



DEPARTMENT OF EPIDEMIOLOGY AND PREVENTIVE MEDICINE, MONASH UNIVERSITY

The Myeloma and Related Diseases Registry

Project Outline v2.2

The Myeloma and Related Diseases Registry Research Team

26 February 2021

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MYELOMA AND RELATED DISEASES REGISTRY (MRDR)

PROJECT OUTLINE VERSION 2.2 DATED 26 FEBRUARY 2021

Important Note:

This study involves the collection of quality of life assessments and information found in patient and pathology notes. It does not involve any change to treatment regimens, therefore the following Project Outline takes the place of the 'Protocol' and will be referred to as the Project Outline in all Human Research Ethics documentation submitted for consideration.

Background

Myeloma, a malignant proliferation of plasma cells associated with anaemia, renal failure, hypercalcaemia and lytic bone lesions, has an age standardised incidence (ASI) rate of 6.9 per 100 000 in Australia, with a higher rate in males, and a median age at diagnosis of 71.¹ The incidence rate of myeloma has increased, and its prevalence is expected to increase due to an ageing population and recent improvements in the overall survival of patients with the disease.² Whilst myeloma is estimated to account for 1.6% of all cancers, it is one of the most common cancers recorded as the primary reason for hospitalisation in Australia, and is estimated to have been one of the twenty most common cancers diagnosed in Australia in 2019.¹

The range of treatment options has changed dramatically over the last decade resulting in improved survival for patients with myeloma. In addition, a large number of second-generation and targeted therapies are under development, expanding the repertoire of agents that are likely to be available in the future. However, the optimal way to utilise these therapies, including combination of agents and treatment algorithms, is yet to be defined.

Despite improved overall and progression free survival through disease control with newer agents, the majority of patients with myeloma cannot be cured and live with the burden of disease or cumulative effect of treatments.³ Therefore, supportive care to maintain quality of life is also becoming increasingly important throughout the course of the disease.⁴

Long-term patient follow-up and review of clinical (safety and efficacy) and correlative data outside of clinical trials will be highly valuable in informing optimal treatment strategies for myeloma and its related diseases. Clinical registries provide a useful mechanism to collect data on patterns of treatment and variation in outcomes (both survival and quality of life). They enable clinicians to benchmark against national and international standards and allow evaluation of the translation of advances in therapy (such as introduction in new targeted therapies) into long-term outcomes outside the setting of clinical trials.

¹ Australian Institute of Health and Welfare 2019. Cancer in Australia 2019. *Cancer series no. 119*. Cat. no. CAN 123. Canberra: AIHW.

² Bird JM, Owen RG, D'Sa S, Snowden JA, Pratt G, Ashcroft J, et al. Guidelines for the diagnosis and management of multiple myeloma. *Br J Haematol*. 2011;154(1):32-75.

³ Snowden JA, Ahmedzai SH, Ashcroft J, D'Sa S, Littlewood T, Low E, et al. Guidelines for supportive care in multiple myeloma. *Br J Haematol*. 2011;154(1):76-103.

⁴ Lonial S. Relapsed multiple myeloma. *Hematology Am Soc Hematol Educ Program*. 2010;2010:303-9.

Hypotheses

There is substantial variation in the therapy provided to patients with myeloma including choice of induction therapy, choice of therapy for primary refractory disease, choice of therapy for relapsed disease and the use of maintenance therapy as well as timing for treatment commencement.

There is significant variation between hospitals in the quality of care that patients with myeloma receive as measured by the following indicators:

- Proportion of eligible patients who are offered high dose therapy
- Proportion of patients who receive bisphosphonate therapy
- Proportion of eligible patients included in clinical trials
- Proportion of patients with primary refractory disease included in clinical trials
- Proportion of patients prescribed thromboprophylaxis
- Proportion of patients who receive vaccinations for streptococcus pneumonia and haemophilus influenzae

The outcomes for myeloma patients residing in non-metropolitan areas are inferior compared with patients residing in metropolitan areas.

Patients who have heavy marrow plasma cell infiltration (>40%) at diagnosis but who are not considered symptomatic based on CRAB criteria rapidly progress to symptomatic myeloma without therapy (and therefore should commence treatment at diagnosis).

Aims

The aims of the Myeloma & Related Diseases Registry are to:

- monitor access to care
- benchmark outcomes nationally and internationally
- explore variation in practice, process and outcome measures
- monitor trends in incidence and survival
- explore the factors that influence outcomes including survival and quality of life
- act as a resource for clinical trials

Study Design

The Myeloma & Related Diseases Registry (MRDR) was established in 2012. Data is collected by clinicians and staff under their direction at participating hospitals and private practices and entered into an electronic Case Report Form by way of a web portal.

In 2018, the MRDR will expand to the Asia-Pacific (APAC) region starting with the inclusion of Korea, Singapore, Malaysia, Taiwan and China. Consequently, there will be two arms of the MRDR; the Australian and New Zealand Myeloma and Related Diseases Registry (ANZ MRDR) and the Asia Pacific Myeloma and Related Diseases Registry (APAC MRDR). The APAC expansion will use the existing infrastructure and study design but will be subject to local ethical and regulatory requirements in the participating countries.

Study Population

Inclusion criteria

Patients with a *new diagnosis* of myeloma, plasmacytoma, plasma cell leukaemia, AL amyloidosis, smouldering multiple myeloma or monoclonal gammopathy of undetermined significance (MGUS).

- New diagnosis
 - Myeloma, plasmacytoma, plasma cell leukaemia, AL amyloidosis, smouldering multiple myeloma: diagnosis no earlier than 3 months prior to HREC approval at the site, to minimise retrospective data collection
 - MGUS: a ‘new diagnosis’ can be within 5 years of the date of diagnosis with MGUS, and no earlier than 3 months prior to ethics approval at the site.
- Age ≥ 18 years.
- Or, cause of death listed as myeloma or a related disease and diagnosis is no earlier than 3 months prior to HREC approval at the site.

Exclusion criteria

- Patients who choose not to participate in the registry.

Identification of Subjects

- Treating clinicians at the site or delegated staff will identify patients at the time of referral through standard referral databases. Patients retrospectively recruited prior to the HREC approval date will be identified from existing pathology and clinical lists.
- Case ascertainment checks with national or state-based cancer registries and participating sites will allow estimation of case capture at sites.

Study Assessments

General Overview

Inclusion on the MRDR does not involve any change in patient therapy; this is an observational study. Study assessments and all other clinical and pathology data are collected by Local Investigators or staff under their direction (who are employed by the participating hospital or private practitioner). With the exception of the quality of life survey detailed below, all data is drawn from the medical and pathology notes collected during standard medical care, with data collected on how the disease has impacted on the patient’s health and functional ability at the time of diagnosis and throughout treatment. ECOG or Karnovsky Performance Status measures will be retrieved from the notes or assigned by the local clinician based on clinical information in the notes.

Quality of Life Survey

Quality of life information is collected via the EQ-5D-5L (EQ5D). The EQ-5D survey is an instrument that is used as a measure of health outcome and quality of life. Data collected from this survey is used by the registry to meet the aim of “exploring the factors that influence outcomes including

survival and quality of life” and also provides data for all of the MRDR’s hypotheses as the type of treatment and disease management prescribed will all impact on patient quality of life.

Kvam, Fayers & Wisloff (2011) noted that health-related quality of life assessments must be able to detect small changes in quality of life that occur over time, particularly important in the absence of a cure for myeloma. The study compared a number of health-related quality of life measures in a group of myeloma patients (n = 239). Results indicated that of the generic questionnaires assessed (of which the EQ5D was one), the EQ5D was the most responsive generic quality of life questionnaire in both patients who improved and deteriorated⁵.

The EQ5D is completed at baseline and then either annually or four monthly as detailed below in the section ‘Detailed schedule of assessments’ depending on the patient’s diagnosis. Annual reviews enable the registry to collect patient outcomes and update treatment information for all patients. Sites can enter reviews more frequently (up to 4 monthly) if they have the resources. Completion of the survey is voluntary (with consent implied by participation) and only takes a few minutes to complete. The survey comprises the following 5 domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: from no problems to extreme problems. Ideally, the survey should be given to the patient to complete at least annually or at each review scheduled by their treating clinician. The treating clinician (or staff under their direction) will give the patient or their caregiver the survey to complete or alternatively the questions can be asked by the clinician. Once completed, the clinician will enter the results into the MRDR database. If the survey was done by proxy (e.g. caregiver), clinicians are able to indicate this on the form. Results of the survey should be entered into the MRDR Database as soon as possible.

