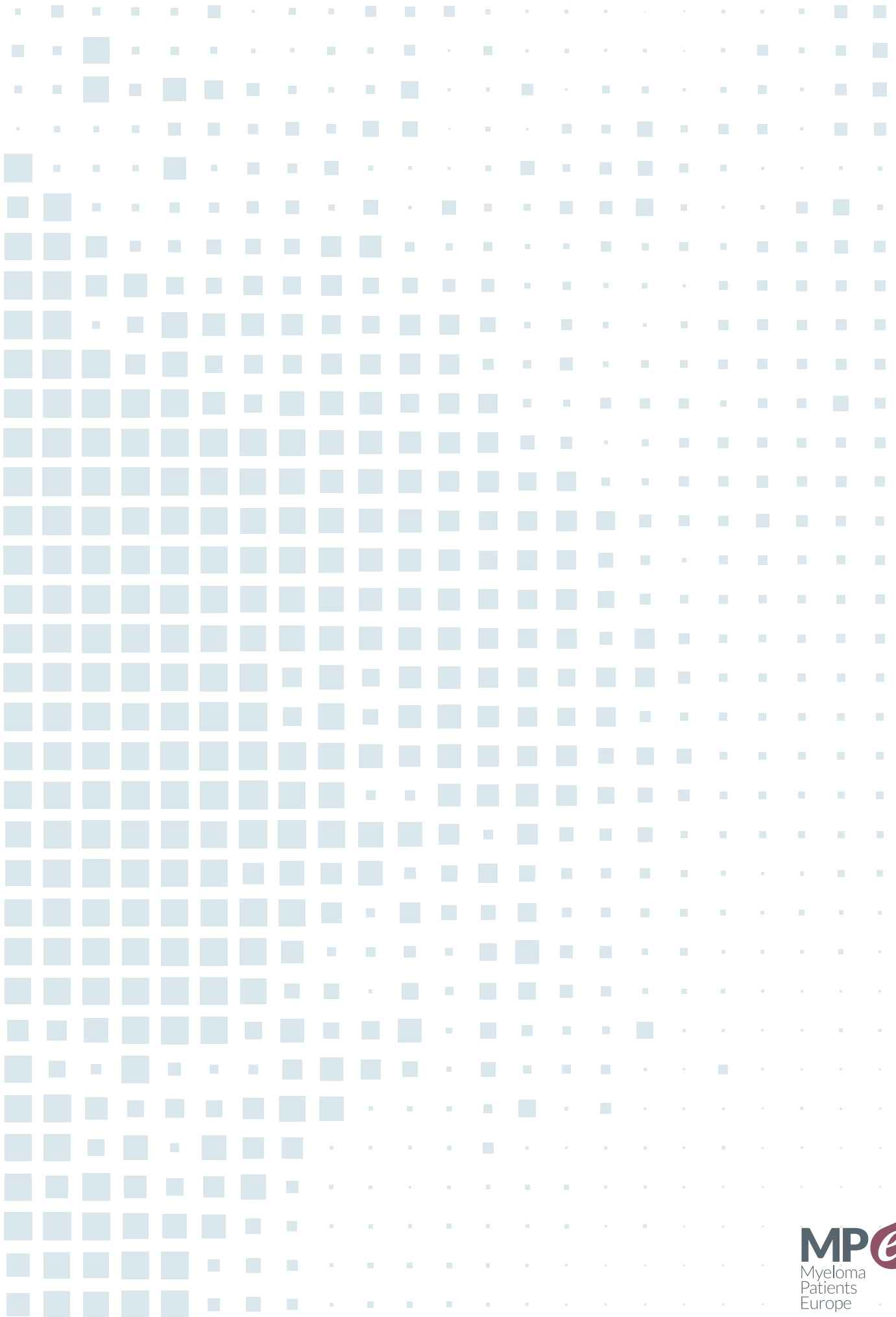


PATIENT AND HAEMATOLOGIST PERSPECTIVES ON MINIMAL RESIDUAL DISEASE TESTING IN MYELOMA



ABOUT MYELOMA PATIENTS EUROPE (MPE)

Myeloma Patients Europe (MPE) is an umbrella organisation representing 48 myeloma and AL amyloidosis patient groups and associations from across Europe and further afield. Our mission is to provide education, information and support to members, and to advocate at European, national and local levels for the best possible research and equal access to the best possible treatment and care. Together, we support thousands of myeloma and AL amyloidosis patients, as well as their caregivers, every day.

