MasDA
Mastectomy Decisions Audit 2015

AUDIT PROTOCOL

FULL TITLE

Mastectomy Decisions Audit: a prospective, multi-centre, population-based audit

SHORT TITLE

MasDA

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On behalf of the West Midlands Research Collaborative.

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KEY CONTACTS

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## 1.0 PROTOCOL SUMMARY

### GENERAL INFORMATION

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<td>Sponsor</td>
<td>West Midlands Research Collaborative (<a href="http://www.wmresearch.org.uk">www.wmresearch.org.uk</a>)</td>
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### STUDY INFORMATION

| Indication | To establish the proportion of mastectomies recommended by multi-disciplinary teams (MDT). |
| Design     | Observational audit |
| Primary Outcome | To determine the indications for recommending mastectomy in the UK in 2015 |

### STUDY TIMELINES

| Main study period | 01/07/2015 – 31/09/2015 |
| Follow-up duration | 0 |
| End of Trial Definition | 12 weeks |
| Data submission | 30/11/15 |
| Data analysis | December 2015 |
| Results available | March 2016 |
## 2.0 ABSTRACT

**Background:** Over 19,000 mastectomies are performed per annum in the UK for invasive breast cancer and *in situ* disease. Several large datasets have all demonstrated considerable variation in mastectomy rates in units across the UK. The reason for this national variation remains unknown. It is unclear what proportion of mastectomies performed are based on patient choice or are recommended by multi-disciplinary teams (MDT).

**Aims:** The Mastectomy Decisions Audit (MasDA) aims to identify the reasons for recommending and performing mastectomies in 2015. It will attempt to describe current UK practice in MDT decision-making for patients undergoing mastectomy. It will also investigate whether post-operative histology confirms the rationale for advising mastectomy as treatment of choice for invasive breast cancer and *in situ* disease.

**Methods:** This multi-centre, prospective, national audit will commence on 1st July 2015. Data collection will run for 12 weeks from the start date of data collection. Data will be collected using a standardised pro-forma and entered locally at each centre on to a secure web application (REDCap™). All women aged >18 years undergoing an elective mastectomy for invasive or *in situ* disease in the UK, either as an initial procedure with or without immediate reconstruction, or following breast conserving surgery (BCS), are eligible for this study.

**Audit Standard:** Indications for mastectomy as per the ‘Surgical Guidelines for the Management of Breast Cancer’ by the Association of Breast Surgery (ABS) 2009 and the ABS Breast Screening Audit Report 2010-2011.
3.0 INTRODUCTION

MasDA is a collaborative trainee-led, prospective, national audit, which aims to identify why mastectomies are clinically advised and performed in the UK. Over 19,000 mastectomies are performed per annum in the UK for invasive breast cancer and in situ disease. Several large UK studies including the National Mastectomy and Breast Reconstruction Audit\(^1\), the NHS Breast Screening Programme Report on screen detected breast cancers\(^2\) and the Breast Cancer Clinical Outcome Measures project reports\(^3\) have all demonstrated considerable variation in mastectomy rates in units across the UK.

Surgical treatment decisions for breast cancer involve the interplay between the patient, their clinicians and family members. Where breast conservation is considered possible, patients are offered a choice between BCS and mastectomy. It seems, however, that regional variation in patient preference for mastectomy exists\(^4\). Patients may prefer to undergo a mastectomy rather than BCS because of concerns over disease recurrence and avoidance of adjuvant radiotherapy or the need for further surgery\(^5\). Nevertheless, ‘patient choice’ alone is unlikely to account for all the variation in observed mastectomy rates.

Even if offered a ‘choice’, most patients will receive the treatment recommended by their surgeon. The ABS Surgical Guidelines for the Management of Breast Cancer 2009\(^6\) and the ABS Breast Screening Audit Report 2010-2011\(^7\) provide some guidance on recommending mastectomy, for example patients with multifocal/multi-centric disease, previous radiotherapy, large (>4cm) areas of micro-calcifications, family history or large tumour to breast volume ratio which would probably result in a poor cosmetic outcome. In clinical practice, the indications for recommending mastectomy have not previously been assessed in the UK. Data from the NHS Breast Screening Programme between 2003 and 2012 suggests that variation in multidisciplinary assessments between units may contribute to the variation in mastectomy rates. For instance, between 2010-2011 regional mastectomy rates for screen-detected tumours <20mm in diameter varied between 11 and 46\(^{\%}\)^7.

MasDA aims to provide an evidence base of current practice in order to establish why mastectomies are clinically advised by MDTs. Data will be collected on patients

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MasDA Audit Protocol v1.8
that choose to have a mastectomy; however this cohort will be excluded from the main analysis as the focus of the study is to establish the rationale for recommending a mastectomy. We will identify whether the post-operative histology confirms the preoperative diagnosis and hence the rationale for advising mastectomy as the treatment of choice. Information will be acquired regarding current practices in neo-adjuvant treatment. The audit findings will aim to enable us to develop recommendations for reducing the variation in mastectomy rates nationwide. All patients undergoing mastectomy for breast cancer or in situ disease, either as an initial procedure or following BCS, in any UK breast unit, will be eligible for inclusion in the audit.

4.0 RATIONALE OF PROPOSED AUDIT

Substantial variation in mastectomy rates is known to exist across the UK. Patient preference for mastectomy alone is unlikely to account for the variation in observed mastectomy rates. It is therefore important to audit the rationale for recommending mastectomy at MDT meetings.

5.0 OBJECTIVES

(i) Determine the indications for recommending mastectomy by MDTs.

(ii) Identify whether the post-operative histology confirms the rationale for advising mastectomy as the treatment of choice.

6.0 DESIGN AND METHODS

- Prospective, multi-centre audit
  - Any UK Breast Unit is eligible to enter patients. A named consultant or breast trainee will act as the local lead investigator. Data collection will be completed by a team of local surgical trainees/breast care nurses working at that hospital. This study of current practice will be
registered and approved by each individual hospital’s clinical audit department.

- **Patient Eligibility**
  - All women over the age of 18 years who undergo mastectomy +/- reconstruction for invasive breast cancer or *in situ* disease.

- **Audit phases**
  - The audit will be performed across eligible centres from 1st July 2015 and run for 12 weeks from the start date of data collection. A guide has been produced for local investigators wishing to include their centre (appendix 1).

### 7.0 DATA COLLECTION

- **Variables to be collected:**
  - **Patient details**
    - 1. Hospital No.
    - 2. Month/Year of birth
    - 3. Menopausal status
    - 4. Side affected (right/left/both)
  - **Pre-operative information**
    - 5. Presentation
    - 6. Pre-operative pathology
    - 7. Pre-operative imaging
    - 8. Mastectomy operation date
    - 9. Immediate reconstruction
  - **Preoperative data**
    - 10. Patient advised to have a mastectomy
    - 11. Patient offered a choice between BCS and mastectomy
    - 12. Neoadjuvant treatment recommended
    - 13. Neoadjuvant treatment given
    - 14. Indication for mastectomy
15. Did the patient choose to have a mastectomy?

Postoperative data

16. Invasive disease
   a. Size of cancer in largest diameter
   b. Number of separate tumours
   c. Type of invasive cancer
   d. Grade
   e. Oestrogen receptor status
   f. HER2 status

17. Ductal carcinoma in situ (DCIS)
   a. Whole tumour size
   b. Grade
   c. Multi-focality

• Data collection:
  o Data will be collected in a standardised pro-forma and transferred to a secure web application called REDCap™. Local investigators will be issued with a username and password to upload data online.
  o Multiple local investigators will be able to enter and view data for the same breast unit. Only the members of your data collection team and the MasDA Steering Group will have details of this.

• Data collection points:
  o Patient identification: Patients undergoing mastectomy will be identified at the MDT meeting.
  o Pre and post-operative data: This will be completed from information collected at the post-operative MDT meeting.
  o Each team should regularly check that all patients are captured over the 12 week audit period by liaising with the audit co-ordinator to ensure that consecutive patients are included.
  o Regular checks should be performed to ensure that the data submitted via REDCap™ is as complete as possible.

• Validation of a unit’s dataset:
• The supervising consultant or local lead investigator will be required to submit the total number of mastectomies performed at their Trust during the 12 week study period as recorded by the MDT co-ordinator or through local cancer database e.g. Somerset.

• Data completeness for all submitted fields should be 90% or greater.

• Data collation:
  o Data will be submitted centrally with all patient identifiers removed. Anonymised data will be analysed and reported by the writing committee.
  o Outcome data specific to each individual surgeon who participates will not be collected.
  o Anonymised hospital data will be compared; **but individual surgeons, hospitals or NHS Trusts will not be identified** and will be kept strictly anonymous. Units will have access to their individual data on request.

• Authorship:
  o Manuscript preparation will be performed by a writing committee. All contributors (medical students, doctors, clinical nurse specialists and supervising consultants) will be listed as ‘Pubmed’ citable on any peer review publications that arise from the audit (see T D Pinkney et al. (2013). Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI Trial). British Medical Journal 2013;347:f4305 as an example). In return, each collaborating team should participate in the creating of the local system, registering the audit, identifying patients and data collection.
  o Medical students and Foundation Year Doctors that contribute to data collection will be provided with certificates to verify their contribution to the study.
  o Units that fail to submit data for at least 90% of the total number of mastectomies performed may be excluded from the ‘Pubmed’ citable list.
9.0 REFERENCES


Appendix 1: How to register this audit

Every hospital has an audit department which should be able to advise on the information required to register the project. Please contact them well in advance to ensure all the paper work is correct (we would recommend at least one month prior to the study commencing).

At Trust level:

1. Identify a local lead investigator at each trust – this is a Consultant who agrees to support the study

2. Create a team including medical students, FY1-2, CTs and StRs

3. Contact your hospital’s Clinical Audit Department preferably by email
   a. They will provide you with a standard audit form to complete, via email or from the intranet
   b. You can copy and paste from this protocol
   c. Ensure that the audit department know that this is part of a larger project and that you will send anonymised data for central collation via secure web application REDCap™.

4. Once the form is completed, you may need to ask your supervising consultant to sign it

5. Form submission
   a. Submit the form and protocol to the Audit Department as soon as possible

6. Please forward the written approval or email to masda@wmresearch.org.uk