Schedule of Assessments

The Registry requires data to be entered at specific time points (see below) after the patient’s date of diagnosis. The ‘Diagnosis’ screen on the MRDR database allows the data collector to schedule the 4 or 12-month review time point so that the patient will appear on the ‘Review due’ list on the Dashboard of the registry data entry portal once the date arrives.

Clinicians will review patients at any time that they feel is necessary; however, it is useful for the Registry to have data collected and entered at fixed time points after diagnosis, to allow for comparable statistical analysis across all sites. Some data managers follow up documentation on active patients on a weekly basis however no contact is made with the patient in this process. There is no pre-determined “schedule of assessments” given the variability of clinical progress of this disease, with the exception of the baseline and scheduled EQ5D surveys. A list of patients due for a review is generated on the Dashboard of the registry.

A minimum data set limited to epidemiologically sound variables has been developed. Data is recorded according to the following schedule, with data items detailed below:

Detailed schedule of assessments

Patient identified	Site clinician or delegated staff identify patients who meet inclusion criteria
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Provision of information to patient	At the time of the patient’s routine visit to the hospital they are given (or sent) the MRDR registry information brochure as well as a verbal (or written) explanation of the registry by the local clinicians (or staff under their direction). They have the opportunity at this and any stage to “opt-out” from the study.
EQ5D Survey	Frequency of administration is dependent on diagnosis: <ul style="list-style-type: none"> - Multiple myeloma/Plasma cell leukaemia/Plasmacytoma: Baseline and at four monthly reviews - MGUS/Smouldering multiple myeloma: Baseline and then annually.
Data entry	Occurs following the provision of the patient information brochure. Key data entry time points are listed below: <ol style="list-style-type: none"> 1. Baseline demographics detailing health at diagnosis 2. Changes in treatment regimen 3. Treatment regimen dates 4. Progression or relapse of disease 5. Depth of treatment response 6. Cause of death.

Data items collected:

- Health at diagnosis
- Demographic details
- Laboratory and imaging results at diagnosis
- Therapy decisions including including pre therapy benchmarking, chemotherapy, autologous stem cell transplants, allogeneic stem cell transplants and maintenance and supportive therapy
- Outcomes (overall and progression free survival, duration of response and time to next treatment and quality of life measures – EQ-5D)
- Long-term Outcomes (through linkage with Cancer and Death Registries).

How the data is collected

Clinicians (or staff under their direction) employed at participating hospitals or by private practitioners undertake data collection. Data collection web-forms have been developed specifically for the registry. As noted above, all medical and laboratory data is drawn from the patient’s medical file, inpatient notes (for patients undergoing hospital admission), clinical and pathology notes, with quality of life information entered via the EQ-5D. Depending on the individual hospital or practitioner, some or all of the medical and pathology information is accessed electronically. Some clinicians and data managers also collect information from site-specific meetings, such as multidisciplinary/haematology meetings.

Potential Benefits

Participants in this project are not likely to receive direct benefit from participation. It is possible that outcomes of this project may enable improved management that could benefit some of the participants as well as future patients diagnosed with myeloma or related diseases.

Data Management

Data collected will be managed according to guidelines for good clinical practice stipulated by the Australian Therapeutic Goods Administration, Australian privacy principles and relevant international laws and regulations in countries where data originate. Hospital-level access to the database is granted to only allow data collectors access to their own patients, with logins assigned by Central Project IT staff via email.

The web interface has been developed using Microsoft .NET technology by a team at Monash University. All data is stored on a redundant Microsoft SQL database cluster located on servers managed by Monash University in Clayton. The database is backed up nightly and mirrored to a geographically separated data centre in Noble Park daily to provide resilience for disaster recovery. Both data centres are under electronic security access and monitoring and can only be accessed by authorised personnel. All data in transit is encrypted to 2048 bits; via SSL on the Web Server, IP Sec tunnel between the Web Server and database. All passwords are stored encrypted in the database. Access to data is controlled by different role accounts within the application that control the authorised access to patient records.

Quality Control

Database

A number of validation measures have been incorporated into the web database to ensure quality data entry. All mandatory fields are required to be entered, and value and date text boxes have specified upper and lower limits. Fields dependent on the value of a parent item are enabled and disabled accordingly and warning messages appear for unknown or extreme values. Consistency checks are also in place. Where possible complex disease-related definitions will be calculated from their derived components to avoid misinterpretation. Data is available for extraction as required.

Sites

Participating hospitals are provided with site-specific reports twice a year describing their patients, treatment and outcomes. A summary of quality indicators and data completeness is included. This enables sites to evaluate their own performance and identify areas with room for improvement. MRDR data will be remotely monitored by assigned MRDR staff at Monash University and data queries sent to sites annually. Outlier management will be guided by the Monash Clinical Quality Registry Outlier Management Guidelines and the ANZ and APAC MRDR Steering Committees if there are concerns about a site's data.

Linkage with national death databases

Mortality data will be cross-checked and completed through linkage with national death databases to ensure its accuracy.

Audits

Auditing will be performed on key data points in 5% of site's cases to assess accuracy of data, and to identify broader issues in data entry such as misinterpretation of definitions. Monash staff or staff under their direction will undertake this work. Results will be reported back to site staff.

Analyses

Analyses of the MRDR data are undertaken by the Department of Epidemiology and Preventive Medicine (DEPM), Monash University and interpreted with the input of specialist clinicians on the Steering Committee. Data analysis plans will be reviewed by the steering committees and by a suitably qualified statistician prior to analysis. Only aggregate, non-identifiable information will be published. Formal data analysis commenced after the 500th patient was registered.

Governance

Multidisciplinary Steering Committees have been established for each arm of the MRDR with membership consisting of relevant stakeholders, a patient and nursing representative, clinical experts and a working group from Monash Department of Epidemiology & Preventive Medicine (DEPM).

The Steering Committees meet quarterly. Terms of reference of the Committees include:

- Monitor the scientific progress of the project including the data quality
- Advise on the collection and interpretation of data
- Assess and advise regarding performance outliers
- Advise on scientific priorities to be addressed in data analysis and publication strategy
- Review publications of the project and advise on their scientific quality
- Review all research and external data requests

Reporting

The MRDR will provide Hospital Data Reports to participating hospital sites twice a year describing their patients, treatment and outcomes. A summary of quality indicators and data completeness are included. An annual report will also be provided to update clinicians, participating hospitals and other stakeholders on registry progress. Six monthly quality reports will be prepared for meetings of the Steering Committee.

Communication with participating institutions

In addition to the Hospital Data Reports, communication is maintained with stakeholders via a newsletter, Data Management meetings, training sessions as required and an Annual Interest Group / stakeholder Meeting.

Publications

Publication of scientific manuscripts is a high priority for the project. Draft publications will be provided for comment and approval to the Steering Committee. Final content, however, will be at the discretion of the authors. Publication sub-committees may be formed in particular areas of interest or expertise. In addition to publications, project data will be presented at scientific meetings

and conferences. Publications arising from the registry will only report de-identified and aggregated patient data to ensure that no individual patient can be reasonably identified.

Ethical Considerations

Ethical approval for the MRDR was obtained from Monash University Human Research Ethics Committee (MUHREC) and the Human Research Ethics Committee (HREC) of the lead site or of each participating hospital. Local approval to participate has been granted at each site. As of March 2021, 51 ANZ MRDR sites have approval to participate with 4345 patients registered.

Patient consent

With the exception of the quality of life survey, the data collected for the registry does not exceed data routinely required by clinicians for management of patients. Data are managed by highly qualified staff in an internationally recognised academic epidemiology unit with expertise in registry management.

Patient consent is important for understanding and participation, and the registry uses an “opt-out” approach, consistent with comparable registries in Australia. Patients are invited to participate by their treating clinicians and provided with information in the patient brochure. The patient brochure provides the names of a contact person at the registry who is able to answer questions about the nature and purpose of the project. Patients will be able to “opt-out” of the registry by contacting registry staff. The brochure may also provide the name of a local Ethics Committee contact person for those with particular concerns or complaints. The opt-out approach allows collection of valid data from an unbiased sample. It is established that “opt-in” consent would result in a biased sample with less than 70% of patients included. The small impingement on privacy is substantially outweighed by the public interest in the improvements to patient care that may result from this project. The number of patients who choose to ‘opt-out’ is not anticipated to be large.

In countries where an opt-out model of consent is not permitted, written informed consent will be sought by the Principal Investigators or appropriately trained delegate. The patient will receive a written information sheet about the study (Patient Information and Consent Form) in their own language, as well as a verbal explanation to address any questions they may have. Each patient will be asked to sign the consent form before study participation. Patients will not take part in the study unless fully-informed consent has been obtained. The patients will also be informed that they can withdraw from the study at any time and this will not affect their future treatment in any way.

The patient information document indicates that the registry will maintain the strictest control over access to the information so as to ensure maximum protection of an individual’s privacy. No identifiable information will be released about any individual unless required by law (e.g. pursuant to a court order, which is unlikely given that more detailed and relevant information would be available at the treating hospital) or if a patient seeks care from more than one participating hospital, in which case information related to diagnosis and the treatment received will be shared between the sites. Access to registry data may be provided to bona fide researchers with prior approval from registry staff, the ANZ MRDR and/or APAC MRDR steering committee, and the approving ethics committee for each hospital involved in accordance with the MRDR Data Access Policy. Under no other circumstances would any individual patient’s information be made available to outside parties, or be used for other purposes by the registry team.

For deceased individuals diagnosed with myeloma not already recorded on the MRDR (or those with myeloma listed as a cause of death) that have been identified by clinicians or national/state-based cancer registries, the research team seek a waiver of consent to collect patient data as detailed below in the section ‘data items collected’. As consent cannot be obtained from deceased patients, a decision was made by the research team not to contact Next of Kin as this may cause undue distress. Information from deceased registry participants, will remain on the MRDR indefinitely. The inclusion of deceased patients with date of diagnosis no earlier than 3 months before site ethics approval on the registry enables the collection of data on the most unwell and severe patients, ensuring that the registry represents all levels of disease severity.


Patient distress

Patients may become anxious about their symptoms and the way that they feel when asked in a quality of life questionnaire, such as the EQ5D. If participants feel distress during or following the completion of the EQ5D, the hospital site staff will identify the most appropriate staff member and / or service within the hospital to meet the patient’s needs and/or refer them on to required community supports such as local cancer helplines. It should be noted that participation in this survey is voluntary and patients are able to decline at any time. Any anxiety or distress believed to be due to participation in the study should be reported to the registry by the investigators.

Opt-out approach safeguards

There are a number of safeguards in place to ensure that patients are given the MRDR patient information document prior to their details being entered in the registry. These include:


- 1) The registry itself contains the following question on the first page (where initial patient details are entered): “Have you given the patient the Patient and Families brochure with 'opt-out' information?” (as illustrated below), prompting clinicians and data managers to ensure that the patient has been provided with the brochure. A similar prompt relating to the Patient Information and Consent Form is available for countries where opt-in consent is required.



Given Name:

Family Name:

DOB: 

Gender: 

Medical ID Type: 

NHI:

Genetic Ethnic Heritage: (Grandparents)









Have you given the patient the Patient and Families brochure with 'opt-out' information? 

- 2) Both the NEAF (Consent Process) and Victorian Specific Module (Section 2.1, iii) specify that patients must be given the brochure prior to their details being entered in the registry. The local investigators at all sites receive and/or sign the NEAF, indicating that they will conduct the study as specified.
- 3) All sites are given a 'Quick Reference Guide' document that highlights that it is an ethics requirement that the participant be given the patient information document.
- 4) Regular reviews and the administration of the EQ5D also serve as a reminder to the patient and/or caregiver that their details are on the registry.

Data Ownership/Access/Usage

The data collected by the MRDR remains the property of Monash University. A policy to facilitate access to researchers has been developed (Myeloma and Related Diseases Registry Data Access Policy). In general, access to registry data will be provided to bona fide external researchers with the approval of the project staff, the ANZ and/or APAC MRDR Steering Committee and relevant Hospital Ethics Committees. Participating clinicians or hospitals are at liberty to publish their own hospital data without any reference to the registry. Hospitals can access their own data at any time.

Confidentiality & Intellectual Property

The intellectual property rights attaching to all material created or prepared by the Monash Department of Epidemiology & Preventive Medicine in connection with performance of the MRDR shall vest in DEPM.

Timeline

	<i>NB: Estimations only</i>
<i>ANZ Pre-development Phase</i>	Nov 2011-Mar 2012
<ul style="list-style-type: none"> • Secure funding • Finalise project plan • Establish Steering Committee 	
<i>ANZ Development phase</i>	Mar 2012-Dec 2012
<ul style="list-style-type: none"> • Finalise data set and data dictionary • Web-database construction • Establish contacts at 6 pilot hospitals • Ethics submission at Monash University and pilot hospitals 	
<i>ANZ Implementation Phase</i>	Jan 2013-
<ul style="list-style-type: none"> • Data collection commences at 6 pilot sites • Amendments made to web-database as required including additional reporting functions • Identify additional sites for inclusion in the Registry 	
<i>ANZ Expansion Phase</i>	June 2013-
<ul style="list-style-type: none"> • Ethics submission at additional sites • Data collection commences at additional sites • Test and develop new or improved measures of outcome 	

Investigators

Chief Investigators

Professor Andrew Spencer DM FRACP FRCPA (Coordinating Principal Investigator)

- Head of Service, Malignant Haematology & Stem Cell Transplantation, Alfred Health and Department of Clinical Haematology, Monash University
- Professor of Haematology, Myeloma Research Group, Division of Blood Cancers Australian Centre for Blood Diseases, Department of Clinical Haematology, Central Clinical School, Faculty of Medicine, Nursing & Health Sciences, Monash University

Associate Professor Erica Wood, MBBS, FRACP, FRCPA

Head, Transfusion Research Unit (within which the MRDR is administered), School of Public Health and Preventive Medicine, Monash University - oversees management of the registry

Dr Zoe McQuilten MBBS (Hons) PhD FRACP FRCPA

Deputy Director, Transfusion Research Unit, School of Public Health and Preventive Medicine, Monash University

ANZ MRDR Steering Committee

1. Professor Andrew Spencer (Chair and Coordinating PI) (Alfred Health & Monash University)
2. Dr Bradley Augustson (Sir Charles Gairdner Hospital, Perth WA)
3. Dr Krystal Bergin (Monash University and the Alfred Hospital, Melbourne)
4. Associate Professor Hilary Blacklock (Middlemore Hospital, Auckland)
5. Professor Joy Ho (Royal Prince Alfred Hospital, Sydney)
6. Dr Noemi Horvath (Royal Adelaide Hospital)
7. Ms Tracy King (Royal Prince Alfred Hospital)
8. Associate Professor Zoe McQuilten (Monash University)
9. Associate Professor Peter Mollee (Princess Alexandra Hospital, Brisbane)
10. Associate Professor Hang Quach (St Vincent's Hospital, Melbourne)
11. Mr Brian Rosengarten (Myeloma Foundation of Australia)
12. Dr Patricia Walker (Alfred Health and Peninsula Health)
13. Professor Erica Wood (Monash University)

ANZ MRDR Operations Committee

1. Professor Andrew Spencer (Alfred Health and Monash University)
2. Professor Erica Wood (Monash University)
3. Associate Professor Zoe McQuilten (Monash University)
4. Dr Elizabeth Moore (Monash University)
5. Dr Cameron Wellard (Monash University)
6. Mr Neil Waters (Monash University)

History of changes to Project Outline for the MRDR

Version	Date	Author	Summary of Revisions
2.0	20/01/2018	Elizabeth Moore	National multi-site version created
2.1	10/04/2018	Naomi Aoki	Inclusion of APAC expansion

References

- 1 Australian Institute of Health and Welfare 2019. Cancer in Australia 2019. Cancer series no. 119. Cat. no. CAN 123. Canberra: AIHW.
- 2 Bird JM, Owen RG, D'Sa S, Snowden JA, Pratt G, Ashcroft J, et al. Guidelines for the diagnosis and management of multiple myeloma. *Br J Haematol.* 2011;154(1):32-75.
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- 5 Kvam, A.K., Fayers, P.M., & Wisloff, F. (2011). Responsiveness and minimal important score differences in quality-of-life questionnaires: a comparison of the EORTC QLQ-C30 cancer-specific questionnaire to the generic utility questionnaires EQ-5D and 15D in patients with multiple myeloma. *European Journal of Haematology* 87 (330–337)