University Hospitals of Leicester NHS
NHS Trust

Care of the Sick Xofigo Patient Policy – Radiation Protection Considerations

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

2023: contact details and supporting references updated. Reformatted to a policy

KEY WORDS

Xofigo, radiation, nuclear medicine

1 INTRODUCTION AND OVERVIEW

This policy is to provide radiation protection considerations for UHL staff who to need to care for patients within 6 weeks of them receiving a Radium-223 Xofigo treatment or for mortuary staff who need to come into contact with a deceased patient within 6 weeks of them receiving a Radium-223 Xofigo treatment.

Radium-223 (Ra-223) Dichloride (Xofigo) is a therapeutic radiopharmaceutical used to treat bone metastases in patients with prostate cancer. Patients receive this treatment every 4 weeks with 6 cycles completing the treatment.

Ra-223 predominantly emits alpha radiation. This type of radiation can only travel a short distance in tissue and cannot pass through standard protective clothing.

This means the main hazard from Ra-223 is if it was to be inhaled or ingested or come into direct contact with skin or mucosa.

As Xofigo treatment is considered a palliative treatment, it is possible that patients will attend for emergency care, need intensive nursing care or pass away.

Ra-223 will be present in the patient's blood, urine, faeces and bones. The quantity will vary depending on how long it has been since their last treatment.

All patients who have received Xofigo therapy treatment will be given an instruction card (see Appendix 1) which will detail when they had their last administration of Ra-223. They are informed to keep this with them at all times and to present it if they attend for a medical appointment.

The overarching principle should be that the immediate medical needs of the patient concerned must be given priority over the radiation hazard. The medical staff involved with the patient's care must be involved in any discussion to ensure the clinical needs of the patient are met.

This document gives an overview of the radiation protection issues and some initial guidance on how to manage these risks.

2 POLICY SCOPE

This policy is aimed at all UHL staff who to need to care for patients within 6 weeks of them receiving a Radium-223 Xofigo treatment or for mortuary staff who need to come into contact with a deceased patient within 6 weeks of them receiving a Radium-223 Xofigo treatment.

3 DEFINITIONS AND ABBREVIATIONS

MPE – Medical Physics Expert

NAIR – National Arrangements for Incidents involving Radioactivity

PPE – Personal protective equipment

Ra-223 – Radium-223

RPA – Radiation Protection Advisor

RPS – Radiation Protection Supervisor

Xofigo – brand name for radioactive metastatic prostate cancer treatment

4 ROLES

4.1 Responsibilities within the Organisation

a) Board Director Lead - Andrew Furlong, Medical Director is responsible for the policy

b) The Head of Nuclear Medicine Physics will review the document and support the communication to the necessary staff groups. They are also responsible for monitoring incidents related to this policy.

c) All staff are required to use the policy for information when a Xofigo patient attends an emergency or inpatient setting and they need immediate radiation protection advice. All staff are also responsible for reporting incidents related to this policy.

d) The RPA, MPEs or trained Nuclear Medicine staff are responsible for providing further advice tailored to individual circumstances when required, for example to mortuary or ward staff and for providing tailored hands on support when required, for example contamination monitoring of staff.

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 Care of a Xofigo Patient Attending for Emergency Care or Requiring In-Patient Care

a) At all time points following the last Ra-223 administration, it is safe for staff to have close contact with the patient, providing standard hygiene procedures are followed (including the use of personal protective equipment (PPE)).

b) If it has been **less than 1 week** since the last administration of Ra-223, please follow these precautions and advice AND the advice in section 2.1 c):

- Wash hands well with soap and water following any contact with the patient.
- If the patient is fit enough, please get them to use a toilet rather than bed pan. Also ask them to sit when urinating and to flush the toilet twice after use. If the use of a bed pan is required, dispose of urine or faeces direct to the drains via a toilet and wear PPE including a face mask (type IIR).
- If any linen or waste is contaminated with the patient's blood, urine, vomit or faeces please double bag separately and mark as 'Radioactive – not for disposal'. Then inform the Nuclear Medicine Service who will check the waste and take it back to Nuclear Medicine if necessary. This MUST NOT be disposed of via standard waste systems.
- Specimens or samples for pathology may be radioactive. Please contact Nuclear Medicine once any samples have been taken who will check them before they are sent to pathology. If the results are urgent, label the samples as 'Radioactive – Please contact Nuclear Medicine - Not for disposal' before sending to Pathology.

c) If it has been **less than 6 weeks** since the last administration:

- If any surgical intervention is required, where it is possible there may be airborne contamination (for example bone sawing or drilling), all staff in theatre at risk of contact with this contamination must wear face masks and visors. It is also possible that the clinical waste may contain some radioactive contamination - please bag separately and mark as 'Radioactive – not for disposal'. Then inform the Nuclear Medicine Service who will check

the waste and take it back to Nuclear Medicine if necessary (see contact list in Section 5.3 for out of hours details)

d) If it has been **greater than 6 weeks** since the last administration of Ra-223, there are no restrictions in place.

5.2 Death of a Xofigo Therapy Patient

a) There are no restrictions on the burial of a deceased patient at all time points following the last Ra-223 administration.

b) If it has been **less than 7 days** since the last administration of Ra-223, handling and storage of the body will not pose a hazard providing standard hygiene procedures are followed (including the use of PPE) and no invasive actions are performed. Contact Nuclear Medicine or the RPA for further advice in this situation.

c) If it has been **greater than 7 days** since the last administration of Ra-223, embalming or post mortem is safe to occur providing standard hygiene procedures are followed (including the use of PPE). Please **contact the Nuclear Medicine** service so that contamination monitoring of the staff performing the post mortem can be carried out as a precaution. It is also safe for cremation to occur at this time as long as the collection of ashes is delayed for a further week (i.e. collection of ashes is at least 14 days since last administration).

d) If it has been **greater than 6 weeks** since the last administration of Ra-223, embalming or post mortem can be performed with no input required from Nuclear Medicine/Medical Physics staff.

5.3 Contacts

Every person working with radioactive sources is required to protect themselves and all others from any hazard arising from their use as far as reasonably practicable and to follow all advice provided by the Radiation Protection Advisor (RPA).

The following staff can provide further advice tailored to the individual circumstances:

Role	Contact details
Radiation Protction Advisor (also Head of Leicester Radiation Safety Service (LRSS))	Medical Physics, ext. 16750.
Nuclear Medicine Medical Physics Experts (MPE)	Nuclear Medicine Reception ext. 15627/13850 Out of hours – via switchboard (numbers are on the NAIR* list).
Clinical Scientists, Nuclear Medicine	Nuclear Medicine Reception ext. 15627/13850 Out of hours – via switchboard (numbers are on the NAIR* list).
Nuclear Medicine Therapy Lead	Nuclear Medicine Reception ext. 15627/13850
Nuclear Medicine Radiation Protection Supervisor (RPS)	Ext. 15627
Radiopharmcy RPS	Ext. 15579

* ‘NAIR’ is National Arrangements for Incidents involving Radioactivity – switchboard have access to contact details for UHL staff for this scheme. This list is also used for out of hours contact arrangements.

Associated Docuements –

Ionising Radiation Safety Policy (Trust Ref B26/2019)

Personal Protective Equipment at Work Policy (Trust Ref B9/2004)

6 EDUCATION AND TRAINING REQUIREMENTS

Awareness of the policy will be made to mortuary staff, Emergency Department staff and Oncology staff (those most likely to need to refer to it) through communications.

7 PROCESS FOR MONITORING COMPLIANCE

What key element(s) need(s) monitoring as per local approved policy or guidance?	**Who will lead on this aspect of monitoring? Name the lead and what is the role of other professional groups**	**What tool will be used to monitor/check/ observe/asses/ inspect Authenticate that everything is working according to this key element from the approved policy?**	**How often is the need to monitor each element? How often is the need complete a report ? How often is the need to share the report?**	**How will each report be interrogated to identify the required actions and how thoroughly should this be documented in e.g. meeting minutes.**
Number of Datix incidents outside of Nuclear Medicine involving Xofigo patients	Head of Nuclear Medicine Physics	Datix trending is monitored at the Radiation Safety Committee (RSC)	Report is produced quarterly for RSC meetings	Report is presented at the meeting for any trending to be identified. Any trending and subsequent actions required relating to Xofigo patient incidents will be detailed in meeting minutes.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Ionising Radiation Safety Policy (Trust Ref B26/2019)

Personal Protective Equipment at Work Policy (Trust Ref B9/2004)

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This policy will be reviewed at least every 3 years, or if any significant changes are required. This is identified as part of a quality management system.

The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trust's PAGL system

Appendix 1 – Example of Ra-223 Instruction Card Given to all Xofigo Therapy Patients

Front page

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Xofigo - Ra-223 Chloride Instruction Card

Radionuclide	**Radium-223**		**Name**	
The holder of this card has received Ra-223 (Xofigo) IV Administrations on the dates noted:	1.	MBq	**Address**	
	2.	MBq		
	3.	MBq		
	4.	MBq		
	5.	MBq	**Hospital ID**	
	6.	MBq	**Consultant**	

Please inform your GP and next-of-kin regarding your treatments and the presence of this card. Carry this card and your list of treatment dates with you at all times and if you need to attend a medical centre (hospital or GP surgery) please show it to the medical staff.

Back page

Contact Details: If you have any questions about your clinical condition please speak to your Consultant. If you have any questions about radiation protection or appointment details for the treatment itself then please contact the Nuclear Medicine Service at Leicester Royal Infirmary on **0116 258 5579** or **0116 258 5627.**	**Radiation Protection Advice:** Please follow the advice given about keeping hydrated and maintaining good hygiene for the **first week** after each injection. You must not father children for **6 months** following each injection.
Safe Dates: It is safe for the following to occur after: Cremation – can take place **7 days (or more) since the last treatment**, but collection of ashes must not take place for a further 7 days (which will be 14 days since last treatment). Post mortem - It is safe for mortuary staff to have contact with patients and for post mortem examinations to be carried out with **no input** from Medical Physics **6 weeks following the last treatment.**	
Prior to the above dates, please contact the Nuclear Medicine Service at Leicester Royal Infirmary on the numbers above or the Oncology team on the Emergency Oncology number 0808 178 2212.	
If this card is found, please return to: Nuclear Medicine Department, Sandringham Building (Level 0), Leicester Royal Infirmary, Infirmary Square, LE1 5WW	