Worcestershire Acute Hospitals NHS Trust

# CESM Protocol

This protocol does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

## Introduction

This document provides the protocol for referral and describes the procedure for carrying out Contrast Enhanced Spectral Mammography CESM.
This document covers the following principal areas:

1. Background
2. Scope
3. Responsibilities
4. Indications for CESM
5. Contra-indications for CESM
6. Referral process
7. Contrast media
8. Procedure
9. Aftercare
10. Documentation
11. Post CESM process

**THIS PROTOCOL IS FOR USE BY THE FOLLOWING STAFF GROUPS:**

Radiologists, Consultant Radiographers, and Radiographers

**Lead Clinician(s)**

| | |
|---|---|
| Julie Broomer | Radiographer, Breast Imaging QA Lead |
| Approved by Breast Services Directorate on: | 9th September, 2024 |
| Approved by Women's and Children Divisional Governance Meeting: | 23rd October, 2024 |
| Approved by Medicines Safety Committee on: *Where medicines included in protocol* | NA |
| Review Date: This is the most current document and should be used until a revised version is in place | 23rd October, 2027 |

**Key amendments to this guideline**

| Date | Amendment | Approved by: (name of committee or accountable director) |
|---|---|---|
| 23rd October, 2024 | First document approved at Governance | Women's and Children's Governance |

## 1. Background

Contrast-enhanced spectral mammography (CESM) is an emerging diagnostic modality in the evaluation and staging of primary breast cancer. By integrating an iodinated contrast agent with conventional mammography, CESM enhances diagnostic accuracy, particularly for women with dense breast tissue. CESM has demonstrated sensitivity and accuracy comparable to magnetic resonance imaging (MRI) for breast cancer assessment.

CESM is primarily used to assess the extent of disease in patients with a diagnosis of breast cancer offering an alternative to MRI. Additionally, CESM is valuable in monitoring the response to neoadjuvant chemotherapy**.**

## 2. Scope

This protocol applies to Radiologists, Consultant Radiographers and HCPC Registered Radiographers who have undertaken PGD training and been authorized to administer contrast media under a valid patient group direction PGD.

## 3. Responsibilities

Responsibility for ensuring that this procedure is adhered to rests with the Consultant Radiologist or Consultant Radiographer supervising the diagnostic procedure.

Radiographers administering Omnipaque must work within the Omnipaque PGD (Appendix 1), they must be registered professionals who have been named and authorised by WAHT to practice under it.
Radiographers must sign the PGD to confirm that they understand the direction and agree to work within it.

Patient group directions do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and professional code of conduct.

## 4. Indications for CESM

Following identification of abnormal mammographic findings, CESM is used to evaluate the extent of disease for the planning of treatment and where appropriate, neoadjuvant therapy.
The primary indication for CESM is identification or suspicion of multifocal breast carcinoma.

## 5. Contra-indications for CESM

- Consent refused.
- Previous adverse drug reactions (allergic, hypersensitivity or other) after administration of iohexol or a contrast agent of a similar nature or to any component of iohexol including iodine (excluding topical preparations).
- Individuals with an eGFR of <30ml/min/1.73m$^2$.
- Known pregnancy.
- Any individual history documented in the radiology/imaging referral/request of:
    - Manifest thyrotoxicosis.
    - Myasthenia gravis.
    - Congestive heart failure, severe cardiac disease or pulmonary hypertension.
    - Homocystinuria.
    - Sickle cell disease.
    - Severe liver impairment or peri-operative liver transplant period.
    - Asthma which is poorly controlled at the time of procedure.
    - Myeloma.
    - Phaeochromocytoma

## 6. Referral process

6.1 Patients may present via:

- Breast screening Assessment clinic
- Symptomatic clinics
- Post-surgical surveillance mammography
- Family history screening

6.2 Process of referral and appointment:

1. **Symptomatic patients**: the referring surgeon will put a request on ICE following discussion with a radiologist.
2. **Screening patients**: the referring radiologist will request on ICE.
3. The referrer will discuss the procedure with the patient and assess for contra-indications.
4. Patient is given or sent patient information leaflet (Appendix 2).
5. CESM requests are vetted by a radiologist.
6. 30-minute slot is given for each procedure for each patient.
7. Patient will be discharged if well with aftercare instructions and details of results after 15 minutes of observation in the department.

## 7. Contrast media

- 100ml Omnipaque 300 – warmed to body temperature.
- 95ml Omnipaque 300 will be administered at a rate of 3ml per second.
- 5ml residual in the introducing system.

