the minimum requirements for safe, consistent, high-quality care in every setting [22].

Training and Competence

1. Departments administering intravascular contrast media must have robust, written procedures that clearly outline:
    a. Training requirements for all staff involved in the administration pathway
    b. Systems for maintaining accurate records of staff training, competence, and authorisation
    c. Audit processes to ensure compliance with governance standards and to support continuous quality improvement [22]

2. Recognised training must be appropriate to the individual's role and their level of responsibility within the contrast administration chain. This should include:
    a. Cannulation [23]
    b. Administration of intravascular contrast media [24] [25]
    c. Operation and safe use of automatic injectors
    d. Recognition and initial management of complications [26], including extravasation
3. All staff involved in the administration of intravascular contrast media must be trained to:
    a. Administer intramuscular (IM) adrenaline as first-line treatment for suspected anaphylaxis and follow the Resuscitation Council UK (RCUK) anaphylaxis

algorithm [27]

4. A safe level of clinical support must be maintained whenever intravascular contrast media is administered, this includes all community and satellite sites [28] [29] [30] [31] [32] As a minimum:
    a. At least one Immediate Life Support (ILS) [12]-certified staff member on site and immediately available at all times.
    b. Immediate on-site availability of a competent doctor or an enhanced/advanced practice radiographer trained to manage adverse events, including anaphylaxis (per RCUK guidance [33]) and significant extravasation.

Resuscitation Facilities and Preparedness

5. Resuscitation and emergency support must be appropriate for any area where intravascular contrast is administered. This requires:
    a. Immediate access to resuscitation equipment, emergency drugs and appropriate monitoring devices in all areas where contrast is given [22].
    b. Routine post-contrast observation in line with manufacturer guidance [35] and/or local risk assessment (commonly up to 30 minutes).
    c. Following suspected anaphylaxis, observation must follow RCUK 2021 risk-stratified guidance [34], rather than a fixed time.
    d. Clear and reliable escalation pathways [22] in every setting, with suitable facilities and staff available to support the patient until advanced help arrives.
    e. Availability of advanced support—either an on-site resuscitation team or an immediate paramedic response [36]—to continue emergency care and ensure safe, prompt transfer to an appropriate location

Governance, Protocols and Learning

6. Services must have robust systems to support the safe management of adverse events associated with intravascular contrast media [22]. This includes:
    a. Clear written procedures for managing minor and major hypersensitivity reactions, and extravasation [37], with defined escalation routes.
    b. Comprehensive documentation and reporting of adverse events and near-misses through local and national systems, with learning fed back via established clinical governance processes.
    c. Regular, structured simulation training to maintain system readiness, strengthen staff competence and confidence, and ensure a consistent and reliable team response across all settings where contrast is administered.

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7. Contrast-associated acute kidney injury (CA-AKI)

These recommendations aim to support safe, evidence-based use of iodine-based contrast media in adults with regards to renal function and acute kidney injury (AKI). This section does not apply to children or certain subpopulations, such as pregnant patients, for whom risks and evidence may differ. Please refer to the relevant sections for specific guidance.

7.1 Use standard AKI criteria to diagnose CA-AKI, typically characterised by rapid serum creatinine rise, non-oliguric presentation and normal urinalysis, after excluding other causes.

CA-AKI refers to sudden decline in kidney function, usually occurring within 24–48 hours of exposure to iodine-based contrast media during radiological investigations or procedures.[1] Typical clinical features include:

- Rapid onset: serum creatinine rise within 24 to 48 hours of iodine-based contrast media exposure, usually modest, peaking at 3-5 days and resolving within a week[2]
- Stable urine output: oliguria or anuria is uncommon, indicating that CA-AKI often presents as a less severe form of kidney injury[3]
- Normal urinalysis: findings are typically unremarkable, consistent with tubular injury rather than glomerular or obstructive causes[4]
-

Severity of CA-AKI should be staged using KDIGO AKI criteria, defined by any of the following[5]:

- Increase in serum creatinine ≥26.5 µmol/l within 48 hours
- Increase in serum creatinine ≥1.5 times baseline (which is known or presumed to have occurred within the prior 7 days)
- Urine volume <0.5ml/kg/h for 6 hours

7.2 Use the term "contrast-associated acute kidney injury" (CA-AKI) in preference to contrast-induced AKI to reflect the uncertainty around causality.

Kidney injury following iodine-based contrast media administration often occurs alongside other causes of AKI, such as acute illness, sepsis, hypovolaemia, heart failure and exposure to known nephrotoxic medications.[6-9] Many patients who develop CA-AKI have underlying chronic kidney disease (CKD) or other comorbidities that increase their susceptibility to kidney injury.[10] It is often not possible to determine whether contrast exposure is the primary cause of kidney injury or merely coincidental in patients already at high risk from other insults. This diagnostic uncertainty is compounded by the absence of a specific biomarker or pathognomonic clinical pattern distinguishing contrast-related injury from other causes. For this reason, terminology that emphasises association rather than causation is preferred, acknowledging that contrast may contribute to AKI but it is unlikely to be the sole determinant.[5]

7.3 Be aware that risk of CA-AKI varies with contrast medium, route and site of administration.

For iodine-based contrast media, observational and experimental evidence suggests a potential role in development of CA-AKI. However, precise mechanisms remain unclear[11,12], with proposed explanations including hypoxic injury to renal parenchyma and toxic effects on renal capillaries and tubules[13]. Risk appears higher with intra-arterial suprarenal or first-pass renal exposure than with intravenous or infrarenal intra-arterial administration, reflecting

combined haemodynamic and tubular mechanisms (vasoconstriction, medullary hypoxia and/or direct tubular effects).

Some older generation gadolinium-based contrast agents that are no longer available for intravascular general use in the UK were documented to be associated with nephrogenic systemic fibrosis (NSF)[14,15] but their role, if any, in CA-AKI remains inconclusive. Isolated case reports suggest a possible association, although interpretation is confounded by factors such as comorbidities and acute illness[16]. For this reason, the remainder of this section refers solely to iodine-based contrast media.

7.4 Administer iodine-based contrast media if the diagnostic benefit justifies its use, and do not delay emergency investigations or procedures while waiting renal function results.

The potential harm of missed or delayed diagnoses, such as aortic aneurysm rupture, pulmonary embolism or sepsis, generally outweighs the small absolute risk of CA-AKI. Decisions about iodine-contrast media administration should be made collaboratively by the radiology team and clinical referrer, based on their clinical judgement. Please refer to the section on legal mechanisms. Factors to consider include the patient's presentation, urgency of the investigation and likely impact on diagnosis or management.

Precautions may be applied for high-risk patients but should not prevent medically necessary investigations or procedures. Not using iodine-based contrast media solely to reduce the small risk of CA-AKI is unhelpful if the use of iodine-based contrast media would improve diagnostic accuracy.

In time-critical settings, such as stroke, major haemorrhage or trauma, priority should be rapid diagnosis and management. Delaying investigations or procedures to wait for laboratory results may worsen clinical outcomes. Monitoring and risk mitigation can be applied following any investigation or procedure, including checking kidney function after emergency scans in patients at risk of CA-AKI.

7.5 In the non-urgent setting, assess patient risk of CA-AKI prior to iodine-based contrast media administration.

For non-urgent investigations or procedures, there is usually time to review kidney function, comorbidities and hydration status. Risk assessment by the clinical referrer should be performed prior to the investigation or procedure. This may include reviewing serum creatinine or eGFR, history of kidney disease or kidney transplant, and other conditions that may susceptibility to kidney injury.

7.6 Be aware that risk of CA-AKI in patients receiving intravenous iodine-based contrast media with an eGFR greater than 30 ml/min/1.73m2 is very low or non-existent.

7.7 Be aware that risk of CA-AKI in patients receiving intra-arterial iodine-based contrast media is greatest at an eGFR less than 30 ml/min/1.73m2 but may be increased at an eGFR less than 60 ml/min/1.73m2 with additional risk factors (see table).

Intravenous contrast:

eGFR (ml/min/1.73m^2)	**Risk of CA-AKI**	**Notes**
≥45	Negligible	Not significantly increased, baseline risk only

30-44	Very low	Incidence: 16% (with contrast) vs 15% (without contrast)
<30	Increased	Incidence: 35% (with contrast) vs 14% (without contrast)

Intra-arterial contrast:

eGFR (ml/min/1.73m^2)	**Risk of CA-AKI**	**Notes**
≥60	Negligible	Not significantly increased, baseline risk only
<60 with significant albuminuria/proteinuria	Increased	62% (proteinuria >1g/day) vs 21% (proteinuria <1g/day)
<60 with diabetic nephropathy or other comorbidities*	Increased	Based on comorbidity associated increased risk[17]
<30	Greatest	31% of patients undergoing arteriography[18]

* Additional risk factors include the presence of diabetic nephropathy, hypovolaemia, heart failure, liver failure, medicines that alter kidney blood flow, and possibly myeloma

7.8 Be aware that risk factors and comorbidities, other than eGFR, are important in the overall risk assessment of CA-AKI.

Risk of CA-AKI is likely very low or negligible in patients with eGFR greater than 30ml/min/1.73m^2 receiving intravenous contrast or greater than 60 ml/min/1.73m^2 (without additional risk factors) receiving intra-arterial contrast. The greatest concern regards patients with eGFR below 30ml/min/1.73m^2, in whom the odds of developing CA-AKI after a single intravenous dose of iodinated contrast media range from similar risk to seven times higher than in patients with normal renal function, even though the absolute risk remains low. Evidence suggests that actively changing renal function, either rising or falling immediately prior to contrast administration, is an independent risk factor for AKI following iodinated contrast media administration.

7.9 Risk-benefit assessments should be undertaken prior to iodine-based contrast media administration and should be individualised.

NICE guidance offers a pragmatic approach to assessing individualised risk of CA-AKI

Step 1. The clinical referrer should discuss risks and benefits of the proposed tests and/or treatment that requires administration of iodine-based contrast media with the patient, and their family or carers if appropriate.

- Do benefits of the investigation outweigh potential risks?
- Are there other appropriate investigations that would avoid iodine-based contrast media exposure and have lower risk?
- Could the investigation or procedure be delayed until the patient is less acutely unwell?

Step 2. In the non-urgent setting, assess whether there is evidence of kidney disease before giving intravascular iodine-based contrast media.

Evidence of kidney disease might include:

a) In stable patients
   - eGFR from the past 6 months

b) In patients with an acute illness
   - A more recent eGFR reading

c) If no eGFR is available, is there a history of:
   - Known kidney disease or kidney transplant
   - Recent referrals to a specialist for assessment of kidney disease
   - Signs or symptoms of sepsis or another condition leading to hypovolaemia
   - Signs or symptoms of urinary retention
   - Other comorbidities such as diabetes, hypertension, heart failure, liver disease or myeloma

d) If these questions raise concerns, arrange assessment of eGFR before administering intravascular iodine-based contrast media; if there are no concerns then there is no need to measure eGFR before administering iodine-based contrast media.

e) Measurement of eGFR is not useful in patients with end stage kidney disease who are receiving dialysis treatment.

7.10 Avoid routine intravenous fluid administration. Consider intravenous fluid for patients at high risk of CA-AKI or when volume-depleted.

Most people can be managed with good oral hydration. Intravenous fluid replacement should be considered in patients at the highest risk of CA-AKI taking into account eGFR and additional risk factors or comorbidities (e.g. eGFR <30ml/min/1.73m^2 with significant comorbidities or AKI). Assessment of clinical fluid status is important. Intravenous fluid should not be given to patients who are fluid overloaded and caution exercised in patients who are at risk of fluid overload. Patients with evidence of fluid depletion should be rehydrated.

If intravenous fluid is indicated, isotonic solutions, such as 0.9% normal saline or sodium bicarbonate, should be given in accordance with NICE guidelines (https://www.nice.org.uk/guidance/ng148). This reflects the mixed evidence on whether intravenous sodium bicarbonate is superior to normal saline.[19-21] At present there is no consensus on duration of intravenous fluids but most sources agree that it should be started before the procedure and continued afterwards. An example IV hydration formula consists of 3ml/kg 0.9% sodium chloride over a duration of 1 hour just before exposure to IBCM, followed by 6ml/kg given over a duration of 6 hours soon after exposure.

7.11 Do not treat advanced kidney disease as an absolute contraindication to contrast-administration.

Patients with advanced kidney disease, including those receiving dialysis, may safely undergo investigations or procedures with iodine-based contrast media when clinically indicated. The procedure should be planned with consideration of iodine-based contrast medium dose, administration route, hydration status and post-procedure monitoring. For patients receiving dialysis therapy, dialysis is not required immediately following iodine-based contrast media administration.

7.12 Consider temporarily withholding renin-angiotensin-aldosterone system inhibitors (RAASi) in patients at increased risk of CA-AKI (e.g. eGFR <30 ml/min/1.73m2).

The decision to withhold RAASi temporarily remains controversial, similar to other situations where there is increased risk of AKI, such as in pre-operative patients with eGFR <30ml/min/1.73m^2. Common RAASi types include angiotensin converting enzyme inhibitors (ACEi) (e.g. ramipril), angiotensin receptor blockers (ARBs) (e.g. candesartan) and renin inhibitors (e.g. aliskiren). Consider temporarily withholding RAASi in patients with an increased risk, with eGFR <30ml/min/1.73m^2, especially if they have additional risk factors such as proteinuria (Albumin Creatinine Ratio (ACR) >30 mg/mmol or Protein Creatinine Ratio (PCR) >50 mg/mmol), diabetes, hypertension, heart failure, liver disease or myeloma. Decision to withhold RAASi should be made by the referring clinician (not the radiology team in isolation). When RAASi are withheld, there should be a documented plan by the referring clinician for their reintroduction, typically within one week of the IBCM administration, as these drugs are often integral to guideline-directed therapy for chronic conditions.

7.13 Do not routinely refer patients to nephrology prior to iodine-based contrast media administration. Reserve referral for patients at an increased risk such as patients with eGFR <30 ml/min/1.73m2 and additional risk factors, dialysis patients and kidney transplant recipients.

Most patients undergoing investigations or procedures with iodine-based contrast media agents do not need pre-emptive nephrology referral. Even when this is considered necessary, it should not delay urgent radiological investigation. Referral prior to any IBCM examination should be considered for patients at an increased risk of CA-AKI such as those with eGFR <30 ml/min/1.73m^2 and additional risk factors (such as acute illness, dehydration or likely requirement of high volume of intra-arterial IBCM). Patients with End-Stage Kidney Disease (ESKD) receiving dialysis should be discussed with a nephrologist. Some dialysis patients may have residual kidney function. Decisions regarding the use of iodine-based contrast media in these patients should be the responsibility of the nephrology team. Kidney transplant recipients should be discussed with a nephrologist if eGFR is <30 ml/min/1.73m^2 or there are other specific concerns.