This project is part of the MPE's Patient Evidence department, which was established to better understand what research gaps exist within the myeloma landscape and to generate evidence that seeks to influence decision-makers and ultimately improve treatment, care, and access for myeloma patients and their families.

ACKNOWLEDGEMENTS

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MPE would also like to thank the MRD Project Steering Committee for their expertise and continuous feedback throughout the project, and Elisabeth Oehrlein for your invaluable contributions.



INTRODUCTION

Myeloma (also known as multiple myeloma) is a cancer of the plasma cells. The plasma cells make an abnormal protein (antibody) known by several different names, including monoclonal immunoglobulin, monoclonal protein (M-protein), M-spike, or paraprotein. Myeloma can be treated in a number of different ways and the treatment of myeloma has three key aims: to stop or slow the progression of myeloma, to encourage and prolong the stable periods (remissions) during which only monitoring is needed, and to improve quality of life, e.g. by relieving symptoms.¹

Minimal residual disease (MRD) - also called measurable residual disease - refers to a very small number of cancer cells that remain in the body during or after treatment. MRD testing uses advanced laboratory methods that can find one cancer cell among one million normal cells (see Table 1).² These remaining cells often cannot be detected through traditional tests of treatment response and may cause no physical symptoms. However, they have the potential to multiply and cause relapse. A positive MRD test result indicates that cancer cells were identified, even at very minute levels, whereas a negative MRD result indicates that cancer cells were not identified.

Table 1. Overview of Laboratory Techniques for Detecting MRD³

Test	Flow cytometry	Polymerase chain reaction (PCR)	Next-generation sequencing (NGS)
Description	Checks individual cells for the presence or the absence of protein markers	Detects genetic abnormalities	Detect mutations and other genetic abnormalities in DNA
Sample	Bone marrow	Bone marrow or blood	Bone marrow
Cells detected	One cancer cell out of up to 100 thousand cells	One cancer cell out of up to 1 million cells	One cancer cell out of up to 1 million cells
Timeline from test to results	Less than 1 day	Up to several weeks	Less than 1 week

MRD testing is already used in other cancers, such as lymphoma and leukaemia, to help guide treatment decisions, find out how well treatment is working or if cancer has come back, or make predictions about cancer prognosis (the likeliness of death, recovery, or relapse).⁴ Clinical studies have found that negative MRD results are associated with favourable health outcomes in people with myeloma.⁵ As a result, there is growing interest in using MRD testing to guide myeloma treatment decisions and evaluate how well new treatments work.

In 2021, a working group organised by the European Medicines Agency published a reflection paper about MRD status as a clinical endpoint in multiple myeloma studies.⁶ The paper recommended additional research about the timing of MRD testing and laboratory methods to demonstrate the strong link between MRD testing and overall- and progression-free survival in people with myeloma. In parallel, the 2021 EHA-ESMO Clinical Practice Guideline endorsed the use of MRD testing as an endpoint in certain clinical trials but stated that using MRD testing to guide treatment decisions for individual patients is still investigational.⁷

Despite growing interest, little is known about myeloma patient and haematologist perspectives, or experiences with MRD testing. To ensure future discussions considering an expanded role of MRD testing in myeloma are guided by their perspectives, MPE engaged patients and haematologists to explore:

- **Awareness** and experiences with MRD testing
- Current and potential **future uses** of MRD
- Impact of MRD testing on an individual's **emotional wellbeing**
- Suggestions for **communicating results** to patients
- How awareness, **understanding and expectations** of MRD's potential align or vary between patients and haematologists
- Use of MRD as an **endpoint** in clinical trials, and in regulatory and reimbursement decisions

This report summarises the methods and results.

METHODS

MPE chose to gather insights on MRD through patient discussion groups and haematologist interviews. A steering committee of patient experts, haematologists, researchers and regulators also convened to guide all phases of this project.

LITERATURE REVIEW

The first phase of the project was a targeted literature review conducted by MPE research staff to learn about:

- The current landscape of MRD testing in myeloma
- Publications describing the perspectives of patients, haematologists, regulatory authorities and health technology assessment (HTA) bodies about the role of MRD testing in health care delivery, medicines development and evaluation
- Outstanding questions about MRD testing in myeloma

Insights from the literature review and discussions with the steering committee informed the development of an educational video for patients and discussion guides.

INTERVIEWS AND DISCUSSION GROUPS

Two virtual discussion groups with a total of 14 myeloma patients from across Europe were organised. Furthermore, a total of nine European haematologists took part in the project through eight one-on-one virtual interviews and one written interview.

Table 2. Patient and haematologist participant countries

Country	Patients	Haematologists
Austria		1
Belgium	1	
Czech Republic		1
Finland	3	1
France	1	2
Germany	1	1
Israel	1	
Netherlands	2	
Malta	1	
Spain		1
Sweden	2	
Ukraine		1
United Kingdom	2	1

The discussions were led by MPE research staff from September - October 2022. The discussion guides can be found in Appendix 1 (Patients) and Appendix 2 (Haematologists). The discussions were recorded, transcribed and thematically analysed. Draft results were presented to the steering committee, refined for clarity and are presented in this report.

HOW FAMILIAR ARE PATIENTS AND HAEMATOLOGISTS WITH MRD TESTING?

Myeloma patients who participated in our group discussions had a wide range of familiarity with MRD testing – from none to personal experience.

Unfamiliar with MRD testing: Five participants were unfamiliar with MRD testing and one stated that their first exposure to MRD testing was via MPE's invitation to participate in the discussion.



I haven't heard very much about MRD, so I'm very curious. I took part in another research project on MRD and that's where I heard about it."

MYELOMA PATIENT

Familiar with MRD testing, but no personal experience with it: Seven participants had read about MRD testing in scientific literature or had heard about it at scientific or patient meetings. One participant had asked their haematologist about it and learned it is not available in their country.



I learned about minimal residual disease when I was at a conference and through some of the reports, but I have no personal experience of any aspect of MRD testing."

MYELOMA PATIENT

First-hand experience with MRD testing: Two patients had undergone MRD testing as clinical trial participants. Another had learned about MRD testing through online research and asked their haematologist if they could have MRD testing, which was available in their country. Through our discussion, we also learned from one participant that they believed they had MRD testing in the past, but it was not until they watched MPE's educational video during the group discussion that they realised that was what the test is called.



I'm being followed by a clinical trial where MRD is the second endpoint. So, every six months, I have an MRD check."

MYELOMA PATIENT

All the haematologists who participated in the interviews were familiar with MRD testing and that MRD testing is primarily completed among patients enrolled in clinical trials. However, seven participating haematologists noted that as they and their colleagues at their hospital have been exposed to MRD testing through clinical trials, they have also begun using it more with patients outside of clinical trials. They noted that access to MRD testing differs across countries and hospitals. University hospitals or those specialising in myeloma may be more likely to offer MRD testing broadly.



I wouldn't say MRD testing has become routine practice, but we use it in the context of clinical trials. Now, almost all the clinical trials ask us to perform MRD at some point, and sometimes several times through the study. It also happens that we also do MRD testing in real life and try to use MRD to kind of tailor treatment of the patients."

HAEMATOLOGIST

PATIENT PERSPECTIVES ON THE ROLE OF MRD TESTING IN CLINICAL PRACTICE

What is "maintenance therapy"?

