MAMMA

MASTITIS AND MAMMARY ABSCESS MANAGEMENT AUDIT

An International Audit of the Management of Mastitis and Mammary Abscess

Study Protocol Version 4
October 2019

Contents

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Project timeline

November 2019	Recruitment of local trainee collaboratives, registration of local audits
January - February 2020	**Phase 1 - International Practice Survey**
February 2020	Phase 1 Data Analysis
February 2020	Phase 1 results released to local centres
14th February 2020	**Deadline for local audit registration confirmation**
1st March - 31st May 2020	**Phase 2 - Prospective Audit**
June 2020	**Phase 2 Data Validation**
July - October 2020	Phase 2 Data Analysis
November 2020	Phase 2 results released to local centres for local audit presentations
November - December 2020	Preparation of abstract for ABS conference submission
November - April 2021	Writing up and submission of manuscript for publication
June 2021	Presentation at ABS Conference
July 2021 - December 2021	**Phase 3 - Prospective re-audit**

1. Background

1.1 Epidemiology mastitis and mammary abscess

Mastitis is an inflammation of the breast tissue, which may be associated with an infection (1). It is defined by the presence of two or more of the following symptoms and signs: tender, hot, red, swollen breast, fever over 38°C, flu-like symptoms, painful breast lump or blocked duct (2, 3). It can be classified into lactational and non-lactational (4). Lactational mastitis is very common, affecting up to a third of breastfeeding women, the main aetiology being milk stasis and nipple trauma (1, 2), which most commonly occurs within the first 12 weeks of delivery or at the time of weaning (5). Up to 11% of these women develop a complication of lactational breast abscess, which is a localised collection of pus surrounded by a capsule of granulation tissue (1, 6, 7). Clinically, a breast abscess presents as a painful palpable mass within the breast tissue with overlying skin erythema, discolouration and/or necrosis (1). On an ultrasound scan (USS), it appears as an avascular hypoechoic collection with a thick echogenic periphery (5).

Non-lactational mastitis and breast abscesses are infrequent, affecting 5-9% of women (4, 5, 7), and can be classified into central (periductal) or peripheral (5, 7). Periductal mastitis is associated with smoking, diabetes, obesity and intra-venous drug use (5-8). Periductal abscesses are often recurrent, difficult to treat and can be complicated by cutaneous fistulae (5-8). Peripheral non-lactational abscesses typically affect older women and are associated with presence of co-morbidity, diabetes, steroid use or recent breast intervention (5). Finally, granulomatous mastitis is a rare aetiology of non-lactational mastitis that can present with a painful breast lump, erythema, skin ulceration and multiple simultaneous peripheral abscesses (4). It is often difficult to treat with failed attempted drainage and poor response to antibiotics (5).

Staphylococcus aureus is the most frequently associated organism, although other species such as Streptococci, E. coli, Bacteroides and Pseudomonas have also been isolated (2, 7, 9-11). Mixed anaerobic growth is more frequently associated with non-lactational abscesses (5, 11), particularly in patients who smoke.

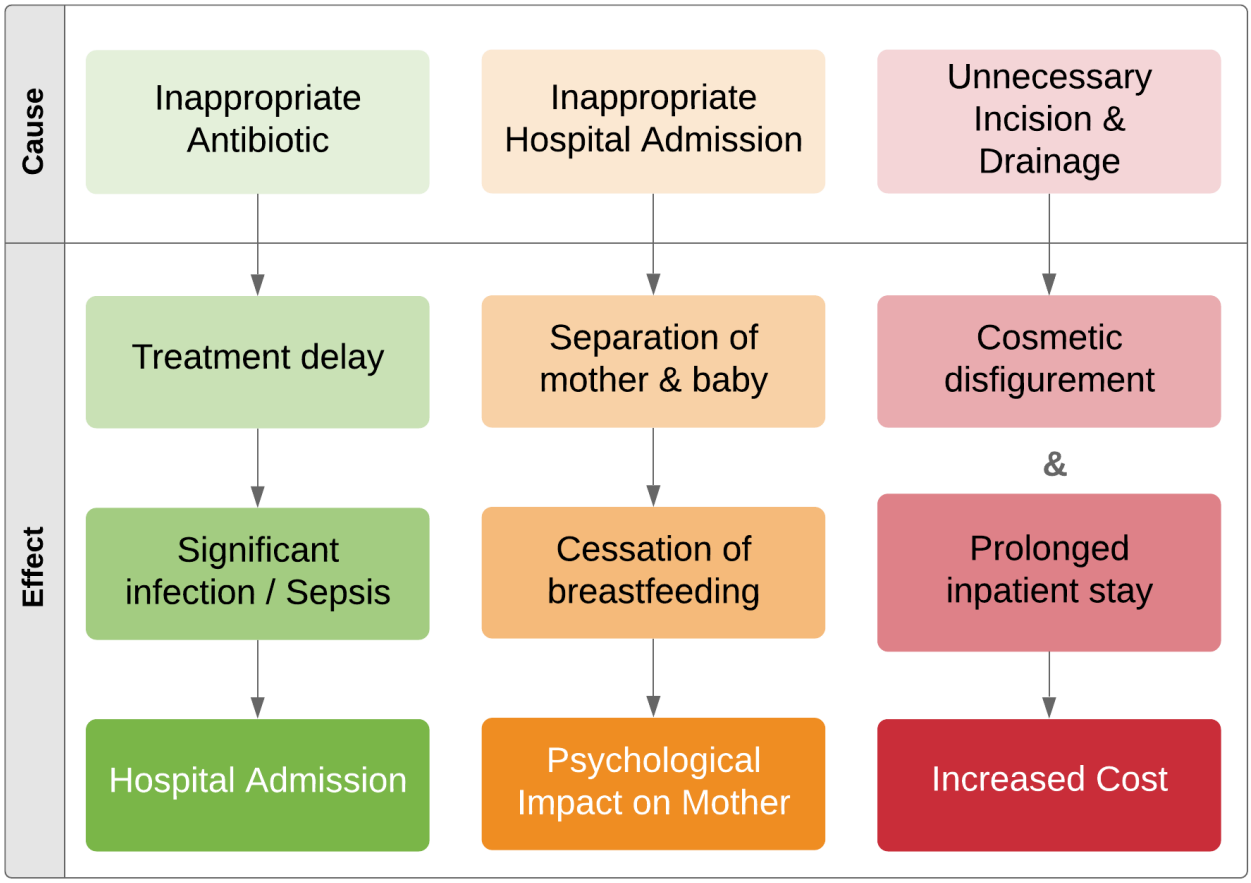
1.2 Management of mastitis and mammary abscess

Management of mastitis depends on the aetiology. Initial treatment for lactational mastitis involves continuation of breastfeeding or expressing from the affected side in order to alleviate milk stasis, regular analgesia, use of hot and cold compresses and rest (1, 2, 12). Where symptoms persist beyond 12-24 hours, despite supportive treatment, or where the patient is very unwell, antibiotics should be commenced and continued for 10-14 days (1, 2).

Management options for breast abscesses include ultrasound-guided needle aspiration and surgical incision and drainage. Although the findings of a recent Cochrane review were inconclusive as to the most effective option (13), several guidelines currently recommend ultrasound-guided needle aspiration as a primary treatment of breast abscesses (1-3, 12). Ultrasound-guided needle aspiration is minimally invasive, less likely to lead to cosmetic disfigurement and can be performed in an outpatient department under local anaesthetic compared to the traditional approach of incision and drainage (1, 13). It is less likely to interfere with breastfeeding and does not require frequent dressing changes (7).

Although none of the guidelines specifically advise on patient selection criteria for surgical incision and drainage, several small studies suggest that the following signs may be indicative of potential failure of percutaneous drainage: abscess over 5cm in diameter (9), skin necrosis (12), late presentation (>6 days) (14), multiloculated abscess (10), failed needle aspiration (12).

Despite guideline recommendations, wide variation in practice has been identified at a local level in a number of national and international publications (11, 12, 15), particularly concerning antibiotic prescribing, rates of incision and drainage and length of inpatient treatment. At least 40% of women are prescribed inappropriate antibiotics (11, 12) and one in three women are



admitted for inpatient treatment (12). However, the rate of incision and drainage is of particular interest as the incidence differs dramatically between studies from 1% (12) to over 85% (16).

Considering that the majority of breast surgeons are no longer participating in the on-call rota and the acute presentation of primary breast infections, we hypothesise that such variation in practice indeed exists across the UK and Ireland, where patients are treated by the non-breast specialist general surgeons and the type of treatment these patients receive depends on that individual surgeon's expertise. However, in order to improve current practice, we need to confirm our hypothesis.

1.3 Importance of this project

Benign breast inflammation and infection accounts for 3% of all breast-related hospital admissions (17). These patients tend to be younger (mean age 40 versus 58 years) and are more likely to present as an emergency (61% versus 2%) compared to patients with malignant breast neoplasms (17). According to the Office of National Statistics, 7,763 patients were admitted to a hospital in England with a primary diagnosis of an inflammatory breast condition during the financial year of 2017 to 2018 (17). This resulted in 9,205 hospital inpatient days (17) at an average cost of bed around £350 per day (18). If an intervention was performed for a non-malignant breast disorder, then the national average cost increased to £2,649 per admission (18). There was a total of 3,673 incision and drainage operations and aspirations performed during the same period with a mean length of hospital stay of 2 days (19). We can therefore estimate that the cost of inpatient management of breast infection and inflammation is over £10 million per annum. However, the vast majority of patients with mastitis can be treated conservatively in the community and most breast abscesses can be treated in an outpatient setting with an ultrasound-guided aspiration with an average cost of £66 (18). Our local experience suggests that implementation of mastitis and breast abscess protocol can result in 90% reduction in the rate of incision and drainage and 50% reduction in the rate of hospital admissions (12). Although we have some idea on how many patients are admitted, the average length of hospital stay and the number of incision and drainage

operations performed (17, 19), the data is not detailed enough to identify any areas for improvement.

1.4 Trainee research collaborative

The most efficient way to perform such an audit on an international scale is through engagement with current trainees throughout the country. Trainee research collaborative is now a well-established practice for conducting large multi-centre clinical trials and national audits. Multiple projects have been successfully delivered through trainee collaborative (20), including:

1. The iBRA study recruited 2655 patients from 81 breast surgery units across the UK with the help of a trainee collaborative over a 2 year period (21)
2. The CholeS study run by the CholeS Study Group and West Midlands Research Collaborative collected data on 8909 patients across 167 hospitals within 2 months (22)
3. National Appendicectomy audit, conducted by the National Surgical Research Collaborative, included 3326 patients from 95 centres with data collection period of only 2 months (23)

Engagement with a trainee collaborative will allow swift data collection on an international level, producing generalisable results that can impact future policy.

International trainee collaborative will be established with the assistance of the Mammary Fold Academic and Research Committee and will be the driving force behind this project. The trainee collaborative will be supported by the academic clinicians, MAMMA Steering Committee and methodologists from Imperial College London.

2. Aims and Objectives

The aim of the MAMMA study is to describe the current practice in the management of mastitis and breast abscesses in the UK and Ireland and to provide recommendations for best practice.

The objectives of the MAMMA study are:

1. Understand patient treatment pathways and patterns of sub-speciality involvement
2. Identify variation between different centres, specifically in terms of antibiotic prescribing, rate of operative versus radiological management, waiting time to ultrasound scan, rate of inpatient versus outpatient treatment, length of hospital stay, rate of follow-up by breast surgeons, number of outpatient appointments
3. Generate data to improve current guidelines on the management of mastitis and breast abscess
4. Determine the feasibility of ongoing prospective international annual re-audit

3. Audit Standards

The following guidelines relate to the management of mastitis and breast abscess and will be used as audit standards:

1. WHO Mastitis Guidelines 2000 (1)
2. GAIN Guidelines on the Treatment, Management & Prevention of Mastitis 2008 (2)
3. ABM Clinical Protocol #4: Mastitis 2014 (3)
4. NICE Clinical Knowledge Summaries: Mastitis and Breast Abscess (4)

3.1 Mastitis

1. Diagnosis

1.1. Adherence to the guidelines on the diagnostic criteria used to define mastitis (2)

2. Investigations

2.1. Routine investigations are not indicated (2-4)

2.2. Breast milk culture and sensitivity is indicated if: no response to antibiotic treatment within two days, recurrent mastitis, a hospital acquired infection, severe and unusual cases, deep burning breast pain (1-4)

3. Supportive treatment of lactational mastitis

3.1. Advice regarding effective breast milk removal should be provided to all women (1-4)

3.1.1. Breastfeeding or expressing should continue, apart from exceptional circumstances (1-4)

3.1.2. Weaning should not be commenced until after resolution of mastitis (2)

3.2. Advice should be given about other supportive treatments:

3.2.1. Hot compresses to help with milk flow prior to breast feeding or expressing (1-4)

3.2.2. Cold compresses to reduce swelling when not feeding or expressing (2, 3)

3.2.3. Rest, appropriate fluid intake and nutrition (1-3)

4. Pharmacological treatment

4.1. Oral anti-inflammatory and analgesic medication should be commenced, unless contraindicated: ibuprofen 400mg three to four times a day after food, paracetamol 1g four times a day (1-4)

4.2. Antibiotics should be prescribed

4.2.1. Without delay in severely unwell patients (1-3)

4.2.2. After 12-24 hours if symptoms are not improving with supportive treatment (1-4)

4.2.3. In the presence of visible nipple fissure (1, 4)

4.2.4. Appropriate options for lactational mastitis include (1-4):

- Erythromycin 250-500mg QDS
- Flucloxacillin 250mg-500mg QDS
- Dicloxacillin 125-500mg QDS
- Amoxicillin 250-500mg TDS
- Cephalexin 250-500mg QDS
- Clindamycin 300mg QDS

- Clarithromycin 500mg BD
- Co-amoxiclav 500/125mg TDS (for treatment failure or recurrence) (4)

4.2.5.Options for non-lactational mastitis (4):

- Co-amoxiclav 500/125mg TDS
- Erythromycin 250-500mg QDS or Clarithromycin 500mg BD Plus Metronidazole 500mg TDS in penicillin allergy

4.2.6.For 10-14 days (1-4)

5. Hospital admission

5.1.Hospital admission should be arranged if the patient (4)

5.1.1.has severe infection/sepsis (heart rate >90, temperature > 38°C, respiratory rate >20 per min)

5.1.2.haemodynamically unstable

5.1.3.immunocompromised (on steroids, HIV, chemotherapy, low WCC)

5.1.4.the infection is rapidly-progressing (spreading erythema, necrotizing fasciitis)

5.2.Hospital admission should facilitate breastfeeding - infant should be admitted with the mother (4)

5.3.Where immediate admission is not indicated based on the criteria above, patient should be managed in primary care or outpatient clinic (4)

3.2 Mammary Abscess

6. Diagnosis

6.1.Refer urgently to breast clinic when a breast abscess is suspected (2, 4)

7. Investigations

7.1.Ultrasound scan to assess size and presence of loculations should be performed (1-4)

7.2.Aspirate samples should be sent for culture and sensitivity (2-4)

7.3.Follow-up ultrasound scan should be perform to assess for any residual disease (2)

8. Abscess drainage

8.1.Ultrasound-guided needle aspiration under local anaesthetic should be performed at the time of ultrasound scan of the breast (1-3)

8.2.In the abscess of ultrasound scan, aspiration should be attempted prior to incision and drainage (2)

8.3.Surgical incision and drainage should be performed under general anaesthetic (1, 2)

8.4.Criteria for incision and drainage include clinically fluctuant or pointing abscess, large size , multiple abscesses, skin necrosis (2, 3)

8.5.Incision should be placed to best facilitate drainage and allow breast feeding during recovery (2)

9. Pharmacological therapy

9.1.Antibiotics

9.1.1.Outpatient course for 10-14 days (2)

- Flucloxacillin 500mg QDS
- Clindamycin 300mg QDS

9.1.2.Inpatient options (2)

- Flucloxacillin 2g IV QDS
- Clindamycin 900mg IV TDS

9.1.3.Should not be used in isolation (1)

9.1.4.Should be prescribed according sensitivities (1)

9.2.Analgesia should be prescribed for pain management (1)

10. Breast feeding advice should be given to all women with lactational breast abscess

10.1.Breast feeding or expressing should continue from unaffected and affected breast (1-4)

10.2.Infant should be kept with mother before and after surgery (1)

4. Study Management

MAMMA Steering Committee will be convened from key stake-holders from a variety of medical and surgical specialties and allied health care professionals that are directly involved in the management of patients with breast infections. The steering group will also include representatives from professional associations and patient associations, as well as statisticians to ensure data validity. It is anticipated that MAMMA Steering Committee will meet twice a year.

A small **Study Management Group (SMG)** will be assembled from the MAMMA Steering Committee members and will be responsible for protocol design, audit management, data analysis, dissemination of results and drafting of publications.

Regional trainee leads will be recruited to represent each of the 19 HEE training regions in the UK and Ireland. They will be responsible for recruitment and coordination of local collaboratives and will be directly accountable to the SMG. They will coordinate with the local trainee leads and will ensure that information about all collaborators is accurately communicated to the SMG. To qualify for citable collaborator authorship, regional leads must recruit and coordinate at least 5 local collaboratives.

Local trainee leads will be recruited to represent each participating centre and will be responsible for:

1. Identifying a local supervising consultant
2. Completion of the international practice survey with the supervising consultant in Phase 1
3. Local audit registration in Phase 2
4. Recruitment of the local collaborative and a data validator
5. Coordination of the local collaborative to ensure prompt data collection and submission within the allocated data collection period
6. Ensuring that the information about all the local collaborators is shared with the regional trainee leads

Local trainee collaboratives will be responsible for identifying all patients that meet the inclusion criteria, data collection and data submission to REDCap database. The maximum number of trainees participating in such a collaborative should be limited to 2 per hospital to ensure substantial contribution to the study. If a high volume of patients eligible for inclusion is anticipated at any of the participating centres, then this should be discussed with the regional lead.

A **data validator** will be recruited for each local collaborative. They should not participate in the data collection but rather check the accuracy of the collected data during the data validation period. They should be a qualified doctor.

5. Methods

This study will be carried out in 3 phases. Progression to Phase 3 will depend on the outcome of Phase 2 of this study and the ongoing support of collaborators.

Mammary Fold, a national breast surgery trainee association, will assist with recruitment of collaborators for this study. The Association of Breast Surgery (ABS) will assist with dissemination of information about this study to their consultant members in order to encourage participation and improve engagement.

5.1 Phase 1 - International Practice Survey

The aim of phase 1 is to gain further understanding into current care pathways and sub-specialty involvement in the management of mastitis and breast abscess.

An international practice survey will be conducted by the local trainee leads in collaboration with lead supervising consultants. They will be required to complete a short questionnaire on REDCap. All acute trusts that treat female patients with breast infections will be invited to participate.

All data must be submitted within a predefined period of 2 months from December 2019 to January 2020. The results will be used to identify centres suitable for inclusion in Phase 2 of the study, to refine the data collection period of Phase 2 and to understand current treatment pathways.

5.2 Phase 2 - Prospective Audit of the Management of Mastitis and Breast Abscess

The aim of phase 2 is to gain further understanding into the management of patients with mastitis and breast abscess through real-time data.

5.2.1 Centre inclusion criteria and clinical governance

Centres suitable for inclusion in Phase 2 of the study will be identified following completion of Phase 1. A supervising consultant must be identified as the lead for the local audit registration. All participating centres will be required to register this audit as per local protocol; this will be the responsibility of the local trainee lead. Confirmation of registration and local clinical audit department approval will be required prior to issuing of REDCap access and commencement of data collection.

5.2.2 Patient inclusion and exclusion criteria

Inclusion Criteria

All female patients over the age of 16 presenting to the acute centre with symptoms of mastitis or breast abscess will be included in this study.

Exclusion Criteria

- All male patients
- Female patients
  - underlying pathology of breast cancer
  - breast surgery within 90 days of presentation
  - breast implant in situ on the affected side

5.2.3 Participation identification and recruitment

Data will be collected for a period of three months from 1st March to 31st May 2020. All participating centres should collect data on all consecutive patients that meet the inclusion criteria.

Suitable patients should be identified by the local trainee collaboratives from emergency departments, surgical assessment units and breast clinics. To ensure that all suitable patients are identified and included in the data collection, local trainee collaboratives should check all presentations to the surgical assessment unit and emergency department, review handover sheets and ward lists, discuss with breast team any new referrals to the breast clinic and liaise with the on-call surgical team on a daily basis.

Contemporaneous data should be collected for all patients. To avoid accidental data duplication, each patient should be given a unique study identification number, made up of the unit initials, last 2 digits of their hospital number and the month of their birth (e.g CXH0101). No patient identifiable information should be collected at any time during this audit. Data should be recorded directly into REDCap database to avoid data loss.

5.2.4. Missing Data

After the close of the data collection period, all data sets will be checked for missing data. Centres where >5% of data is missing will be excluded from data analysis, local trainee leads will be notified and the collaborators will be withdrawn from the list of citable authors. However, their contribution will be acknowledge as per protocol.

It will be the responsibility of the local trainee leads to ensure data completeness.

5.2.5 Data Validation

At the close of the data collection period, all centres will be required to validate their data through a nominated data validator over a specified period of 1 month to ensure accuracy.

To achieve that, the data validator will need to review all collected data for 10 random patients. If during this process, major discrepancy is identified within the data set, then the centre's data will be excluded completely from the analysis. The local trainee lead will be notified and the collaborators will be withdrawn from the list of citable authors. However, their contribution will be acknowledge as per protocol.

It will be the responsibility of the local trainee leads to ensure the accuracy of data and that the members of the local trainee collaboratives had appropriate level of training for data collection.

5.3 Phase 3 - Prospective Re-audit of the Management of Mastitis and Breast Abscess

The aim of phase 3 is to ensure maintenance of good practice in the management of mastitis and breast abscess following implementation of the new guidelines.

It is anticipated that the Phase 2 of this study will identify areas for improvement in the management of mastitis and breast abscesses. New guidelines will be proposed and disseminated to all surgical units across the UK, as well as presented at the national and international conferences.

The impact of these interventions will be assessed in the Phase 3 of this study. A detailed protocol for the Phase 3 will be written upon completion of the Phase 2 of the study.

6. Data Collection

The following data set will be collected by the local trainee lead / collaboratives using REDCap database facility.

6.1 Phase 1 - International Practice Survey

1. Local Mastitis / Breast abscess protocol present: Yes ☐ No ☐
2. Average number of Mastitis / Breast abscess cases seen at the Trust a month (excluding post-op surgical site infection following breast operation): _____
3. Patient treatment pathway:

   3.1.Predominant source of referral: A&E ☐ GP ☐ UCC ☐ Self-referral ☐ Maternity ☐

   3.2.Predominant location of treatment of breast abscess:

   A&E ☐ Inpatient ☐ Outpatient/Breast clinic ☐ Transferred to another centre ☐

   3.3.Predominant treatment team: General Surgical oncall team ☐ Breast team ☐

   3.4.Average waiting time for clinical review: Same day ☐ Next day ☐ Within 1 week ☐

   3.5.Breastfeeding support available: Post-natal ward ☐ Lactational specialist ☐

   Dual admission of mother and baby ☐ Patient information leaflet ☐

   Nil ☐ Don't know ☐
4. Review by Breast surgeon / clinician/ associate specialist :

   All patients ☐ Selected patients ☐ Not routinely referred ☐

   4.1.Type of review: Inpatient ☐ Outpatient ☐ N/A ☐

   4.2.Waiting time to review: Same day ☐ Next day ☐ Within 1 week ☐

   4.3.Provision of 'out of hours' breast surgery cover: General Surgeons ☐ Breast Surgeons ☐
5. Dedicated breast clinic slots: Daily ☐ Weekly ☐ Nil ☐

   5.1.Direct GP access: Yes ☐ No ☐

   5.2.Direct A&E access: Yes ☐ No ☐

   5.3.Direct on-call team access: Yes ☐ No ☐
6. Dedicated interventional radiology clinic for breast infection: Yes ☐ No ☐

6.1.Direct GP access: Yes ☐ No ☐

6.2.Direct A&E access: Yes ☐ No ☐

6.3.Direct on-call team access: Yes ☐ No ☐

6.4.Patient must be seen by the breast team prior: Yes ☐ No ☐

7. Criteria for admission: All patients ☐ Large abscess ☐ No response to antibiotics ☐

   Sepsis / Significant Infection ☐ Immunocompromised ☐ Haemodynamically unstable ☐

   Other _____ ☐

8. Diagnostic Breast Ultrasound Scan:

   8.1.Performed in: All patients ☐ Selected patients ☐ Not routinely performed ☐

   8.2.If selected patients, what is the criteria for requesting USS: _____

9. Primary mode of treatment for breast abscess (select one):

   US-guided aspiration ☐ Surgical Incision & Drainage ☐

10. Indication for surgical incision and drainage (select all applicable):

    Skin changes / necrosis ☐ Pointing ☐ Size ≥5cm ☐ Multiloculated abscess ☐

    Duration of symptoms ≥5 days ☐ Other _____ ☐

11. Average waiting time for intervention: Same day ☐ Next day ☐ Within 1 week ☐

12. Antibiotics recommended on hospital guidelines (select all applicable):

    Erythromycin ☐ Flucloxacillin ☐ Dicloxacillin ☐ Amoxicillin ☐ Cephalexin ☐

    Clindamycin ☐ Co-amoxiclav ☐ Vancomycin ☐ Metronidazole ☐

6.2 Phase 2 - Prospective Audit

Patient Demographics

1. Age (years): <20 ☐ 21-30 ☐ 31-40 ☐ 41-50 ☐ 51-60 ☐ 61-70 ☐

   71-80 ☐ >80 ☐

2. BMI: < 18.5 ☐ 18.5-24.9 ☐ 25-29.9 ☐ 30-39.9 ☐ >40 ☐

3. Postpartum: Yes ☐ No ☐

3.1.Number of weeks since delivery: _____ weeks

Patient treatment pathway

4. Day of presentation: Weekday ☐ Friday ☐ Weekend ☐

5. Time of presentation: Day ☐ Evening ☐ Night ☐

6. First seen by: Breast team ☐ General surgical on call/take team ☐ A&E ☐

7. Source of referral to surgical / breast team: A&E ☐ GP ☐ Maternity services ☐

   Direct Self-referral ☐

   7.1.Did the patient see her GP prior to being seen in A&E: Yes ☐ No ☐

8. Antibiotics prior to being seen in hospital: Yes ☐ No ☐

   8.1.1.How many courses: 1 ☐ 2 ☐ ≥3 ☐

9. Breast surgeon/clinician/associate specialist review: Yes ☐ No ☐

   9.1.Inpatient ☐ Outpatient ☐

   9.2.Breast clinic follow-up: Yes ☐ No ☐

Diagnosis

10. Number of hours/days from onset of symptoms prior to seeking help: ____ hours/days

11. Diagnosis: Lactational Mastitis ☐ Lactational mastitis with Breast Abscess ☐

    Peri-ductal mastitis ☐ Peri-ductal mastitis with Breast Abscess ☐

    Peripheral non-lactational mastitis ☐

    Peripheral non-lactational mastitis with Breast Abscess ☐ Granulomatous mastitis ☐

Risk Factors

12. Breastfeeding: Yes ☐ No ☐

    12.1.Using breast pump regularly: Yes ☐ No ☐

13. Previous Breast infection (abscess / mastitis): Yes ☐ No ☐

14. Risk factors other than lactation: Smoking ☐ Diabetes ☐ Breast Trauma ☐

Steroid Use ☐ IV drug use ☐ Recent Breast Intervention ☐ Co-morbidities: _____ ☐

Treatment

15. Advice to continue breastfeeding from the affected breast given: Yes ☐ No ☐ N/A ☐

16. Antibiotics prescribed at the hospital (list all): Yes ☐ No ☐

16.1.Name: Erythromycin ☐ Flucloxacillin ☐ Dicloxacillin ☐ Amoxicillin ☐

Cephalexin ☐ Clindamycin ☐ Co-amoxiclav ☐ Vancomycin ☐

16.2.Route: Oral ☐ IV ☐

16.3.Course duration (days): ≤7 ☐ 7-10 ☐ 10-14 ☐ >14 ☐

16.4.Reason for choice of antibiotic: Hospital Protocol ☐ Patient Allergies ☐

Previous treatment ☐ Other_____ ☐

17. Location of treatment: Inpatient ☐ Outpatient ☐

17.1.Length of hospital stay: _____ days

17.2.Reason for admission: severe infection/sepsis ☐ haemodynamically unstable ☐

immunocompromised ☐ rapidly-progressing infection ☐ IV Antibiotics ☐

Other _____ ☐

18. Decision made to admit by (select most senior decision-maker involved):

Nurse practitioner ☐ HO/FY1 ☐ SHO/FY2/CT ☐ Registrar/>ST3 ☐ Consultant ☐

19. Diagnostic breast ultrasound scan: Yes ☐ No ☐

19.1.Waiting time to diagnostic breast ultrasound scan : _____ days

20. Needle aspiration: Yes ☐ No ☐ N/A ☐

20.1.Under ultrasound guidance: Yes ☐ No ☐

20.2.Waiting time to 1st needle aspiration: _____ days

20.3.Number of aspirations performed in total: _____

21. Surgical Incision and drainage: Yes ☐ No ☐ N/A ☐

21.1.Indication for surgical incision and drainage: Skin changes / necrosis ☐ Pointing ☐

Size ≥5cm ☐ Multiloculated abscess ☐ Duration of symptoms ≥5 days ☐

Other _____ ☐

21.2.Waiting time to I&D: _____ days

21.3.Returned to theatre for repeat I&D: Yes ☐ No ☐

22. Aspirate sent for culture and sensitivity: Yes ☐ No ☐ N/A ☐

22.1.Pathogen isolated: Yes ☐ No ☐

22.2.Pathogen: _____

7. Data Management and Storage

Data collection practice will comply with Caldicott principles. No patient identifiable information will be collected in this audit and all data will be anonymised.

Study data will be collected and managed using REDCap electronic data capture tool hosted at The Kennedy Institute of Rheumatology at the University of Oxford (24, 25). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (24, 25).

REDCap database is a very popular research solution and has been utilised in more than 735,000 projects worldwide to date.

8. Data Analysis

All data analysis will be performed by the Study Management Group with the assistance and support of the statisticians and methodologists. SPSS Statistics (Version 25) will be used to perform statistical analysis.

8.1 Phase 1 - International Practice Survey

Data will be summarised using appropriate statistical methodology and a report will be produced to illustrate current international practice. Any identified outliers will be reported back to the individual centres concerned and the variation in practice discussed with the local leads.

The results of the international practice survey will help to refine sample size projections and calculations of the data collection period required to obtain high quality data. In addition, data collection proforma for the Phase 2 of the study may be modified based on the results from the Phase 1 survey.

8.2 Phase 2 - Prospective Audit of the Management of Mastitis and Breast Abscess

Data will be summarised using appropriate statistical methodology and a report will be produced to illustrate current international practice. Individual centre results will be summarised and reported back to the local trainee leads for the presentation at the local clinical governance meeting. Any identified outliers will be highlighted to the individual centres and comparison with the international stand will be provided.

The data analysis from the Phase 2 of the study will guide the protocol development for the Phase 3.

9. Publication and Authorship Policy

All publications and presentations will be made on behalf of the MAMMA Study Trainee Research Collaborative. A three-tier authorship policy will be used based on the level of participation.

9.1 Named Author

It is anticipated that there will be a small group of individuals that will meet the International Committee of Medical Journal Editors (ICMJE) criteria for named authorship, including:

- *"Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
- *Drafting the work or revising it critically for important intellectual content; AND*
- *Final approval of the version to be published; AND*
- *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."(26)*

Named authors will be followed by the following statement: 'on behalf of MAMMA Steering Committee and MAMMA Study Trainee Research Collaborative'. The names and roles of all citable collaborators will be listed at the end of the paper.

9.2 Citable collaborators

Collaborators who contribute substantially to this study, but whose contribution does not meet the ICMJE standard, will be included in the list of citable collaborators as part of MAMMA Study Trainee Research Collaborative.

Substantial contribution includes being a regional trainee lead, a local trainee lead for each centre or any collaborator that collects and submits data for a minimum of 10 patients. Prior to publication, local trainee leads will be consulted on the list of collaborators that should be cited or acknowledged.

9.3 Acknowledged collaborators

Collaborators, whose contribution to this study does not meet the citable collaborator criteria, will be acknowledged and will receive a certificate of participation. Consultants, who contribute patients to this study but do not personally participate in data collection will also be acknowledged.

The individual centre data will be owned by the local collaboratives and the individual Trusts, and can be presented as part of the local clinical governance meeting.

10. Audit Governance

The aim of the MAMMA study is to describe the current practice in the management of mastitis and breast abscesses in the UK and to provide recommendations for best practice.

Data will be analysed once the data collection has been completed. Rates of US-guided aspiration and surgical incision and drainage procedures will be calculated for each participating centre and compared to the calculated international average. Significant deviations from the mean will be discussed with the individual centres by a member of the Study Management Group in order to check data validity and understand the reasons for deviation. A summary of the international audit results will be reported back to ABS.

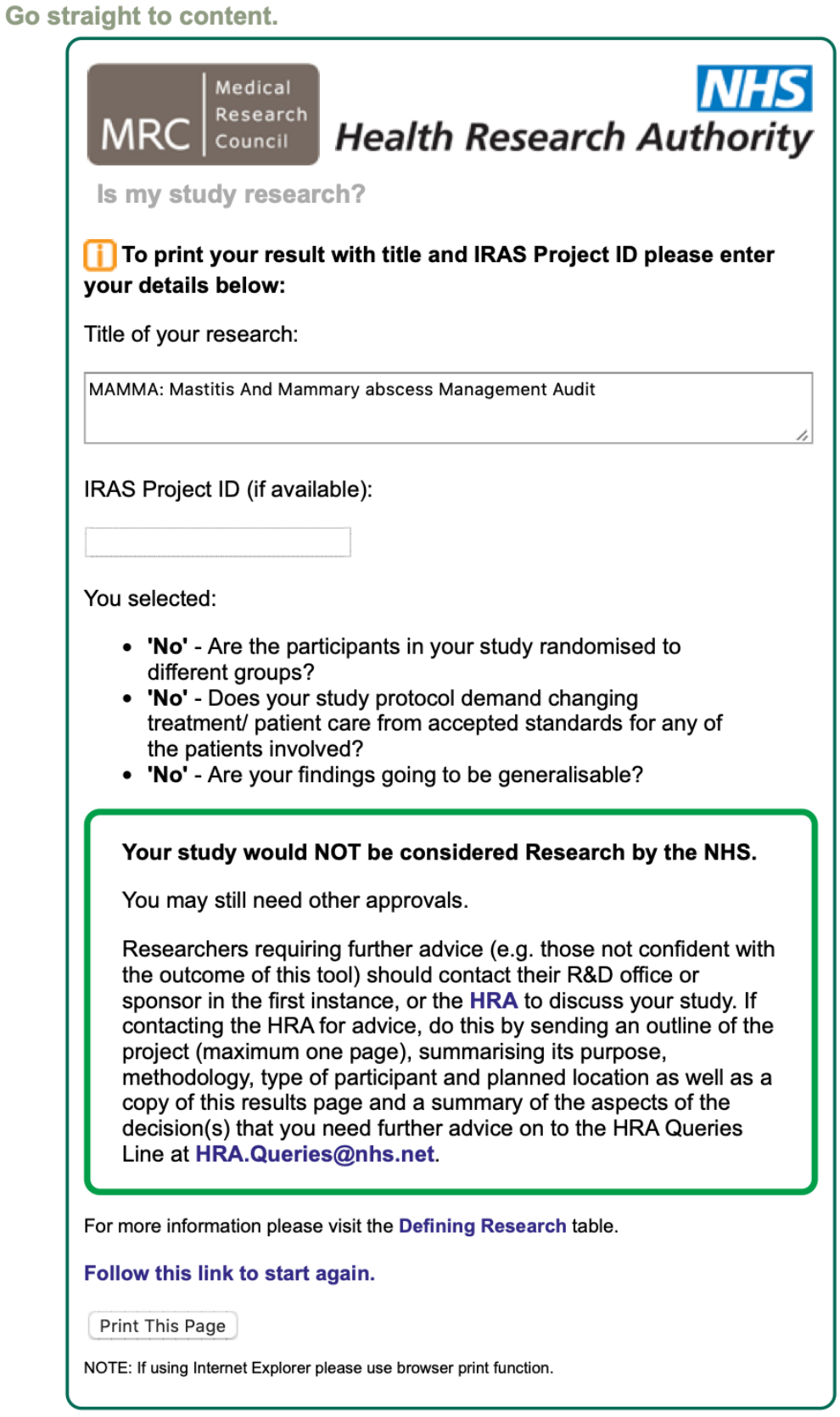
Appendix 1: Instructions for the local trainee collaborative

1. Select a local trainee lead and contact the steering group (www.mammastudy.com or mamma.study@gmail.com) to confirm your participation in this study.
2. Identify one supervising consultant.
3. Register your audit with the local clinical audit department and email a copy of the approval confirmation to mamma.study@gmail.com. To ensure compliance with the local clinical governance policy, REDCap database access for Phase 2 of the study will only be issued after the audit registration confirmation has been received by the steering group. This process must be commenced without a delay as it may take up to 1 month for the local audit department to grant approval. Data collection cannot commence until the audit is formally approved. In your application, you must notify the audit department that this is part of an international audit and that all data will be anonymised. No patient identifiable information will be collected. If you have any difficulties in registering your audit, please contact your supervisor, regional trainee lead or the steering group for help and advice.
4. Complete Phase 1 International practice survey with the supervising consultant and submit to REDCap database within the data collection period (November to December 2019).
5. Recruit local trainee collaborative: maximum of 2 collaborators plus 1 data validator.
6. Once the evidence of local audit registration is received by the steering group, REDCap database access for the Phase 2 will be issued.
7. Organise a local trainee collaborative meeting to devise strategy and delegate tasks and responsibilities in preparation for the Phase 2 data collection. Check individual training needs. You may wish to test your strategy prior to the official start of the data collection period.
8. Commence data collection (1st March 2020 to 31st May 2020), ensuring that all eligible patients are included in this audit and that no fields are left incomplete as centres with data sets missing >5% of data will be excluded from the data analysis.
9. Log all contemporaneous data to REDCap database and regularly check to ensure the accuracy and completeness of collected data.
10. Complete your data collection within the specified data period
11. Commence and complete data validation within the data validation period (1st to 30th June)
12. Submit the names of the collaborators to the the regional trainee lead to ensure accuracy of the citable authorship
13. Present the results of the local audit at the local clinical governance meeting once the summary of results has been released to the local trainee lead.

Appendix 2: Regional Trainee Leads

HEE Region	Region Lead Name	Contact Email
England (14)		
East Midlands East of England Kent, Surrey and Sussex North East North West South West (Severn) South West (Peninsula) Thames Valley Wessex West Midlands Yorkshire and Humber London North West London North Central & East London South		
Wales (1)		
Scotland (1)		
Northern Ireland (1)		
Republic of Ireland (2)		

Appendix 3: HRA Decision Tool



Go straight to content.

MRC Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

MAMMA: Mastitis And Mammary abscess Management Audit

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net.

For more information please visit the Defining Research table.

Follow this link to start again.

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NOTE: If using Internet Explorer please use browser print function.

Appendix 4: MAMMA Steering Committee Charter

Roles and responsibilities

The roles of the MAMMA Steering Committee members include:

- Review and approval of the study protocol and statistical analysis plan
- Advising the Study Management Group (SMG) on all aspects of the study and overall supervision
- Ensuring that the study adheres to Good Clinical Practice principles
- Monitor progress of the study
- Attendance of bi-annual meetings
- Opportunity to comment on the study reports and publications

Benefits

All members of the MAMMA Steering Committee will be citable collaborators on all publications that ensue from this work. Steering Committee members will be invited to join the Study Management Group if they wish to become involved in the day-to-day delivery and conduct of the study.

Membership

The membership of the MAMMA Steering Committee will be compliant with the Medical Research Council (MRC) and the Health Technology Assessment (HTA) guidance and as a minimum will have:

- Independent Chair
- Non-independent Principal Investigator and co-investigator
- Two independent clinicians
- One independent statistician or methodologist
- One independent diagnostician
- One patient representative

At least 50% of the MAMMA Steering Committee members will be independent of the investigators, employing organisation and funder.

Meetings

There will be an initial meeting to approve the study protocol and set targets and deadlines for recruitment, data collection and analysis. This will be followed by bi-annual meetings, although extraordinary meetings may be arranged by the Principal Investigator on an ad-hoc basis if required. All the relevant information will be circulated in advance of the meeting and an accurate minute of the meetings will be prepared and disseminated by the Principal Investigator. The format of the meetings may be face-to-face or teleconference, depending on the availability of the members. Reasonable travel, accommodation and other costs will be reimbursed.

Committee process

For the Steering Committee meeting decisions to be valid, 67% of the registered members should be present at such a meeting as per HTA guidelines.

Confidentiality

All materials and discussions of the MAMMA Steering Committee should be treated as strictly confidential, unless advised otherwise.

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