7.14 Monitor kidney function after intravascular iodine-based contrast media administration based on risk of CA-AKI.

Patients at highest risk of CA-AKI (eGFR<30 mL/min/1.73m^2 with additional risk factors) should have eGFR checked the day after the investigation or procedure using iodine-based contrast media, with further monitoring if serum creatinine is elevated above baseline. Those with eGFR <30 mL/min/1.73m^2 but no additional risk factors, and who are clinically stable, should have eGFR rechecked within 72 hours of the investigation or procedure. For clinically stable patients with eGFR >30 ml/min/1.73m^2 there is no indication for routine monitoring of kidney function following intravascular iodine-based contrast media administration. Patients undergoing emergency investigations or procedures using intravascular iodine-based contrast media are typically acutely unwell, so renal function is likely being monitored as part of routine care; if not, we recommend checking renal function the day after the investigation or procedure. In each of these situations, monitoring should be individualised based on co-existing comorbidities and whether there is acute illness

7.15 Manage patients with CA-AKI according to standard AKI protocols (NICE, UKKA etc).

When AKI is detected following the administration of intravascular iodine-based contrast media, this should be investigated and managed in a similar way to anyone with AKI, following NICE NG148[22], UK Kidney Association Clinical Practice Guidelines for AKI[23] and local guidelines or care bundles. Investigation should include consideration of possible causes of AKI other than, or in addition to, intravenous or intra-arterial iodine-based contrast media. Management should include review of current and recent medicines (including over

the counter medicines), urinalysis, consideration of bladder outflow obstruction and consideration of imaging of the kidneys and urinary tract if AKI does not improve within 3 days or if the underlying cause of AKI remains uncertain.

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8. Metformin and Contrast Media

Metformin and gadolinium contrast agents

8.1 No special precautions are necessary when patients on metformin are given gadolinium-based contrast agents in the usual dose range of 0.05 to 0.3 mmol per kg of body weight[3].

Metformin and Iodine based contrast media – eGFR estimation

8.2 Outpatients taking metformin who are stable and not acutely unwell should have an eGFR estimation performed no more than three months before the administration of Iodine based contrast media.

8.3 Patients taking metformin who are inpatients or have AKI or an acute illness should have an eGFR performed in the 48 hours before the administration of Iodine based contrast media.

Metformin and Iodine based Contrast media given intravenously or intra- arterially with second pass renal exposure (contrast injected into the right side of the heart, the aorta below the renal arteries or intravenously)

8.4 Continue metformin in a patient with an eGFR of 30mL/min/1.73 m2 or more and no evidence of AKI or acute illness.

8.5 Stop metformin at time of procedure in a patient with an eGFR of less than 30mL/min/1.73 m^2, or who's recent eGFR is unknown, or who has AKI or acute illness.

Restarting metformin: in these circumstances notify the referring team to repeat eGFR after at least 48 hours have passed from the time of the examination and to consider restarting metformin provided eGFR is greater than 30mL/min/1.73 m^2. The manufacturers advise against the use of metformin in children and adults if eGFR is less than 30mL/min/1.73 m^2 in any case. The referring doctor should be informed.

Metformin and iodine based contrast media given Intra-arterially with first pass renal exposure (contrast injected into the left side of the heart or the aorta at or above the renal arteries)

8.6 Continue metformin in a patient with an eGFR of 60mL/min/1.73 m^2 or more and no evidence of AKI or acute illness.

8.7 Stop metformin in a patient undergoing an intra-arterial procedure with first pass renal exposure who has an eGFR less than 60mL/min/1.73 m^2, or who has AKI or is unwell.

Restarting metformin: notify the referring team to repeat eGFR after at least 48 hours have passed from the time of the examination and to consider restarting metformin provided the repeat eGFR demonstrates no decline in the pre procedure eGFR. The manufacturer advises against the use of metformin in children and adults if eGFR is less than 30mL/min/1.73 m^2. The referring doctor should be informed.

Metformin and risk of lactic acidosis

Metformin is widely accepted as a first line therapy for Type 2 Diabetes Mellitus although it may also be used in other insulin resistant conditions such as Polycystic Ovary Syndrome.

Metformin appears to inhibit hepatic glucose production from lactate resulting in lactate accumulation. Although Metformin has no direct nephrotoxic effect, it is cleared by the kidneys and therefore contrast associated acute kidney injury (CA-AKI) may result in an accumulation of Metformin and thus lactate.
Historical warnings regarding the use of contrast media in patients taking metformin did not distinguish between patients with differing degrees of renal impairment. Metformin induced lactic acidosis appears rare with an incidence of less than 10 events per 100,000 years of patient exposure1. There is a lack of clarity as to whether the metformin or co-existing conditions are at the root cause of the lactic acidosis2.

Developing knowledge has resulted in there being a wide range of conflicting recommendations in available guidelines on the use of contrast media in patients taking metformin3,4. Although two recent meta analyses have suggested that there is minimal risk in patients with eGFR of greater than 30mL/min/1.73 m^2 receiving IV contrast1,2, and the manufacturers advise against the use of the drug in any circumstances if the eGFR is less than 30 mL/min/1.73 m^2. There is still little clear evidence to base recommendations regarding intra-arterial contrast, particularly with first pass renal exposure, in patients with moderately impaired renal function 5,6.

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9. Other medical conditions and medication history to consider before the administration of intravascular iodine based contrast media (IBCM)

9.1 Asthma

9.1.1 The referring clinician should ensure they evaluate for the presence of asthma before requesting a scan they anticipate might require IBCM. If present, they should evaluate the level of control or severity of asthma (e.g. Asthma Control Test (ACT) - readily available online).

9.1.2 If there is moderate/severe or poorly controlled asthma (e.g. ACT <20), and the referrer deems a contrast-enhanced scan urgent, they should discuss the request with a Radiologist to evaluate whether another imaging modality may be performed. If IBCM is still required, a referral to Respiratory medicine should be made to optimise asthma control and/or aim to quantify the risk beforehand.

9.1.3 If a radiographer finds a patient reports a known diagnosis of asthma on pre-scan screening, they should escalate this to the supervising Radiologist or follow set protocols.

9.1.4 A patient with known asthma, having undergone a scan with administration of ICM, should remain in the department with the cannula in situ for at least 30 minutes. Resuscitation facilities, including nebulisers, must be readily available.

IBCM use increases the risk of bronchospasm in at-risk individuals with asthma. The risk of a reaction is highest in those with poorly controlled asthma [1]. Using low osmolar IBCM reduces the risk of a reaction. GBCAs for MRI are safe in patients with asthma and no special precautions are required.

9.2 Beta-adrenergic blockers

9.2.1 Beta blockers are not a contra-indication to IBCM or GBCA administration.

9.2.2 If anaphylaxis occurs administer IV glucagon 1-2mg IV over 5 minutes if the reaction does not rapidly respond to adrenaline in patients who take betablockers.

There is no significant increased risk of hypersensitivity reaction in patients on beta blockers following IBCM administration, however if a hypersensitivity reaction develops it is more likely to be moderate or severe, and the reaction rendered resistant to treatment with adrenaline. In such cases consider glucagon IV 1-2mg over 5 minutes if the reaction does not rapidly respond to adrenaline.

9.3 Dialysis

9.3.1 In anuric patients, no specific precaution is needed regarding IBCM administration[2].

9.3.2 In oliguric patients, or those that produce urine, an alternative imaging modality or the involvement of a nephrologist to plan post-imaging dialysis may be warranted to preserve any residual kidney function.

9.3.3 Do not recommend intravenous hydration without involvement of the Nephrology team.

9.3.4 Modern GBCAs are considered safe in standard doses in dialysis patients.

9.4 Drug reaction with eosinophilia and systemic symptoms (DRESS)

9.4.1 Those with a known history of DRESS relating to iodine based contrast should be referred to Allergy and Immunology services.

9.4.2 IBCM should be avoided in patients with a history of DRESS following administration of an IBCM, where no safe alternative has been identified and documented.

9.4.3 If a patient with a history of DRESS following IBCM is deemed to clinically require IBCM emergently, urgent consultant to consultant discussion between clinical referrer, Radiology and Allergy specialist (or an Intensivist with an interest in Immunology) is advised.

9.4.4 DRESS has also very rarely been recorded following GBCA use and in such a patient a similar approach as per IBCM is advised.

DRESS is a rare T-cell mediated (usually delayed – i.e. weeks) hypersensitivity drug reaction, which manifests as a severe cutaneous response with associated eosinophilia, lymphocytosis, fever, lymphadenopathy and at least one organ involvement. This can be life-threatening.[3]

Diagnosis is aided by use of the RegiSCAR criteria. It can be supported by skin biopsy. Treatment involves removal of the causative agent and corticosteroid therapy. Skin-testing Under specialist supervision can help identify non-causative IBCM.

9.5 Homocysteinuria

9.5.1 If a patient known to have homocysteinuria is referred for IBCM enhanced examination, consider an alternative modality or non-contrast imaging if appropriate.

9.5.2 If IBCM is obligated following discussion with a consultant Radiologist, the referrer should establish the patient's serum homocysteine levels.

9.5.3 Serum homocysteine <30mmol/L: no precautions are necessary. Serum homocysteine >30mmol/L: pre-hydration is advised (oral water if eGFR >60mL/min/1.73m2; or IV 0.9% sodium chloride if eGFR< 60mL/min/1.73m2).

Homocysteinuria is a genetic disorder of protein metabolism, leading to build up of homocysteine. Clinically, this can lead to cardiovascular, cerebrovascular, thromboembolic and osteoporotic disease. Treatment is usually with B6, folate and B12 vitamin supplementation and dietary protein restriction[5].

There is association of elevated levels of homocysteine with risk of contrast-associated AKI[6]. That risk rises with homocysteine level making the knowledge of recent homocysteine blood levels important.

Patients with homocystinuria will normally be under the care of a regional specialist and receive regular monitoring of blood levels (e.g. every 6 months where <15mmol/L is normal, 15mmol/L - 30mmol/L is mildly elevated, 30mmol/L - 100mmol/L is moderately elevated, and >100mmol/L is severely elevated).

9.6 Interleukin-2 therapy

9.6.1 Interleukin-2 (IL-2) therapy is not a contra-indication to IBCM administration.

9.6.2 Current or recent IL-2 therapy within the last 6 months: a period of 30 – 60 minutes observation in the Radiology department with a cannula in situ is advised. Counsel for possible mild increased risk of delayed hypersensitivity reaction.

Interleukin-2 therapy is linked to a slightly higher incidence of delayed severe hypersensitivity reactions to IBCM[7] and patients should be cautioned about that small risk. No specific precautions are required. Modern GBCAs do not carry increased risk.

9.7 Multiple Myeloma

9.7.1 If the patient is adequately hydrated, eGFR >45mL/min/1.73m2, and not hypercalcaemic, no precautions before the administration of IBCM are necessary.

9.7.2 Hypercalcaemia and/ or dehydration should be corrected before the administration of IBCM.

9.7.3 If eGFR <45mL/min/1.73m2, pre-hydration (oral water or IV 0.9% sodium chloride) should be considered.

9.7.4 There is no need to check paraprotein levels or proteinuria before administration of IBCM.

9.7.5 GBCAs used for MRI have not been associated with adverse events and thought safe to use in patients with myeloma.

Hypercalcaemia can accelerate acute kidney injury in monoclonal gammopathy and/or Multiple Myeloma patients exacerbated by the administration of IBCM[8].

9.8 Myasthenia gravis

9.8.1 If indicated and no alternative modality is feasible (e.g. MRI with GBCA), IBCM may be administered in patients with myasthenia gravis in a hospital environment where resuscitation facilities and critical care is immediately available.

Patients should be counselled that there is a low risk (~5%) of worsening of their symptoms (including breathing difficulties) within the following 24 hours and should be discharged with a responsible adult[9].

9.8.2 Consider observing the patient in the Radiology department for at least one hour following scan completion.

The risk of worsening of symptoms relating to myasthenia gravis following IBCM administration is low, and in delayed cases this is usually attributable to an acute deterioration in the patient's health state[10].

Rare cases have been reported of acute respiratory arrest, requiring intubation, 1-2 hours following ICM administration.

Please refer to MGFA classification for more information regarding clinical features of myasthenia gravis.

Modern GBCAs are safe for use in patients with myasthenia gravis.

9.9 Phaeochromocytoma

9.9.1 IBCM are safe when administered intravenously in patients with phaeochromocytoma and do not precipitate hypertensive crisis regardless of whether the patient is on treatment [11]. Therefore, there is no need to avoid the use of IBCM for CT in these patients.

9.9.2 Direct IBCM injection via catheter into adrenal or renal arteries or veins may precipitate a hypertensive crisis and should therefore be avoided in patients with known phaeochromocytoma, unless the patient is appropriately treated with alpha +/- beta blockers[12].

Phaeochromocytoma can secrete catecholamines and may lead to hypertensive crisis which can be life threatening.

No specific precautions are required prior to intravenous administration of IBCM in patients with suspected phaeochromocytoma. Modern GBCAs are safe to use in patients with phaeochromocytoma.

9.10 Renal-angiotensin system inhibitors (RASi)

9.10.1 In outpatients with stable eGFR >30mL/min/1.73 m2, there is no need to stop ACE inhibitors or angiotensin 2 receptor blockers prior to intravascular IBCM administration.

9.10.2 In those considered at high risk of deterioration in renal function (in-patients, eGFR <30mL/min/1.73 m2, Acute Kidney Injury, need for large contrast volumes), discuss with the clinical team responsible for prescribing the RASi medication. Do not cease the RASi without a discussion, which must include a clear plan for restarting any paused RASi.

9.10.3 GBCAs used for MRI are thought safe to use in patients on RASi therapy.

RASi administration is not thought to increase the risk of contrast associated AKI in stable CKD stage 3 and 4 patients[14]. The decision regarding withholding RASi prior to intravascular ICM administration should not be undertaken by the Radiology team independently, as there are risks to stopping (and not stopping) these medications including precipitating heart failure, rebound hypertension and acute kidney injury[15]. No precautions are required for GBCAs.

9.11 Sickle cell disease

9.11.1 If indicated, and no other modality or non-contrast imaging is feasible, low or iso-osmolar IBCM can be administered.

9.11.2 Patients should be counselled about the potential small risk of increased pain or crises relating to sickling of red blood cells following IBCM administration.

9.11.3 Consider input from the Haematology team before the scan takes place (OP referral or on-call, depending on urgency).

9.11.4 Consider observation in the Radiology department for an hour following scan completion.

9.11.5 GBCAs used for MRI have not been associated with precipitation of sickle cell crisis and thought safe to use in sickle cell patients.

High osmolar IBCM are linked to higher risk of vaso-occlusive sickle cell crises due to increased sickling of erythrocytes. This is not frequently observed with low osmolar agents, with a risk profile of adverse events, including contrast nephropathy, similar to that of the general population[9]. Gadolinium based contrast agents do not carry increased risk of sickle cell crises.

9.12 Severe liver impairment

9.12.1 There is no evidence of contra-indication to IBCM (or modern GBCA use) in patients with severe liver impairment or who are undergoing transplant assessment[18,19].

Liver specific GBCAs (e.g. gadoxetate (Primovist) and gadobenate (MultiHance)) can still be used provided the lowest effective dose is used and dosing intervals as per SPC are respected[20].

9.13 Thyroid disease

Euthyroid

9.13.1 Routine ascertainment of thyroid function prior to and monitoring of function post IBCM administration is not recommended.[21]

Hyperthyroid:

9.13.2 Use of iodine based contrast media in untreated hyperthyroidism, is not recommended and alternative modalities should be used until the patient is investigated and treated.

If the scan is urgent and IBCM obligated, liaison with an Endocrinologist is advised. If there is no one immediately available to advise, and the Consultant Radiologist and Consultant Clinical referrer deem the contrast enhanced scan necessary, contrast can be given. The patient should be referred to Endocrinology by the clinician that requested the examination (on an outpatient basis) and that should be reflected in the radiology report.

9.13.3 In subclinical or treated hyperthyroidism, IBCM are not contra-indicated, but it is recommended that thyroid function tests are monitored more frequently (e.g. in General Practice).

Specialist Endocrinology input may be required in cases where repeated IBCM enhanced examinations are likely over months or years (e.g. cancer follow-up imaging).

9.13.4 The use of prophylactic agents (propylthiouracil or carbimazole/methimazole) to prevent thyrotoxicosis after the administration of IBCM is not advised.[1]

Hypothyroid

9.13.5 Untreated and subclinical hypothyroidism are not contra-indications to IBCM, however, post-administration thyroid function testing may be considered.

9.13.6 No monitoring is advised in treated hypothyroidism (e.g. those taking Levothyroxine).

Radioisotope imaging and treatment

9.13.7 Avoid IBCM in Patients who will be having radioisotope imaging of the thyroid or radioactive iodine treatment (including for thyroid cancer). Consider another imaging modality (e.g. MRI).

Most cases of IBCM-induced hyperthyroidism may not need treatment, unless there is chronic autoimmune thyroiditis, pregnancy or planning for pregnancy, or in young, symptomatic patients.

IBCM can prevent radioisotope thyroid uptake for up to 8 weeks. MRI is the preferred staging modality in thyroid cancer patients.

No precautions are required before administration of modern gadolinium-based contrast agents (GBCAs) in patients with thyroid disease.

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10. Gadolinium-based contrast agents (GBCAs) – specific considerations

Please note: This is UK guidance and applies for GBCA used in the UK

There are six GBCAs currently authorised for intravenous use in the UK:

General intravascular use Macrocyclic GBCAs:

- Gadoteric acid (Dotarem®,Clariscan®)
- Gadoteridol (ProHance®)
- Gadobutrol (Gadobutrol®)
- Gadopiclenol (Elucirem®, VueWay®)

GBCAs authorised specifically for liver imaging if required:

- Gadobenate dimeglumine (MultiHance®)
- Gadoxetate disodium (Primovist®)

10.1 Screening for kidney disease is no longer thought justifiable or cost-effective in adult patients scheduled for GBCA enhanced MRI with the modern available agents in approved doses and hence routine eGFR testing is no longer recommended.

Risks of Contrast-Associated Acute Kidney Injury (CA- AKI)
Although GBCAs are experimentally nephrotoxic when used in equimolar doses to iodine-based contrast media (IBCM) they are used in much lower doses than ICM and there is no known clinically significant risk of CA-AKI following their administration in clinically recommended doses.

Nephrogenic Systemic Fibrosis (NSF)
NSF was an extremely rare, but debilitating, painful and, in a small percentage of cases, potentially fatal disease first identified in 1997. The cause of NSF remains not fully understood but the consensus is that it was associated with the administration of linear chelate GBCAs in severely renally impaired patients (end-stage-kidney disease or on dialysis), especially with high dose and/or repeated examinations. Those linear chelate GBCAs that were associated with development of NSF have not been available for intravascular use in Europe since 2018. The only linear chelate GBCAs available in Europe now are those specifically suited to liver imaging (gadobenate and gadoxetate) for which these compounds remain licensed, furthermore these particular GBCAs have not been associated with NSF. In the modern era in Europe only macrocyclic chelate GBCAs are licensed for general intravascular use and NSF has not been observed to occur in relation to unconfounded administration of these agents, regardless of renal functional status. Hence the need for any specific precautions prior to the use of authorised modern GBCAs in approved doses has been called into question.

10.2 GBCA enhanced examinations may be performed without any specific patient informed consent.

Renal function and consent
The need for knowledge of a patient's renal functional status when considering GBCA use has historically related to risk stratification in regard to the prevention of NSF rather than CA-

AKI. Given the lack of evidence that the use of macrocyclic GBCAs is associated with development of NSF then screening for renal disease is no longer thought justifiable or cost-effective and hence no longer recommended. Furthermore, GBCA enhanced examinations may be performed without any specific patient informed consent.

10.3 When patients are scheduled for GBCA enhanced MRI and an iodine-based contrast examination (e.g. CT or invasive angiography) on the same day then the MRI should be performed first (with the exception of renal imaging with CT urography). Consider a waiting time of 2 hours between the examinations in the elective setting.

Combining examinations with IV administered contrast media (MRI and CT or invasive angiography)

The short-lived effect of GBCA enhancement (in terms of x-ray attenuation) and the low doses used for MRI mean that there will be little if any impact on subsequent x-ray based examinations (e.g. CT) aside from enhancement of the renal collecting systems, ureters, and bladder. Conversely, there is evidence that the effects of iodine-based contrast media are longer-lived and more disturbing on subsequent contrast-enhanced MRI with a shortening effect on T1 and T2 times, with an increase in T1 signal and a decrease in T2 signal. Therefore, contrast enhanced MRI with a gadolinium-based agent should be performed before contrast enhanced CT (or invasive angiography) with an iodine-based contrast medium when both are to be performed at the same attendance due to the potentially confounding effects of IBCM on MRI studies, except in the case where CT urography is required when CT is best performed before MRI. To minimise the interference of gadolinium on x-ray based examinations and the disturbing effects of IBCM on MRI a waiting time of 2 hours between examinations is suggested unless in an emergency situation when shorter waiting times are employed relative to the clinical urgency. In these circumstances, there should be direct discussion between the referring clinician and the radiologist.

10.4 Following a single dose of GBCA a further dose within 30 minutes of the first injection may usually be performed when indicated.

Multiple GBCA Injections

On rare occasions patients may require more than the anticipated GBCA dose on attending for MRI in order to ensure a diagnostic examination. For example, there may have been a contrast extravasation, issues with timing for cardiovascular studies, patient movement, clinical deterioration or technical failure. Firstly, check the summary of product characteristics (SPC) for the GBCA in question. With the use of modern agents a second dose within 30 minutes of the first injection may usually be performed. Out with this, any additional dosing at that attendance would be at the discretion of the supervising imaging clinician and dependent upon indication and patient factors.

10.5 When there is a very strong indication for enhanced MRI during pregnancy, the smallest possible dose of GBCA consistent with a diagnostic scan should be used. Following administration of GBCA to the mother during pregnancy, no specific neonatal tests are necessary.

Administration during Pregnancy

Exposure to MRI during the first trimester of pregnancy compared with non-exposure to MRI is not associated with increased risk of harm to the foetus or in early childhood. In the largest study available exposure to gadolinium-enhanced MRI at any gestation was not associated with a greater risk of congenital anomalies. However, in this study contrast enhanced MRI

using GBCAs at any time during pregnancy was associated with an increased risk of a broad set of rheumatological, inflammatory, or infiltrative skin conditions in infancy, and for stillbirth or neonatal death (adjusted HR of 1.36 for any rheumatological, Inflammatory or infiltrative skin condition up to age 4 years, and an adjusted RR of 3.70 for still birth or neonatal death). However, this was with very few events in the gadolinium MRI exposed group. Although propensity score matching was used to reduce confounding by indication bias there was still potential bias since the pregnant patients undergoing contrast-enhanced MRI will have had the scans for perhaps more significant maternal medical conditions, leading to an increased chance of confounding by indication compared to non-contrast-enhanced MRI. Along with other potential causes of statistical error the authors cautioned that the findings should be considered exploratory. Hence, when there is a very strong indication for enhanced MRI during pregnancy, the smallest possible dose of GBCA consistent with a diagnostic scan should be used and no specific neonatal tests are necessary.

10.6 For a breastfeeding patient no special precaution or cessation of breastfeeding is required.

Administration during Breast Feeding

Only a very small percentage of the injected dose of GBCA enters the breast milk and virtually none is absorbed across the normal gut. No special precaution or cessation of breastfeeding is required.

10.7 Although there are no documented harms in regard to the phenomena of gadolinium retention or anthropogenic environmental gadolinium, GBCA enhanced MRI should always be performed with the lowest dose for the patient consistent with a diagnostic scan.

Gadolinium Retention

Trace amounts of gadolinium can be shown as being retained in the body (bone, liver, skin and brain) following contrast-enhanced MRI. This occurs independent of renal function and may occur after any agent. However, greater amounts are retained after non-ionic linear chelate GBCAs (no longer available in Europe). It is not known whether the detected gadolinium remains chelated. Bone and liver retention do not produce clinical symptoms, and no relevant neurological symptoms have yet been confirmed. Nevertheless, using the precautionary principle: *the lowest dose of GBCA that will result in a diagnostic scan should always be used*.

Anthropogenic Gadolinium

Highly stable GBCAs are difficult to remove in wastewater treatment plants and hence trace amounts of gadolinium can be shown in the environment, in groundwater and municipal tap water - especially in metropolitan areas in countries with highly developed health care systems. There are no related health risks known, but the potential long-term effects of population exposure to low doses have not been studied.

10.8 No specific precautions required in patients in the peri-operative liver transplant period with use of the modern available GBCA in approved doses.

No evidence to support any extra specific precautions when administering GBCA to patients in the peri-operative liver transplant period with use of the modern available GBCA in approved doses. As with all patients use the single lowest gadolinium dose possible consistent with a diagnostic scan.

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11. Pregnancy and breastfeeding special considerations

Pregnancy

11.1 The use of intravascular IBCM and GBCA in pregnancy is not contraindicated if absolutely indicated for the benefit of maternal and/or foetal health. If used the lowest effective contrast dose should be given.

11.2 Be aware that iodine based contrast media crosses the blood–placental barrier but no evidence to suggest that IBCM administered at any time in pregnancy causes significant harm to the foetus.

11.3 Be aware gadolinium based contrast agent used in MR imaging crosses the blood-placental barrier. No evidence of harm to the foetus has been shown but due to the lower level of evidence in comparison to IBCM they are best avoided, particularly in the first trimester (1). (see gadolinium section)

11.4 In all cases firstly consider use of non-contrast imaging or alternative imaging modality when feasible.

There is a potential risk of neonatal hypothyroidism following intravascular IBCM administration due to the iodine content and therefore heel prick testing during the first week of life should take place (this is routine in the UK).

Breastfeeding

11.5 Breastfeeding can continue after intravascular IBCM and GBCA administration with no change in breastfeeding routine required (2).

A very small percentage of the injected dose for both IBCM and GBCA enters the breast milk but virtually none is absorbed across the gut of the infant with no evidence of risk to the breast fed child (2).

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12. Paediatric considerations

Gadolinium based Contrast Agents (GBCA):

12.1 Benefit of use must outweigh the risks:

a. **In surveillance imaging the use of contrast should consider the baseline appearances of the disease.**
b. **Always consider the diagnostic value of post gadolinium imaging.**

12.2 In cases of known impaired renal function or acute kidney injury consider non-contrast imaging/alternative imaging modalities and/or consult a Paediatric Nephrologist.

12.3 Where gadolinium is required for diagnosis: use macrocyclic GBCA authorised for general intravascular use or GBCA authorised specifically for liver imaging [1].

12.4 Newer macrocyclic gadolinium contrast agents are becoming available that allow the same enhancement effect at lower doses of Gadolinium and, where licensed, should be considered for a paediatric population.

12.5 Use weight based doses (Appendix 3).

12.6 Avoid double doses of GBCA.

Iodine Based Contrast Media (IBCM):

12.7 Use Non ionic, low osmolar IBCM.

12.8 Use weight based doses (Appendix 3).

12.9 Warm contrast as per product SPC to reduce viscosity and allow injection of contrast through narrow bore cannulas [2].

12.10 Where clinically appropriate, dilute contrast with normal saline to reduce viscosity when performing vascular procedures with contrast.

12.11 Manual injection is preferable over pump injection, particularly when injecting through a small bore cannula [2].

12.12 Use appropriate rates of injection and adjust the timing of the scan to reflect low flow rates (Appendix 4) [2].

12.13 Central line can be used via hand injection of contrast by authorised personnel only.

12.14 Consider the risk of Contrast Associated Acute Kidney Injury (CA-AKI) particularly in patients with:

a. **Renal insufficiency or chronic renal disease**
b. **Current AKI**
c. **Patients receiving multiple doses of IBCM over a short period of time**
d. **Inadequate hydration**

12.15 Children should be advised to drink sufficiently during the day prior to the imaging study and on the day of the imaging study even without known renal impairment.

12.16 In cases of known impaired renal function or acute kidney injury consider non-contrast imaging/alternative imaging modalities and/or consult a Paediatric Nephrologist.

Special considerations: neonates, preterm infants, small children

12.17 Neonates and premature infants have immature renal function, reducing clearance of both iodine and gadolinium based contrast media; dose adjustments and increased caution are essential.

12.18 Unless urgent, delay contrast-enhanced studies until renal maturity improves.

12.19 Use manual injection rather than power injector in very small infants to avoid excessive flow pressure or vascular injury.

12.20 Monitor more intensively post contrast media administration: vital signs, renal function, volume/hydration status.

12.21 In neonates, the threshold for the use of intravascular contrast media should be higher than in older patients and alternative/non-contrast imaging modalities (e.g. ultrasound, MRI without contrast) should always be considered.

12.22 For management of hypersensitivity reaction please see the section on adverse reaction.

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Further evidence and reading

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13. Environmental considerations and sustainability

13.1 Services should consider the carbon footprint of their contrast media supply and disposal chain as part of the procurement/tender process to encourage carbon neutral strategies

- **a. While this will not be the prime driver for selection of a contrast media supplier it should feature as part of the tender to signal to suppliers that services are interested in those with low carbon footprints**

13.2 Services should appoint a sustainability champion/lead to focus on improving the sustainability of contrast media delivery

13.3 Services should involve all relevant staff in adopting a greener approach to contrast media administration

13.4 Services should review the use of single use items and identify where more sustainable alternatives could be used e.g. single use tourniquets, plastic glove use

13.5 Services should plan for and deliver contrast media using multi dose, large volume supplies and equipment where possible

- **a. See SPS guidance (https://www.sps.nhs.uk/articles/administration-of-contrast-agents-under-a-pgd-by-multiple-hcps/) for managing multi dose machines**

13.6 Services should identify and develop local recycling opportunities for containers and equipment used in contrast media administration

13.7 Services should identify a route to recycle unused contrast media

13.8 Services and networks should harmonise and optimise examination/imaging protocols to ensure that contrast is only used when absolutely necessary.

13.9 Services should ensure that contrast agent protocols apply best practice/weight based dosing

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Appendix 1: Legal mechanisms for contrast media prescribing and administration by profession

Profession	Can prescribe contrast media independently	Can prescribe contrast media as a supplementary prescriber with a clinical management plan	Can administer contrast media under a Patient Group Direction.	Can administer contrast media using a Prescription or Patient Specific Direction.	Can administer contrast media under Exemption in Regulation 240 of the Human Medicines Regulations [1]
Doctor	On registration[2]	No	No	Yes[2]	N/A
Diagnostic radiographer	No	Yes, With post-registration qualification and HCPC annotation, and within their scope of practice[2]	Yes	Yes	Yes
Therapeutic radiographer	Yes With post-registration qualification and HCPC annotation, and within their scope of practice[2]	Yes With post-registration qualification and HCPC annotation, and within their scope of practice[2]	Yes	Yes	Yes
Registered nurse	Yes With post-registration qualification and NMC annotation, and within their scope of practice[2]	Yes With post-registration qualification and NMC annotation, and within their scope of practice[2]	Yes	Yes	No

Non-registered staff	No	No	No	Yes	Yes When entitled as IR(ME)R operators and authorised for the NM procedure

[1]if entitled as an operator in the Nuclear Medicine Employers' Procedures and working on the authorisation of an ARSAC licence holder to a written protocol

[2] May prescribe and administer directly when fully registered. Provisionally registered doctors (F1) require supervision when prescribing

Explanation

Doctors, on full registration, have broad authority to prescribe, supply, and administer all Prescription Only Medicines

They can

- Prescribe and administer contrast agents directly.
- Create Patient-Specific Directions/prescriptions (PSDs) for others to follow,
- Clinically sign PGDs
- Administer medicines to save a life in an emergency.
- Foundation year 1 doctors require supervision in prescribing

Radiographers and registered nurses, can complete further training to

- administer intravenous contrast media
  - follow a Patient-Specific Direction (PSD) written by a prescriber
  - use a Patient Group Direction (PGD) when trained and authorised to do so.
- Write a Patient Specific Direction (PSD) or prescription if annotated as a supplementary prescriber working under a clinical management plan where this falls within their Scope of Practice
- administer certain medicines to save a life in an emergency (Reference to Schedule 19: https://www.legislation.gov.uk/uksi/2012/1916/schedule/19)

Therapeutic radiographers and registered nurses can also

- write a Patient Specific Direction (PSD) or prescription if annotated as an independent prescriber and this is within their scope of practice

Staff not on a statutory register, such as sonographers not otherwise statutorily registered, nuclear medicine technologists, supportive and assistive staff, can be trained and authorised to

- administer contrast media using a PSD
- administer contrast media under a legal exemption for Nuclear Medicine examinations
- administer certain medicines to save a life in an emergency.

Appendix 2: Expanded explanation of legal mechanisms

Patient Group Direction

A PGD allows authorised staff to administer contrast agents to patients without individual prescriptions, provided the conditions outlined in the Patient Group Direction (PGD) are met. They are not a form of prescribing.

In 2017, NHSE commissioned The Specialist Pharmacy Service to develop template PGDs for contrast agents to support radiology service delivery and remove unwarranted variation. Services must verify that PGDs are appropriate, legal, and that relevant governance arrangements are in place before development. The relevant organisation must authorise the PGDs.

- The lead doctor and pharmacist (who are the signatories)
  - should be senior professionals who consider the clinical service in which the PGD will be used
  - During PGD development, provide clinical advice and support, guiding the feasibility of options for clinical care and adherence to clinical guidelines.
  - Share joint responsibility and accountability for the accuracy of both clinical and pharmaceutical content of the PGD which should be clear and specific.
  - ensure the PGD is safe and appropriate for a predefined group of individuals within agreed-upon parameters.
  - are also responsible for ongoing clinical advice and support once the PGD is in practice, following audits and during PGD reviews.
  - Should involve a representative from the professional group using the PGD during development and when signing.

The authorised radiographer or registered nurse:

- Is responsible for
  - assessing the patient and ensuring they fully meet the inclusion criteria to have contrast media
    - Deviations from the PGD are permitted.
  - Referring patients as per PGD's referral advice if criteria are not met (usually to a radiologist).
- can only administer the specified medicine, formulation, and quantity in the PGD, (can be linked to imaging protocols.)
- cannot use clinical judgment to administer medicines outside the criteria.
- cannot delegate any aspect of the administration
  - The entire episode of care, including patient assessment, preparation of the contrast media, and administration, must be undertaken by one radiographer or one registered nurse operating under the PGD.
- When using a PGD for Multi-dose devices
  - set up must be by a radiographer authorised to use the PGD
  - is responsible for assessing the patient and administering the contrast media as per the relevant PGD.
  - During setup, must document according to local guidance:
    - Details of the contrast/sodium chloride loaded.
    - Date and time of loading.
    - Batch numbers and expiry dates.
    - Confirmation that infection prevention and control (IPC) procedures have been followed.

- Ensure that no other personnel, such as radiography assistants, assist in setting up the multi-injector device
- must check all related records if they take over the administration during an imaging session
  - The correct contrast/sodium chloride has been loaded.
  - It is within the permitted timeframe for use.
  - IPC procedures have been followed.
  - Appropriate patient consent has been obtained.
  - Records are completed.
- check all processes are verified, before they administer the contrast/sodium chloride under the relevant PGD.

It is good practice to involve local drug and therapeutics committees, area prescribing committees, and similar advisory bodies in PGD development. Cross-organisational service delivery requires careful consideration of all aspects of the medicines chain, with particular attention paid to staff competence and training, authorisation, and continuing professional development (CPD). NHS-commissioned PGD templates for contrast media developed by the Specialist Pharmacy Service and endorsed by the RCR and SoR are available.

- **PGDs should be put together by a multi-disciplinary group including a doctor, a pharmacist and a representative of any professional group expected to supply the medicines under the PGD.**
- **Organisations should ensure that they understand PGD requirements for their sector and location e.g. independent sector providers delivering NHS services or devolved countries**
- **PGDs developed for use in complex commissioning scenarios should be supported by robust governance processes and memoranda of understanding**

References

Authorising and preparing to use a PGD
Authorising Independent Healthcare Provider (IHP) PGDs
Patient group directions: who can use them
Competency framework for health professionals using patient group directions:
Implementing the NICE guideline on patient group directions (MPG2)
https://www.nice.org.uk/guidance/mpg2
Understanding roles and responsibilities of PGD signatories
SPS radiology template PGDs
PGD use in services provided by multiple organisations

Administration of contrast agents under a PGD by multiple HCPs

Prescription/Patient Specific Direction (PSD)

While not defined in legislation, a PSD is a written instruction signed by a prescriber for medicines to be supplied and/or administered to a named person. The prescriber must have individually assessed the person. Legislation states that all POM medications, such as intravenous contrast media, must have a written direction for administration.

A PSD is required for contrast media

- where a patient doesn't meet the criteria for administration using a PGD,
- there is no PGD in place

- where the healthcare professional administering the contrast media is not authorised to use the PGD.

Legal Exemptions

Exemptions are exceptions to the general rules on selling, supplying and/or administering medicines for some groups of healthcare professionals. Schedule 19 for emergency medicines is one such exemption, as is the provision in Regulation 240 of the Human Medicines Regulations 2012 [18] for IR(ME)R operators to administer prescription-only medicines (POM) required as part of nuclear medicine procedures.

Rights reserved for Emergencies

The law permits certain medications to be administered by injection in an emergency. This exemption applies to anyone, regardless of their profession or registration status. A list of medicines subject to this exemption can be found in Schedule 19 of the Human Medicines Regulation 2012 and includes adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis.

References

Professional guidance on the safe and secure handling of medicines
Professional Guidance on the Administration of Medicines in Healthcare Settings
Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources p34
Medicine administration by registered and non-registered staff
Good practice in prescribing and managing medicines and devices
A Competency Framework for all Prescribers
Human Medicine Regulations Schedule 19
Retaining legal mechanism documentation

Pros and cons of PSD v PGD

	Patient Specific Direction	Patient Group Direction
Applies to an individually identifiable patient	Yes	No
Applies to a specific group of patients identified in written criteria that apply to a group	No	Yes
Has written exclusions	No	Yes
Any HCP can be authorised to administer via this mechanism	Yes	No
Must be a written instruction for an individually identifiable patient signed by a prescriber	Yes	No
Must be developed and authorised by a senior doctor, pharmacist and the organisation in which used	No	Yes
Contrast media is prescribed	Yes	No
Prescriber conducts a patient assessment	Yes	No
Prescriber accountable for the decision to administer	Yes	No

HCP administering accountable for the decision to administer	No	Yes
Patient assessment, preparation and administration must be completed by one HCP	No	Yes
HCP administering takes consent for administration and ensures that safety checks are complete	Yes	Yes
HCP can vary from written instruction	No	No

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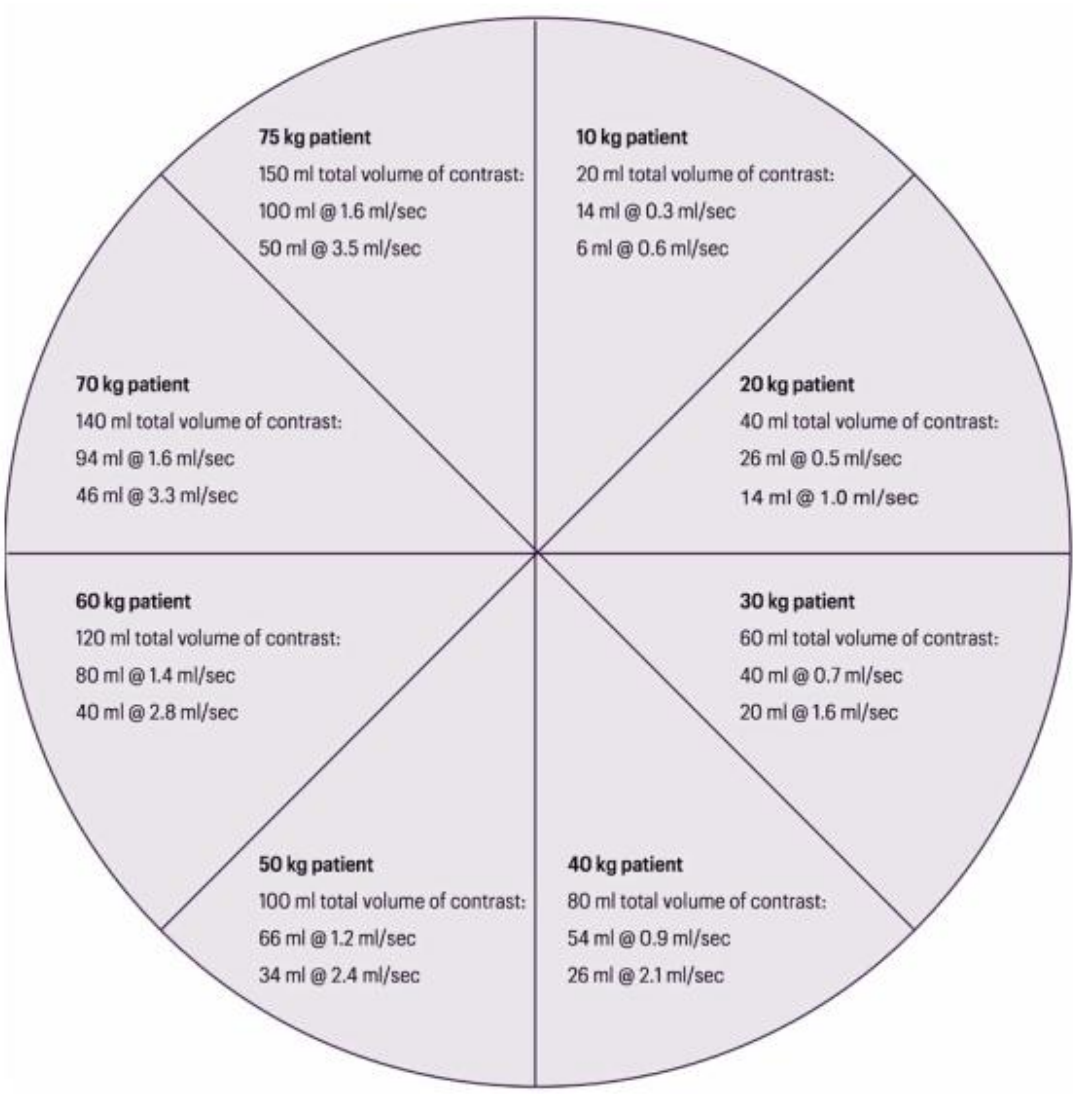
Appendix 3: Paediatric considerations – dose of contrast

Refer to Camp Bastion Contrast Calculator

(ref: RCR Paediatric Major Trauma Protocols: https://www.rcr.ac.uk/media/y3qf4iei/camp-bastion-contrast-calculator-and-ct-dose-optimisation.pdf)

Scan protocol: 2/3 contrast volume injected at slow rate x, and 1/3 volume injected at approximately 2x. Contrast rates are calculated for injection phase to last 70 secs. Scan initiated at 70 seconds.



Dotarem: 1ml/5kg
Gadovist & Primovist: 1ml/10kg: Both are licensed for paediatric use but, if not on a PGD, need a prescription for each individual patient.

Omnipaque 300:
1ml/kg for head CT
2ml/kg for everything else to a max of 100mls
New technologies will allow for reduced doses.

Dose/kg and volume given will differ according to concentration and CT technologies and area of concern.
Take advantage of low dose technologies – use low dose to get best diagnostic image.

Appendix 4: Paediatric considerations – Rate of injection

Table 1: Maximum suggested injection rate per access size for paediatric CT studies

Maximum injection rate	Catheter size
5.0mL/s	16-18 gauge
4.0mL/s	20 gauge
2.5mL/s	22 gauge
1.0mL/s	24 gauge

Table 2: Suggested IV contrast media injection rates for routine (non-CT angiography) contrast-enhanced CT studies in paediatric patients

Injection rate	Study
1.0 – 2.0 mL/s	Head CT
1.0 – 2.0mL/s	Neck, chest, extremity, or abdomen/pelvis CT

Note – injection rates of less than 1.0mL/s may be acceptable for certain indications, and some implanted ports, peripherally inserted central catheters, or small gauge (24- gauge) angiocatheters may necessitate a rate of 1.0mL/s or less.

Working Group

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