Worcestershire Acute Hospitals NHS Trust

Tomosynthesis 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

The purpose of this protocol is to ensure digital breast tomosynthesis is employed appropriately in the Breast Imaging department to increase the effectiveness of assessment without unnecessarily increasing the radiation dose to the patient. This protocol covers the use of tomosynthesis for screening and for symptomatic patients to ensure all examinations are performed in accordance with IR(ME)R 2017 and NHSBSP guidelines.

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

Referral criteria

Referral is only accepted from a responsible assessor in an assessment clinic or from the reporting clinician in a symptomatic setting. Tomosynthesis must not be used as first line breast imaging, or for patients with no abnormalities demonstrated on initial 2D mammography.

Breast screening patients tomosynthesis may be used in an assessment clinic where an abnormality has been demonstrated on initial standard 2D screening mammography. It should not be routinely performed for a clinical recall where the screening imaging is normal.
The responsible assessor should indicate where tomosynthesis is to be used within assessment and specify which images are needed.

Symptomatic breast imaging patients tomosynthesis may be used where an abnormality has been demonstrated on initial standard 2D mammography. The referring clinician must clearly specify which images are needed.

Indications for tomosynthesis

Assessment of a mass or asymmetric density

- further characterise a lesion
- assess the margins of a lesion
- determine the level of suspicion
- identify further lesions

Assessment of a distortion

- differentiate architectural distortion from composite glandular tissue.

Detail

- 3D images must only be taken of the breast in which an abnormality has been demonstrated on initial standard 2D mammography.
- 2-views should be obtained, usually cranio-caudal (CC) and medio-lateral oblique (MLO)
- Positioning should be modified to most effectively demonstrate the mammographic abnormality being assessed. For instance, the CC view may be extended to better demonstrate the medial or lateral aspect of the breast.
- Multiple images for larger breasted clients should be avoided where it is possible to ensure complete demonstration of the affected area in limited views
- Avoid unnecessary additional 2D imaging – paddle views etc if possible without compromising the examination

- **Imaging of breast implants is not possible with tomosynthesis** - the implant projection would cause image artefact obscuring breast tissue.

- It may be possible for patients with breast implants to have tomosynthesis of Eklund views or modified Eklund views providing the area of concern can be positioned in the field of view clear of the implant. This may be limited to one view depending on the location of the area of concern.

- Imaging should be viewed in planes rather than slabs

- It should be borne in mind that 2D reconstructed images are not a suitable replacement for 2D images

Appendix

NHSBSP
Breast screening: digital breast tomosynthesis - GOV.UK (www.gov.uk)
Ionising Radiation (Medical Exposure) Regulations IR(ME)R 2017:
https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance

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 whether tomosynthesis imaging is performed in line with this protocol	Audit of all tomosynthesis imaging examinations	4 times a year	QA Lead	Superintendent Radiographer 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:** Tomosynthesis Protocol			
What is the aim, purpose and/or intended outcomes of this Activity?	Ensure tomosynthesis imaging is performed appropriately in line with national guidance and IRMER legislation. 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?	✓ ❑ ❑ ❑	Service User Patient Carers Visitors	✓ ❑ ❑ ❑	Staff Communities Other _____
Is this:	✓ Review of an existing activity ❑ 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.	Breast screening: digital breast tomosynthesis - GOV.UK (www.gov.uk) https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance Breast screening: clinical guidelines for screening assessment - GOV.UK
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 fit for purpose

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 Claire Sutherland, Consultant Breast Radiologist & DoBS
Date signed	19.11.2024
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