Royal Cornwall Hospitals
NHS Trust

Bone Marrow Aspiration and Trephine Biopsy Standard Operating Procedure

V2.0

January 2024

Table of Contents

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. This SOP is for clinical nurse specialists trained and assessed as competent to perform bone marrow biopsy (BMB) procedures for the treatment and care of patients with haematological conditions. The procedure is undertaken with the approval of the haematology consultant team in order to attain clear diagnostic goals.

1.2. A BMB is a test that entails extracting a sample of the liquid portion of the marrow (aspirate) along with a solid portion of the marrow (trephine/core) from an accessible area of the bone marrow, typically the right or left posterior iliac crest of the pelvis.

1.3. The sample results provide detailed information about the condition of blood cells and the bone marrow environment. Information utilised in the diagnosis, monitoring and treatment response for a number of haematological conditions which may be malignant, non-malignant or reactive in nature.

1.4. This version supersedes any previous versions of this document.

2. Purpose of this Standard Operating Procedure

This document provides a SOP for approved clinical nurse specialists to complete BMB procedures on patients meeting the inclusion criteria and for the following objectives:

- Safe practice.
- To utilise consultant clinical time more effectively.
- To improve the patient experience.

3. Ownership and Responsibilities

3.1. This procedure has been drawn up by a multidisciplinary group representing clinicians and nurses

3.2. **Consultants Haematologist** to be responsible for the requesting of BMB procedures with clear diagnostic goals, providing oversight through the on-call haematologist to support the safe operating of this procedure and for ensuring clinical nurse specialists are properly trained in the application of this procedure.

3.3. **All competent practitioners trained in taking BMB** are responsible for following the instructions in this procedure and assessing their competency to practice the procedure.

4. Standards and Practice

4.1. **Equipment**

- BMB patient information form.
- Patient BMB consent form.

- Printed patient specific ARIA BMB request form.
- Patient labels and clinical pathology forms.
- Sterile dressing pack.
- Chloraprep with tint applicator.
- Plastic Apron.
- Procedure trollies x 2.
- Local anaesthetic of suitable dilution for example lidocaine 1% 100mg in 10mls.
- Selection of syringes for sampling and administration of local anaesthetic 2 x 5mls 2 x 10mls.
- Selection of needles to administer local anaesthetic.
- Bone marrow aspirate needle.
- Cytology slides and coverslip.
- Specimen bottles (for example histology formalin, EDTA and cytogenetics).
- Bone marrow trephine needle.
- Scalpel.
- Sterile gauze.
- Pressure dressing.

4.2. **Pre-procedure**

4.2.1. Patient identification and explanation of the BMB procedure should be made and a valid written consent obtained from the patient prior to the procedure. The practitioner should provide and explain the standard written BMB information to the patient; including all the risks involved and any questions arising.

4.2.2. The practitioner should check appropriate blood results and assess the patient is safe to undergo a BMB, including confirming all anticoagulant or antiplatelet medications have been stopped and appropriate monitoring blood results are available or discussed with on-call Haematologist prior to starting any BMB.

4.2.3. Patients with Myeloproliferative disorders have the highest risk of bleeding.

4.2.4. Patients with severe thrombocytopenia do not routinely need platelet support prior to the procedure, however a platelet count below 30d^9/l should be discussed with the on-call haematologist prior to the

procedure.

4.2.5. Patients with a thrombocytosis above 750 d^9/l, will similarly be at an increased risk of bleeding.

4.2.6. Patients with a diagnosis of DIC or history of bleeding, should be discussed with the on-call haematologist prior to the procedure.

4.2.7. For patients on warfarin, a check INR 7 days prior to procedure should be taken. If within therapeutic target and the patient has a stable trend, then no further monitoring is required prior to the procedure.

4.2.8. For patients on warfarin without a stable INR trend an INR test is required within 24 hours of the planned BMB and should be discussed with the on-call haematologist if the result outside the patients' therapeutic range.

4.2.9. For any patient with previously undisclosed or failure to stop anticoagulant and antiplatelet medication, no BMB should be completed without the consent of the on-call haematologist.

4.2.10. A sterile field of practice should be established using surgical aseptic non-touch techniques (ANTT) allowing the easy access of all equipment, sample slides and specimen bottles for the practitioner.

4.2.11. A second assistant should be available for the management of samples and for patient observation during the procedure and the practitioner should brief the assistant to the role they will provide.

4.2.12. The patient should be positioned appropriately for the taking of the BMB. Lying on their side, with legs drawn up in a position comfortable to maintain for approx. 20 to 30 minutes.

4.3. **Procedure – Bone Marrow Aspirate Collection**

4.3.1. Wash hands and perform physical examination of the patient to identify biopsy site on the chosen posterior iliac crest and assess the equipment for the procedure.

4.3.2. Additional equipment may be required due to patient morbidity which should be prepared prior to proceeding with BMB.

4.3.3. Wash hands and apply sterile gloves, using an ANTT approach clean the patient's skin at identified biopsy site thoroughly with 2% chloraprep and 70% isopropyl alcohol solution.

4.3.4. Prepare local anaesthetic syringe in accordance with the ARIA request form details and infuse to site for biopsy with both subcutaneous and intradermal injections to anaesthetise an area with approx. 15mm diameter.

4.3.5. Allow sufficient time and assess patient's response to local anaesthetic prior to proceeding further.

4.3.6. If patient discomfort is not controlled at any time during the procedure additional local anaesthetic can be utilised subject to the ARIA request form.

4.3.7. However, if patient is unable to tolerate procedure and consent to proceed is withdrawn, the procedure should be halted, the patient made safe and comfortable, and the on-call haematologist should be contacted.

4.3.8. Check the dedicated aspirate needle is functional. Introduce the needle and advance point to the biopsy site periosteum. Recheck patient for analgesia, prior to advancing the needle through the bone cortex and into the medulla.

4.3.9. Once in position within the medulla, remove the stylus from the aspirate needle and collect the first aspirate cells, using a 5ml syringe. Approx. 0.5mls of aspirate is required to prepare the initial cytology slides, with a minimum of 6 slides required.

4.3.10. Using a second 5ml syringe withdraw any further aspirate for the processing of cytogenetics and/or surface markers. To be taken in accordance with the ARIA request form, using the appropriate sample receptacles.

4.3.11. Once all the required aspirate samples are collected, the needle can be withdrawn, and the area closed using pressure and sterile gauze.

4.3.12. If no further samples are required and the wound site is haemostatically stable, the wound should be covered with a suitable sterile pressure dressing, which is to be kept clean and dry for 24 hours then removed by patient.

4.3.13. If a dry tap is obtained, consider repeating the procedure. If appropriate discuss the procedure with the patient, to gain their consent for any further aspirate attempts.

4.3.14. Alternatively, aspirate may be taken via trephine needle prior to trephine collection.

4.4. **Procedure – Bone Marrow Trephine**

4.4.1. Surgical ANTT approach, physical examination and anaesthetic as per aspirate procedure.

4.4.2. A small incision in the skin may be required to facilitate the trephine procedure and this can be completed with a scalpel blade.

4.4.3. Check the dedicated trephine needle is functional and introduce the device into the same insertion site as the aspiration needle.

4.4.4. However, the sample site should be removed from the aspiration site to prevent sample artefact.

4.4.5. When the periosteum is reached. Re-assess the patient's analgesia prior to advancing the needle through the cortex using a gentle rotating motion. Once the medulla is reached the stylus of the needle should be removed.

4.4.6. The trephine needle should be gently advanced to the estimated core length of 20mm. The sample length should be checked using the metallic stylet provided. Continue to advance and re-check the core length until the recommended sample length is achieved.

4.4.7. The trephine core is collected using the metallic spring stylet provided. Once in place the trephine needle and spring stylet are removed together, and the wound closed with pressure and sterile gauze. Once the wound is haemostatically stable, an appropriate pressure dressing should be applied over the wound and kept clean and dry for 24 hours and removed by the patient.

4.4.8. The trephine core is to be rolled on 2 cytology slides and then placed into the formalin container.

4.5. Post procedure

4.5.1. All samples need to be labelled at the end of the procedure, prior to patient discharge, procedure details need to be documented in the patient's notes or on the ARIA electronic system.

4.5.2. Histology and genetic laboratory forms should be completed and appended to the ARIA request form with the samples and hand delivered to the Haematology Laboratory.

4.5.3. Post procedure analgesia, dressing care and infection monitoring should be discussed with the patient and emergency contact details for patients highlighted.

4.5.4. If patient post procedure recovery is complete, they can be discharged to home.

4.6. Inclusion criteria

Patient inclusion shall be determined by the patient's consultant haematologist, or the on-call Haematologist consultant only and meet the following inclusion criteria:

4.6.1. Inclusion criteria

- Patients consenting to participate.
- Patients with appropriate ARIA request raised by consultant haematologist or designated specialist registrar.

4.6.2. Exclusion criteria

- Patient deemed unable to participate due to lack of capacity* as defined under the Mental Capacity Act (2005). Unless supported by a best interest decision and documented form 4 consent.
- Patients who decline to participate.
- Any patient with a clotting disorder

*Note: If there is any doubt about the patient's capacity to make decisions, further guidance can be found in the RCHT Mental Capacity Act Policy.

4.7. **Competency**

Competent Practitioners

4.7.1. All practitioners required to undertake BMB collection within their role should seek the approval of the Haematology governance lead: Competency will be gained by undertaking a period of supervised practice with a designated tutor and undertaking a clinical assessment period prior to being signed off as a competent practitioner.

4.7.2. On completion a written or electronic document, will be issued to the practitioner and should be kept along with the supervised practice log as evidence of the competency.

5. Dissemination and Implementation

5.1. The SOP will be shared with all practitioners who undertake BMB.

5.2. No training needs identified.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Availability of blood test results. Appropriate prescribing decision.
Lead	Specialty NMP.
Tool	Adherence to procedures will be monitored as part of the ongoing audit process within the department on a Word or Excel template specific to the topic.
Frequency	2 yearly.

Information Category	Detail of process and methodology for monitoring compliance
Reporting arrangements	To haematology department.
Acting on recommendations and Lead(s)	Any future recommendations will be discussed by the Haematology MDT before a plan is formulated.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned immediately. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

7. Updating and Review

Review in 3 years through the care group approval process.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Bone Marrow Aspiration and Trephine Biopsy Standard Operating Procedure V2.0
This document replaces (exact title of previous version):	Bone Marrow Aspiration and Trephine Biopsy Standard Operating Procedure V1.0
Date Issued / Approved:	December 2023
Date Valid From:	January 2024
Date Valid To:	January 2027
Author / Owner:	John Botfield, Haematology Clinical Nurse Specialist.
Contact details:	01872 253239
Brief summary of contents:	Standard operating procedure for bone marrow aspiration and trephine biopsy.
Suggested Keywords:	Bone marrow, biopsy, aspiration, trephine, haematology.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Specialist Governance Meeting.
Manager confirming approval processes:	Ian McGowan.
Name of Governance Lead confirming consultation and ratification:	Suzanne Atkinson.
Links to key external standards:	None required.
Related Documents:	None required.
Training Need Identified:	No.

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical / Cancer Services.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
November 2020	V1.0	Initial issue.	Caroline Williams, Haematology CNS.
December 2023	V2.0	No changes to content. Formatted to latest Trust template.	Caroline Williams, Haematology CNS.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Bone Marrow Aspiration and Trephine Biopsy Standard Operating Procedure V2.0
Department and Service Area:	General Surgery and Cancer Services.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Caroline Edwards, Haematology Cancer Nurse Specialist.
Contact details:	01872 253239

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Haematology specialist nurses and doctors who are competent to perform bone marrow biopsy.
2. Policy Objectives	To ensure safe, evidence-based practice.
3. Policy Intended Outcomes	To ensure good quality samples and to provide the best possible patient experience.
4. How will you measure each outcome?	Feedback from patients. MDT discussion of samples.
5. Who is intended to benefit from the policy?	Patients and staff.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Specialist Governance Meeting.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	Mindful of cultural and religious belief.

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Caroline Edwards, Haematology CNS.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis