EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST

DEPARTMENT OF PATHOLOGY

BLOOD METAL MONITORING FOR METAL-ON-METAL (MOM) HIP REPLACEMENTS

Version:	3
Ratified by:	Long Term Conditions-Intermediate Care Board.
Date ratified:	25-10-2012
Name of originator/author:	Miss Elizabeth Hall
Director responsible for implementation:	Professor Friedrich Muhlschlegel
Date issued:	April 2021
Review date:	Two years after date issued
Target audience:	Clinical staff (medical, nursing and scientific), Trust wide and primary care

Version Control Schedule

Version	Date	Author	Status	Comment
1.0	22-1-2013	Elizabeth Hall	Archived	
2.0	9-12-2016	Elizabeth Hall		Frequency of testing Instructions for blood sampling New SCPs
3	5-2-2021	Elizabeth Hall		Updated in line with MDA/2017/018 Updated email for SCP

Contents

1 Policy Summary

This policy gives guidance on requesting metal (cobalt and chromium) ion measurements for monitoring patients with metal on metal (MoM) hip replacements.

2 Introduction

In June 2017 the Medicines and Healthcare products Regulatory Agency (MHRA) issued an updated Medical Device Alert (MDA)[1] outlining the requirements for surveillance of patients who have received MoM hip replacements. The MDA gives details of the frequency that monitoring, with measurements of blood metal ion concentrations and with imaging, is required in different subgroups of patients.

3 Purpose and Scope

This policy outlines the arrangements for surveillance of MoM hip replacements within East Kent. It may be used for patients both within the Trust and in primary care and the community.

4 Definitions

Medicines and Healthcare products Regulatory Agency (MHRA): an agency of the Department of Health.
Medical Device Alert (MDA): notice from the MHRA with recommendations regarding specific medical devices.
Metal on metal (MoM) hip replacements: where both surfaces are metal.
Metal ions: the metals of concern with MoM hip replacements are cobalt and chromium.

5 Duties

All staff involved in the care of patients with MoM hip replacements, whether clinical or laboratory, must adhere to this policy.

6 Policy for blood metal monitoring for metal-on-metal (MoM) hip replacements

Hip replacements where both surfaces are metal have a higher failure rate than other types of implant (around 10% over 5 years compared to less than 5%[2]). Rising blood concentrations of cobalt and chromium or fluid collections around the joint may indicate impending failure. There is no evidence of an increased risk of cancer or other systemic health problems from this route of exposure to cobalt and chromium. Also, there is no evidence of significant increases in metal ions in patients with metal-ceramic or metal-plastic implants.

The MHRA advises that patients with MoM replacements should be monitored to detect rising blood concentrations of cobalt and chromium[1]. The recommended frequency of monitoring varies with the type and size of device and with the sex and symptoms of the patient. The interpretation of blood results, with or without accompanying imaging investigations, is complex. It has been estimated that most GPs in our area will have no more than one or two such patients under their care. Conversely, the Hospitals Trust orthopaedic team have a wealth of experience of dealing with such patients. Furthermore, the blood tests are expensive and require special sampling conditions to avoid contamination.

In consultation with our primary care commissioners and to optimise use of NHS resources, it has therefore been agreed that cobalt and chromium measurements will not be available as a direct access test to primary care for hip replacement patients. These tests will only be undertaken when requested by an orthopaedic consultant. It is preferred that the blood sample is collected by phlebotomists at K&CH, QEQMH, WHH or RVH Folkestone who are trained in the techniques that avoid contamination of the sample. If a patient must be bled elsewhere it is essential that whoever is to take the sample first phones the Duty Biochemist on 01233 616287 for instructions. In summary, an EDTA (purple top) blood sample is required. At least two other samples must be collected through the same needle before collecting the sample sent for analysis. The first two samples may be used for other tests, as appropriate, or discarded. An empty EDTA tube from the same lot number must be sent with the sample sent for cobalt and chromium.

The orthopaedic surgeons at EKHUFT are proactively following-up all East Kent MoM hip patients with appropriate counselling and tests. More details can be obtained from the Surgical Care Practitioners (SCPs) Susan Graham susan.graham24@nhs.net and Selina Eastwood selina.eastwood@nhs.net. Patients with hips done outside the NHS may be referred by their GP. Any patient, with any type of hip replacement, with symptoms that may suggest a failing implant should be referred for evaluation.

An initial measurement of blood cobalt and chromium concentrations is recommended for all MoM Repeat measurements should be guided by local protocols based on the MHRA guidelines, but not more frequently than once a year except when assessing patients with an initial raised concentration of either ion. Patients with an initial concentration of either cobalt or chromium ≥7 ppb should be assessed at 3 months to determine whether concentrations are rising.

7 Key Stakeholders, Consultation, Approval and Ratification Process

East Kent Hospitals University NHS Foundation Trust is the key stakeholder for this policy.

Consultation has been through e-mail and face-to-face communication between clinical biochemistry staff (Miss Elizabeth Hall, Dr Edmund Lamb), Trust consultant orthopaedic surgeons (Mr Philip Housden) and nursing staff, Dr Caroline Jessel (Medical Advisor and Sustainability Lead, NHS Kent and Medway) and GP groups (Long Term Conditions-Intermediate Care Board) during February to October 2012. Copies of correspondence are held by Clinical Biochemistry on the shared drive.

8 Review and Revision Arrangements

Two years from implementation date, by author.

9 Dissemination and Implementation

Proactive implementation through the Care Groups by appropriate clinical leads and by proactive dissemination to primary care partners.

10 Document Control including Archiving Arrangements

Archive of this document will be through QPulse.

11 Monitoring Compliance

Within the Trust, compliance with this policy must rest with the requesting Care Groups. Maintenance vetting and occasional audit of compliance with this requesting guidance will be undertaken by Clinical Biochemistry.

12 References

1. MHRA. Medical Device Alert MDA/2017/018 All metal-on-metal (MoM) hip replacements
2. National Joint Registry. Public and patient guide to the NJR Report 2011. www.njrcentre.org.uk

13 Associated Documentation

Not applicable

Appendix A - Equality Impact Assessment

Equality and Human Rights Impact Analysis (EHRIA)

Part One – Screening Tool

Name of the policy, strategy, function or methodology:	Blood metal monitoring for metal-on-metal (MoM) hip replacements

Details of person completing the EHRIA	
Name	Miss Elizabeth Hall
Job Title	Principal Clinical Scientist
Department/Speciality	Pathology/Clinical Biochemistry
Telephone Number	ext 722-2868

1. Identify the policy, strategy, function or methodology aims

What are the main aims, purpose and outcomes of the policy, strategy, function or methodology?
To ensure a consistent approach to monitoring of patients with MoM hip replacements across the health service in East Kent.
Does it relate to our role as a service provider and/or an employer?
Service provider.

2. Assess the likely impact on human rights and equality

Use this table to check if the policy, strategy, function or methodology:

- could have a negative impact on human rights or on any of the equality groups, or
- could have a positive impact on human rights, contribute to promoting equality, equal opportunities or improve relations.

It is not necessary to complete each box, nor to mark whether it is positive or negative, although you can do this if you find it helpful.

	Protected Characteristic								
	Race	**Sex**	**Disability**	**Sexual Orientation**	**Religion or belief**	**Age**	**Gender reassignment**	**Marriage & Civil Partnership**	**Pregnancy & Maternity**
Could this policy, procedure, project or service affect this group differently from others? **YES/NO**									
Could this policy, procedure, project or service promote equal opportunities for this group? **YES/NO**									
Right to life *e.g. decisions about life-saving treatment, deaths through negligence in hospital*									
Right not to be tortured or treated in an inhuman or degrading way *e.g. dignity in care, abuse or neglect of older people or people with learning disabilities.*									
Right to respect for private and family life e.g. *respecting lgb relationships, confidentiality*									
Right to freedom of thought, conscience and religion *e.g. respect for cultural and religious requirements*									
Right to freedom of expression *e.g. access to appropriate communication aids*									
Right to freedom of assembly and association *e.g., right to representation, to socialise in care settings*									
Right to education *e.g. access to basic knowledge of hygiene and sanitation*									
Right to liberty e.g. informal detention of patients who do not have capacity									

3. How does it impact on people's human rights and equality?

Using the table above, explain anticipated impacts. If a full EHRIA is recommended, you can summarise the impacts - it is not necessary to set these out in detail,

Could people's human rights be impacted negatively? Could the policy, strategy, function or methodology result in inequality or discrimination?
No
Could this policy, strategy, function or methodology result in positive impacts on people's human rights or equality? Could it present opportunities to promote equality?
No

4. Recommendations

Is a full EHRIA recommended? If not, give reasons
No. The policy has equal impact.

5. Publication of EHRIA

Give details of where Screening Tool or the full EHRIA will be published and when this will take place
With document.

Details of person completing the EHRIA	
Name	Miss Elizabeth Hall, Principal Clinical Scientist

Signed …… Date: ……

Approval and sign-off	Name
Head of Department/Director	Dr Sally Stock, Head of Service Clinical Biochemistry

Signed …… Date: ……

	Name
Trust Board approval and sign-off	not applicable

Signed …… Date: ……

Appendix B – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY:

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**	Yes	
4.	**Ratification process**	Yes	
5.	**Review arrangements**	Yes	
6.	**Control of documents, including archiving arrangements**	Yes	
7.	**Associated documents**	n/a	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	n/a	
10.	**Any other requirements of external bodies**	n/a	
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	n/a	

Appendix C – Plan for Dissemination of Policies

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

Acknowledgement: University Hospitals of Leicester NHS Trust (Amended)

Title of document:	Blood metal monitoring for metal on metal (MoM) hip replacements		
Version Number:	3		
Approval Date:	dd-2-2021	**Dissemination lead:**	Elizabeth Hall
Previous document already being used?	Yes		
If yes, in what format (paper / electronic) and where (e.g. Directorate / Trust wide)?	Electronic on QPulse and TrustNet		
Proposed instructions regarding previous document:	Electronic archive		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (i.e. paper or electronic)**	**Comments:**
Trust clinical staff	TrustNet	electronic	
Primary care	GP zone of Trustnet	electronic	
Clinical Biochemistry staff	QPulse	electronic	

Author's Dissemination Record - to be used once document is approved – to be kept with the master document

Date document forwarded to be put on the Trust's central register / in SharePoint:		**Date document put on Directorate register (if appropriate) / on Directorate webpage (if applicable)**	

Disseminated to: (either directly or via meetings, etc.)	**By Whom?**	**Format (i.e. paper or electronic)**	**Date Disseminated:**