## 8. Procedure

- Equipment QC (including CESM specific CNR test) must be undertaken to confirm the mammography unit is functioning correctly. (Appendix 3)
- Contrast media is warmed to body temperature

- Contrast media is loaded into the pump injector following departmental work instruction (Appendix 4) 95ml Omnipaque 300 is administered at a rate of 2-3ml per second (depending on canula gauge) 5ml residual in the introducing system.
- Procedure is explained to the patient and consent gained
- The patient is cannulated
- The contrast media details are entered in the examination on the mammography unit
- The procedure is explained to the patient again in the mammography room with particular emphasis on the timing of positioning and exposing.
- The contrast media is administered, and the examination timer started.
- Imaging is performed 2 minutes after injection
- Two views (CC and MLO) are performed on each breast
- The unaffected breast is usually imaged first

## 9. Aftercare

- The patient remains in the breast imaging department for 15 minutes after the procedure.
- The canula is left in situ for 10 minutes to maintain venous access in case of adverse reaction.
- Raise an emergency call 2222 if anaphylaxis is suspected

## 10. Documentation

- Patient CRIS request
- Patient Information Leaflet
- Completed patient contrast questionnaire
- Patient Survey Experience
- Extravasation leaflets (if appropriate)

## 11. Post CESM process

- Departmental Secretary/Administrator must ensure that the CESM patient details are added to the MDM list for discussion.
- Radiology report entered on CRIS and NBSS where the patient presents via the screening pathway.
- Completed patient contrast questionnaire must be scanned into the patient record on CRIS.

## Appendix

| | | |
|---|---|---|
| 1 | Omnipaque PGD | https://nhs.sharepoint.com/sites/RWP_Pharmacy_Hub/SitePages/Patient-Group-Directions.aspx |
| 2 | Patient information leaflet | M:\Acute\Radiology\BreastScreeningPOWCH\QMS\Core processes\9 Assessment\CESM\CESM patient information.docx |
| 3 | Equipment QC instructions | M:\Acute\Radiology\BreastScreeningPOWCH\QMS\Core processes\4 Quality Control\Pristina\2D 3D CESM\Alex Pristina Weekly, monthly 2D 3D CESM.docx |
| 4 | Bayer pump injector WI | M:\Acute\Radiology\BreastScreeningPOWCH\QMS\Core processes\9 Assessment\CESM\bayer (1) pump instructions.docx |

## Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

| Page/ Section of Key Document | Key control: | Checks to be carried out to confirm compliance with the policy: | How often the check will be carried out: | Responsible for carrying out the check: | Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)* | Frequency of reporting: |
|---|---|---|---|---|---|---|
| | **WHAT?** | **HOW?** | **WHEN?** | **WHO?** | **WHERE?** | **WHEN?** |
| | Review of accuracy of CESM in comparison to MRI whilst both examinations continue to be performed. Once CESM is established and no longer performed additionally to MRI, this will need to be reviewed | Audit of all CESM examinations.<br>Review of Datix record of incidents in relation to CESM and MRI | 10 times a year | QA Lead | Superintendent Radiographer<br>Sub directorate | 4 times a year |
| | | | | | | |
| | | | | | | |

## REFERENCES

All references should be 'Harvard' referenced, eg,

*A book by a single author:*

Seedhouse, D. (1997) *Health promotion: philosophy, prejudice and practice.* Chichester, John Wiley.

**Contribution List**

This key document has been circulated to the following individuals for consultation;

| Designation |
|---|
| Director of Breast Screening |
| Superintendent and Deputy Superintendent |
| Advanced Practitioner team |
| Training Team |

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

| Committee |
|---|
| Breast directorate |
| Breast Imaging sub directorate |
| Women and Children's division governance team |

## Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Worcestershire Acute Hospitals NHS Trust

Worcestershire Acute Hospitals NHS Trust

**Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form**
**Please read EIA guidelines when completing this form**

**Section 1 - Name of Organisation** (please tick)

| | | | | | |
|---|---|---|---|---|---|
| Herefordshire & Worcestershire STP | | Herefordshire Council | | Herefordshire CCG | |
| Worcestershire Acute Hospitals NHS Trust | ✓ | Worcestershire County Council | | Worcestershire CCGs | |
| Worcestershire Health and Care NHS Trust | | Wye Valley NHS Trust | | Other (please state) | |

| | |
|---|---|
| **Name of Lead for Activity** | |

| | | | |
|---|---|---|---|
| **Details of individuals completing this assessment** | **Name** | **Job title** | **e-mail contact** |
| | Julie Broomer | QA Lead Breast Imaging | Julie.broomer@nhs.net |
| | | | |
| | | | |
| **Date assessment completed** | 18.11.2024 | | |

**Section 2**

| | | | | |
|---|---|---|---|---|
| Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.) | **Title:** CESM Protocol | | | |
| What is the aim, purpose and/or intended outcomes of this Activity? | Ensure CESM imaging is performed appropriately in line with national guidance and IRMER legislation.<br>Monitor effectiveness of CESM in comparison to MRI.<br>Maximise cancer detection whilst keeping dose of ionizing radiation as low as reasonably achievable | | | |
| Who will be affected by the development & implementation of this activity? | ✓<br>❑<br>❑<br>❑ | Service User<br>Patient<br>Carers<br>Visitors | ✓<br>❑<br>❑<br>❑ | Staff<br>Communities<br>Other _____ |
| Is this: | ✓ Review of an existing activity<br>❑ New activity | | | |

| | |
|---|---|
| | ❑ Planning to withdraw or reduce a service, activity or presence? |
| What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc. | https://nhs.sharepoint.com/sites/RWP_Pharmacy_Hub/SitePages/Patient-Group-Directions.aspx<br>M:\Acute\Radiology\BreastScreeningPOWCH\QMS\Core processes\4 Quality Control\Pristina\2D 3D CESM\Alex Pristina Weekly, monthly 2D 3D CESM.docx<br>M:\Acute\Radiology\BreastScreeningPOWCH\QMS\Core processes\9 Assessment\CESM\bayer (1) pump instructions.docx |
| Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required) | Discussion with consultant radiologists, consultant radiographers, service leads, senior colleagues in advanced practice team and training team. |
| Summary of relevant findings | Protocol required to ensure new imaging modality provides same diagnosis assurance as MRI. |
| | |

## Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

| Equality Group | Potential positive impact | Potential neutral impact | Potential negative impact | Please explain your reasons for any potential positive, neutral or negative impact identified |
|---|---|---|---|---|
| **Age** | ✓ | | | Ensures quality of service for clients eligible for breast screening – aged 50-70 years |
| **Disability** | | ✓ | | |
| **Gender Reassignment** | ✓ | | | Breast screening reduces impact of breast cancer in clients identifying as female |
| **Marriage & Civil Partnerships** | | ✓ | | |
| **Pregnancy & Maternity** | | ✓ | | |
| **Race including Traveling Communities** | | ✓ | | |
| **Religion & Belief** | | ✓ | | |
| **Sex** | ✓ | | | Breast screening reduces impact of breast cancer in clients identifying as female |
| **Sexual Orientation** | | ✓ | | |

| Equality Group | Potential positive impact | Potential neutral impact | Potential negative impact | Please explain your reasons for any potential positive, neutral or negative impact identified |
|---|---|---|---|---|
| **Other Vulnerable and Disadvantaged Groups** (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.) | | ✓ | | |
| **Health Inequalities** (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies) | ✓ | | | Ensures all clients receive the same high-quality service, allowing them to benefit from early diagnosis and treatment of breast cancer |

**Section 4**

| What actions will you take to mitigate any potential negative impacts? | Risk identified | Actions required to reduce / eliminate negative impact | Who will lead on the action? | Timeframe |
|---|---|---|---|---|
| | N/A | . | | |
| | | | | |
| | | | | |
| **How will you monitor these actions?** | | | | |
| **When will you review this EIA?** (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation) | | | | |

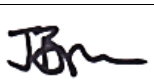
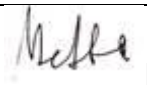
**Section 5 -** Please read and agree to the following Equality Statement

## 1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

| | |
|---|---|
| **Signature of person completing EIA** |  Julie Broomer |
| **Date signed** | 18.11.2024 |
| **Comments:** | |
| **Signature of person the Leader Person for this activity** |  Dr Maria Carrillo |
| **Date signed** | 20.11.2024 |
| **Comments:** | |

## Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

| | Title of document: | Yes/No |
|---|---|---|
| **1.** | Does the implementation of this document require any additional Capital resources | no |
| **2.** | Does the implementation of this document require additional revenue | no |
| **3.** | Does the implementation of this document require additional manpower | no |
| **4.** | Does the implementation of this document release any manpower costs through a change in practice | no |
| **5.** | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff | no |
| | Other comments: | |

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval