

Fair Processing Notice and Further Information
Rory Morrison Registry (RMR)



D'Sa, Shirley

University College London Hospitals

October 2018

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Introduction

There are about 350-400 new diagnoses of WM in the UK per year and being a rare disease, clinical trials in this field are somewhat limited. However, in the past few years there has been major progress in the treatment of WM, including a better understanding of the biology and behaviour of the disease and the advent of new effective treatments and so it is vital that we capitalise on this.

In order to fully understand WM in the UK, there is an urgent need to collect 'real-world' data on UK patients affected by WM and related conditions. This includes accurate and detailed population based statistics and clinical information (the nature of the disease affecting the individual), treatments and the experience of living with the disease (so-called 'patient-related outcomes' or PROs).

The Rory Morrison WMUK Registry (RMR) Project focuses on patients who have Waldenström's macroglobulinaemia (WM) and related conditions including (but not limited to) Bing Neel syndrome, peripheral neuropathies such as anti-MAG neuropathy, cold agglutinin disease (CAD) and cryoglobulinaemia. It is dedicated to a patient, the beloved BBC news reader and continuity announcer, Rory Morrison who sadly lost his battle with WM in 2013. It has been made possible by funds raised by the WM community in the UK which have been generously donated to enable the set up and running of the web-based platform that is used to capture the data.

The clinical information will be collected by the clinical team looking after you. In addition we believe that it is important that we record data from patients - the patient-related outcomes. If you are happy to do this, then there is an option to receive questionnaires via an automated Emailer system. This will direct you to a series of surveys focussing on the impact of WM on your day – to – day lives. These include questions on symptoms such as fatigue, side effects of treatment and the overall mental, physical and social impact WM may have. If you are interested in receiving further details about the online patient reported outcomes extension of the Rory Morrison Registry then please contact Registry@wmuk.org.uk

Such information (which is not available in within the NHS at present) will provide the data needed to gain an accurate picture of this complex disease and to prove the efficacy of novel therapies in the UK. It will also provide an excellent resource for clinicians and patients to better understand WM on a country wide level. It will facilitate the design and entry of UK patients into clinical trials and demonstrate the clinical value of novel drugs considered by the Cancer Drugs Fund (CDF) and National Institute for Health and Care Excellence (NICE) within the NHS.

Data is already collected by various bodies and organisations, including the NHS. However, such data is collected for objectives that vary from ours, such as recording treatments used in cancer and commissioning (funding) chemotherapy. The RMR is different from national data collection initiatives, because it aims to monitor **the whole patient pathway including complications and outcomes**, specifically relevant to WM and related conditions.

Your written consent is **not** needed for inclusion of your data. Approval has been received from the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA) for the upload of patient data without specific consent. All data collected is subject to strict rules of confidentiality under Acts of Parliament, including the Data Protection Act 1998, the Health and Social Care Act 2001 and the

General Data Protection Regulation (GDPR) that came into force in May 2018. No patient identifiable data will be shared or released. You should however express any concerns you have about the inclusion of your data in to the Registry. If it is your wish that your data is not included, you should contact us via the email registry@wmuk.org.uk so that we can ensure that your data is not collected. This will not in any way affect the care that you receive.

The Registry has been set up so that doctors can upload demographic and clinical information about their patients directly on to the Registry using the NHS number, which is unique to every person. We also need to record the date of birth, geographical location of the patient and their local hospital. In each case, the doctor will be able to upload information for patients under his or her care and be able to see only their own patients' data. There will be Registry administrators who are part of the Registry Review Committee, with additional responsibilities of training all new users and ensuring that the Registry is managed in accordance with the Data Protection Act 1998 and GDPR and that the quality of the data entry is of a high standard.

With close to 600 patients registered already, the Rory Morrison Registry is the largest WM registry in the world. It has been 'live' since August 2017 and is expanding at a rapid rate. We are already beginning to develop a picture of WM in the UK; however there is still a long way to go. Your involvement by signing up to the PRO extension or by discussing the registry with your consultant is absolutely critical to its success.

As newer treatments become available, either via clinical trials or through NICE or the Cancer Drugs Fund, the registry has been recognised as a very useful tool in ensuring assessing the impact of the novel therapies. However, it cannot be successful without the combined effort from patients and clinicians. A successful registry will provide the backbone for WM in the UK; it will ensure patients are receiving the gold standard of treatments, those who are eligible for trials do not miss out on the opportunity and will ultimately bring to the fore patients with this rare condition.

Frequently Asked Questions

Q1: What is a patient Registry?

Simply put, a patient Registry is a database or collection of information about people affected by a particular condition. The Rory Morrison WMUK Registry (RMR) is used to collect statistics about the WM population, their diagnostic and treatment information and, importantly, the overall impact on daily living WM and its related conditions may have.

Q2: Why is a patient Registry needed?

Scientific advances over recent years have led to substantial changes in the understanding and treatment of WM. New therapeutic strategies are being developed and, for some of these treatments, trials are already underway. Several new treatments that target WM in a different way to conventional chemotherapy are being tested in clinical trials. When a clinical trial is being planned, it is very important that patients suitable for that trial can be identified easily and approached promptly.

The best way of ensuring this can happen is to make sure that patients' details are all collected together in a single database or "Registry" that contains all the information that researchers will need, including each patient's particular disease features and other key information about their disease.

The Registry will also provide critical information about the state of the service in the UK particularly the regional differences in treatments and the approaches of varying centres to clinical trials. This will act as a backdrop for the subsequent development of a WM support network for clinicians across the UK so that they can provide the most update and accurate information to the patients.

Q3: Who is running the RMR project?

A consortium of WMUK, doctors and patients, and Dendrite Clinical Systems is running the RMR Project. WMUK is a Registered Charity dedicated to improving outcomes for patients with WM and related conditions by bringing WM patients and medical professionals closer together. Dendrite is a British company specialising in disease Registry database systems. The Project's Lead is Dr Shirley D'Sa, Consultant Haematologist and Lead of the WM Service at University College London Hospitals NHS Foundation Trust, London in conjunction with a dedicated clinical fellow, Dr Joshua Bomsztyk, who is based at UCLH, but will be in close liaison with participating centres.

Q4: Which patients are eligible?

All patients with a confirmed diagnosis (or pending diagnosis) in one of the conditions for which registries exist are eligible for inclusion, including but not restricted to the following:

- Asymptomatic Waldenström's macroglobulinaemia / lymphoplasmacytic lymphoma
- Waldenström's macroglobulinaemia / lymphoplasmacytic lymphoma requiring treatment
- Bing-Neel syndrome (central nervous system involvement by WM)
- IgM MGUS

- IgM-associated peripheral neuropathy
- IgM-associated Cold Agglutinin Disease (CAD)
- IgM-associated Cryoglobulinaemia
- IgM-associated AL amyloidosis

Q5: Who will contribute data to new RMR Project?

At the time of launch, 11 hospitals (10 in England and 1 in Wales) were signed up to submit their data to the national Registry on a regular basis. However this number has increased with a further 5 centres having joined and a dozen further centres in beginning to start the registration process. So far, Scotland is not yet included as separate rules are needed, but this is being considered in the future as we wish to capture data from across the UK.

Hospitals registered with RMR Project

	LEAD CONSULTANT	ADDRESS
1	Dr Shirley D'Sa	UCLH NHS Foundation Trust Cancer Division 3rd Floor West 250 Euston Road London NW1 2PG
2	Dr Helen McCarthy	Royal Bournemouth Hospital Castle Lane East Bournemouth BH7 7DW
3	Dr Guy Pratt	University Hospitals Birmingham NHS Foundation Trust Birmingham, B15 2GW
4	Dr Jaimal Kothari	Oxford University Hospitals NHS Foundation Trust Churchill Hospital Old Road Headington Oxford OX3 7LE
5	Dr Jindriska Lindsay	East Kent University Hospitals NHS Foundation Trust Ethelbert Rd Canterbury CT1 3NG
6	Dr Roger Owen	St James's University Hospital Beckett Street Leeds, LS9 7TF
7	Dr Josephine Crowe	Royal United Hospital Combe Park Bath BA1 3NG
8	Dr Rajesh Krishna	Department of Haematology, 2nd Floor Sandringham Building Leicester Royal Infirmary Leicester LE2 7LX

	LEAD CONSULTANT	ADDRESS
9	Dr Jonathan Wallis	Freeman Hospital Freeman Rd High Heaton Newcastle upon Tyne NE7 7DN
10	Dr Sunil Iyengar	The Royal Marsden Hospital Downs Rd Sutton SM2 5PT
11	Dr Nilima Parry-Jones	Nevill Hall Hospital Brecon Road Abergavenny NP7 7EG Wales
12	Dr Deborah Turner	Torbay Hospital Loves Bridge Torquay TQ2 7AA
13	Dr Kirsty Cuthill	King's College Hospital Denmark Hill London SE5 9RS
14	Dr Rebecca Auer	Bart's Hospital W Smithfield London EC1A 7BE
15	Dr Kim Linton/Dr Richard Chasty	Christie Hospital Wilmslow Road Manchester M20 4BX
16	Dr Chara Kyriakou	Northwich Park Hospital Watford Road Harrow HA1 3UJ

If your centre is not on the list, you could request a referral to one of the listed centres for purposes of capturing your data. This does not mean you have to transfer all your care to this centre but will require yourself or your clinician to provide the required information for the RMR centres to upload.

If your regular consultant, who is not at one of the registered centres but would like to know more about the RMR then they can email registry@wmuk.org.uk for more information.

Q6: How can I join the RMR and where will my data go?

The clinical information will be collected by the clinical team looking after you. They will include all information related to you since your were diagnosed with WM or related condition, and continue to follow up your progress in a prospective way, by adding further information every time you are seen in the clinic. You will also be asked to provide information through a series of questionnaires (so-called patient-related outcomes or PROs) which will be provided to you via an automated E-mailer system provided you agree to supply your email address. If you do not have an email address or prefer to complete paper versions of the questionnaires, these can be done when you are seen in the clinic.

The RMR team is committed to sharing data with other clinicians and health-related organisations to ensure the greatest possible outcomes from the hard work of collection. The Registry Review Committee will oversee and approve all requests on a case-by-case basis to decide which ones will be approved.

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It is important to remember that any shared data will remain anonymised and comply with the strictest confidentiality guidelines.

Q7: Who will have access to my medical records?

The RMR clinical team (Dr D'Sa and Dr Joshua Bomszyk, the Registry fellow) and Dendrite Clinical Systems (who are approved custodians of the data) will have access to the information on the Registry in its entirety. Your local consultant will have access to data belonging to the patients at their hospital.

Q8: What data items are collected?

The RMR is designed to collect data at diagnosis, treatments and outcomes. The addition of direct entry of patient-related outcome measures (PROMs) will be launched within a few months, via web-based and mobile platforms.

Diagnostic information includes:

- 1) NHS number
- 2) Date of birth
- 3) Gender
- 4) Date of diagnosis
- 5) Hospital at which diagnosed
- 6) Symptoms (if any) at diagnosis
- 7) Details of other illnesses (if any)
- 8) Eastern Cooperative Oncology Group ECOG performance status (a measure of general well-being)
- 9) Nature of diagnosis: WM (whether in need of treatment or on a 'Watch and Wait' programme), IgM-related disorders such as amyloidosis, neuropathy, cold agglutinin disease, cryoglobulinaemia, Bing-Neel syndrome (involvement of the central nervous system).
- 10) Results of diagnostic tests (where available) including:
 - a) Bone marrow biopsy and genetics (MYD88 and CXCR4) status
 - b) Scan results
 - c) Comprehensive blood profile.

Treatment information records:

- 1) Why treatment was needed (which symptoms)
- 2) Date of commencement
- 3) Regimen(s) used, number of cycles
- 4) Whether or not part of a clinical trial
- 5) Duration of response to that treatment (length of remission)
- 6) Complications of treatment

The following information would be recorded at each clinic visit:

- 1) Blood test results
- 2) ECOG performance status (a measure of general well-being)
- 3) Whether so-called 'B' symptoms (fever, weight loss) or other symptoms are present
- 4) Details of the clinical examination by the doctor

- 5) Infections history including any need for antibiotics

Patient status at follow up

This will be recorded at each visit and will continue for the duration of study (15 years).

- 1) Survival status
- 2) Disease status according to international criteria (responding to treatment, progressing disease etc)
- 3) Patient reported outcomes via online forms or hand written forms in clinic

Q9: How is RMR data processed?

The hospital trust providing your care will send your information to Dendrite Clinical Systems Ltd electronically using secure data transfer methods.

Dendrite will act as processors of your data and will store it securely. In order to cross-reference information on the RMR, a request for data linkage will be made to an organisation known as NHS Digital to acquire additional information from NHS databases held by Public Health England which also fall under the Data Protection Act 1998 and the Health and Social Care Act 2001. These databases hold patient information relating to hospital stays, chemotherapy and survival. Your name, date of birth and NHS number will be used to link RMR to the NHS databases. The linked information will help us to cross-check the information on the RMR. Data linkage will also provide information that will help us to improve our understanding about treatment choices and how best they can be combined to benefit patient care and survival.

Q10: How will I be identified in the Registry?

Upon entry to the Registry, you will be assigned a unique code. Your personal details (NHS number, hospital number, name, date of birth and postcode) will also have to be stored in the Registry so that you can be correctly identified and your data cross-checked with NHS databases. When your data is transferred outside Registry for analysis, **none** of your personal details will be used, and your records will only be identifiable by the code they have been assigned. Researchers who are analysing any of your data therefore cannot identify you personally from the information they have access to.

Q11: Does the RMR hold any sensitive data? How will it be kept safe?

Yes – the Registry holds detailed clinical records on patients but the whole system resides on a secure server within the dedicated NHS computer network. Data protection and privacy is an important part of RMR so no individual patient names can be identified in the results. Strict rules will be adhered to, to ensure this. Identifiers such as the NHS number, patient postcodes and date of birth are used at the point of data entry in to the Registry to ensure that the identity of the patient is correct, but items will then be partly camouflaged (such as using the month and year instead of the full date of birth and using the first three characters of the postcode instead of the full postcode) to minimise the chance of revealing identity.

The data controller (Dr Shirley D'Sa, UCLH) and the data processor, Dr Peter Walton of Dendrite Clinical Systems will make sure the data collected is subject to strict rules of confidentiality as laid down by Acts of Parliament, including the Data Protection Act 1998, the Health and Social Care Act 2001 and the GDPR 2018.

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Your data will be kept for 15 years under the responsibility of the Chief Investigator of the RMR Project. Since creating a Registry requires the existence of a file containing a patient's personal and medical data, this file will be subject to the regulations on data protection (the Data Protection Act 1998 and GDPR 2018). All information kept in the Registry will be treated confidentially. If any research or other documents based on data from the registries is published, this research will never identify you by name.

Third parties wishing to have access to data in the Registry (such as researchers or companies planning clinical trials or conducting research on new therapies) will only be given anonymous information identifiable only by a code in the form of a report. They will never be given direct access to the Registry database. Before they are granted access even to this anonymous information, they have to have the approval of the Registry Review Committee. Your data will not be made available to employers, governmental organizations, insurance companies or educational institutions, nor to your spouse, other members of your family or your doctor.

Q12: Will you ever give my name and address to a company running a clinical trial?

No, the Registry will never pass on any personally identifiable data to anyone outside the Registry. The only legal way that patients can be recruited for trials, is through the robust mechanism that is in place for recruitment to trials that is subject to the EU Clinical Trials Directive (Directive 2001/20/EC of 4 April 2001).

Q13: How will I benefit from being included in the RMR?

Registries are intended as a public service for the benefit of patients living with a particular disease. You will not receive any payment or any other financial benefit as a result of your data being entered on the Registry. Nevertheless, there may be other benefits to participating, including the following: You may be more likely to be identified as a suitable candidate for a certain clinical trial. You will also be informed of any new information relating to your disease which might be of interest to you – for example if better ways of caring for patients with your condition have been identified. The data collected might also provide benefits to other patients with your disease, for example by revealing statistics on how many people across the country have the same condition, or providing information for researchers interested in the best standards of care for your disease.

Q14: Do I have to participate in a Registry and can I withdraw if I change my mind?

National Registry data is most effective when it contains information from as many patients as possible. If you do not want your information to be collected for the RMR audit, please tell the people who are treating you or email registry@wmuk.org.uk to opt out from the RMR. It is possible that some RMR information may already have been transferred to Dendrite Clinical Systems Ltd. When the people who are treating you inform Dendrite about your decision, Dendrite Clinical Systems Ltd will make sure that any RMR information that can be removed from the Registry is destroyed. This will not affect your treatment in any way.

Should you wish to withdraw your data from a Registry you will be free to do so without having to provide any explanation. If you wish to withdraw, you should get in touch with the staff in charge of the Registry (contact information provided later).

Q15: How long will we keep your information?

We will retain the RMR data for a period of up to 15 years to enable us to collect, assess and report on the complications and outcomes of treatments.

Q16: Who should I contact if I have any questions?

If you have any general questions about this Registry project, please contact Registry@wmuk.org.uk