Maintenance therapy is a treatment given to patients to help keep cancer from coming back after it has disappeared following the initial therapy

Patients found MRD testing compelling and stated that it would be particularly useful if research shows that it is an indicator that maintenance therapy can be stopped. Maintenance therapy is a treatment given to patients to help keep cancer from coming back after it has disappeared following the initial therapy.⁸ Most patient participants stated they would be open to more frequent bone marrow tests, provided that the information was useful for decision-making. They also agreed they would undergo more frequent MRD testing if those testing methods were less invasive, i.e. through blood serums. However, they noted a lot of research they would like to see completed before MRD testing is used to guide individual treatment decisions.

QUESTIONS THAT PATIENTS HAVE ABOUT MRD TESTING INCLUDE:

Is there enough evidence to support the use of MRD testing in clinical practice?

- At what time points or upon which treatment milestones should MRD testing be completed?
- How is MRD testing used in different countries?
- Does the location of a biopsy matter in terms of the accuracy of the results?



At the moment, from my reading, there's no evidence supporting that MRD is a good thing to know in terms of your treatment."

MYELOMA PATIENT

While research is still ongoing, the patients who participated in our discussions would only be comfortable with MRD testing if it is in tandem with other tests. One patient participant questioned if MRD testing would provide additional information compared to less costly tests, such as more frequent m-protein testing.



I want to know if there is a time or a routine in different countries when they should perform MRD. Once a year? Once every six months? Or does it depend?"

MYELOMA PATIENT

HCP PERSPECTIVES ON THE ROLE OF MRD TESTING IN CLINICAL PRACTICE

All haematologists who participated in interviews were optimistic about the potential use of MRD testing in clinical practice. They anticipated that in the future, MRD testing will play an important role in guiding treatment decisions for people with myeloma. Potential opportunities include:

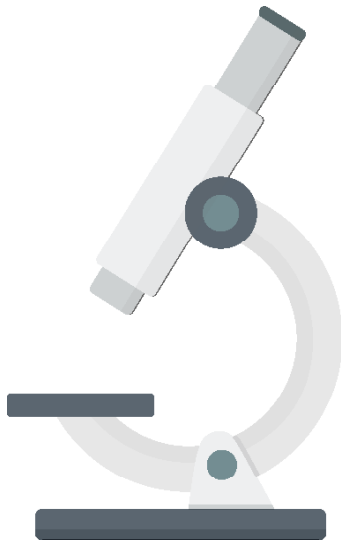
To guide treatment decisions such as continuing or discontinuing maintenance therapy, or whether to perform a second stem cell transplant or not under certain circumstances.

Six haematologists mentioned that at their institutions, haematologists are increasingly requesting MRD testing among patients who have had maintenance therapy for several years and are considering stopping treatment due to side effects or personal circumstances, such as moving further from a hospital. In future, MRD testing may assist haematologists in reducing the overtreatment of patients.

One haematologist commented that emerging evidence suggests that MRD testing is useful in guiding maintenance therapy among individuals with a standard genetic risk profile. But, given current evidence, they would not recommend patients with a higher genetic risk profile to rely on MRD status to guide decisions to go off maintenance therapy.

To guide decisions about whether to perform a second stem cell transplant or not.

Many newly diagnosed myeloma patients undergo an autologous stem transplant (using their own stem cells) as part of their first line of treatment. One HCP mentioned that a common situation in which they will directly use MRD testing to guide decision-making is determining whether to perform a second stem cell transplant. If a patient has a negative MRD test after a first transplant, they may decide not to do a second transplant. Similarly, another HCP mentioned that they order MRD testing approximately three months after a transplant.



Haematologists emphasised the importance of being transparent with patients and explaining that MRD testing is experimental, and evidence is still being collected.



We have many unanswered questions, and we are moving step-by-step, but we need to do more clinical trials to understand what to do with the results of MRD tests. It is important that people also understand this, because I'm sure they keep listening about the idea of MRD, but I'm not sure they realise that it's difficult and that we have more questions than answers for the time being. Of course, it will improve, but step-by-step."

HAEMATOLOGIST

IMPLEMENTING MRD TESTING IN CLINICAL PRACTICE

Without specific guidelines, haematologists decide individually, or as an institution, when to request MRD tests and how to use the information.



There isn't yet unified guidance on how to use the information from MRD testing therapeutically. We are mostly doing it after the transplant because we are telling the patient the depth of their response traditionally at that point anyway.

The other time is when patients are on maintenance therapy. These are very individualised discussions where we make the patient aware that there isn't strong data or evidence supporting any decisions that are made based on the MRD results that we get back. So, we are always very careful.

We also have patients that actively request a discussion about MRD and then we consider it on an individual patient basis. But we do normally request MRD tests before having a discussion with the patient about what the potential outcomes could be and what it could mean for them."

HAEMATOLOGIST

Challenges implementing MRD testing in clinical practice

Haematologists noted several challenges that need to be overcome for MRD testing to be implemented across Europe. These challenges include:

Laboratory capacity and capabilities

Haematologists noted that for MRD testing to be implemented equitably across European countries, including in both urban and rural settings of care, laboratory capacity needs to be expanded. Many haematologists stated that laboratories conduct reliable and consistent tests. However, one HCP had observed different laboratories producing different results using the same sample.



My concern is that there are no guidelines as to what the results produce... For example, if you had a treatment matrix, and you get the results of these MRD tests, and somewhere you fit into that matrix, and they can show that a specific part of the treatment is the best thing to change, for example: Y drug has to be increased, or Z drug decreased, or a new different drug should be tried, or the situation should just be monitored... my feeling is that there is insufficient information to make it as beneficial as it could be."

MYELOMA PATIENT

Training about MRD testing for haematologists and laboratory staff

Haematologists commented that they would require additional training on when to use MRD testing and how to apply findings to guide decisions. One haematologist also suggested that laboratory staff from countries less experienced with MRD testing could benefit from additional training, for example, participation in a short fellowship or internship at another European laboratory.

Similarly, training on how MRD testing can and should be used across a patient's treatment journey would be useful for haematologists and laboratory staff. For example, one HCP mentioned that MRD testing requests were initially declined because a patient did not have a baseline, pre-treatment MRD value, so post-treatment MRD values may be difficult to interpret. The HCP stated that they disagreed with the rationale and that post-treatment MRD test results could provide valuable information about relapses even without pre-treatment baseline values.

Another specific topic where guidelines or training could be beneficial is what to do when MRD test results conflict with the results from other relevant tests.

Paying for MRD testing

Haematologists commented that MRD testing is not covered by all insurers in all health systems. In some countries, patients need to pay out-of-pocket for MRD testing and may not be able to or understand why they are required to pay for additional tests. One HCP commented that the cost of MRD testing is significantly less than the cost of treatment (e.g. unnecessary maintenance therapy), so there are potential cost savings in the future. Separately, patients were cautious about linking discussions about cost savings with stopping maintenance therapy since MRD testing is still experimental.

IMPACT OF MRD TESTING ON PATIENTS AND THEIR FAMILIES

Patient participants commented that their emotional responses would be unique to their circumstances and experiences. Haematologists also commented that the levels of discomfort experienced with biopsies and scans differs significantly among patients.



When the time for other lab tests were approaching, the tests became the whole focus of my life, and not just me, but also for other members of my family."

MYELOMA PATIENT



The potential...for a personalised approach to treatment, for the fine-tuning of treatment ... for me it would be very attractive to know what your status was. But I think it's a double-edged sword because you're going to desperately want the results to be negative"

MYELOMA PATIENT



Several participants commented that testing and awaiting results would be extremely stressful for them and their families. They stated that the emotional impact of going in for an examination or waiting for the results could last for days. Additionally, participants pointed out that MRD biopsy techniques (e.g. bone marrow biopsies, bone marrow aspirations), can be burdensome as these methods are quite invasive. Others did not anticipate a negative emotional impact and stressed that the result could be useful for planning their personal lives, for example, whether to undertake a home renovation or not.

Patient participants emphasised that a "positive" result would be much worse without the availability of additional treatment options. It is very important for haematologists to be prepared to discuss treatment options when MRD results are delivered, including discussions surrounding side effects and whether treatment options are covered by health insurances.

One HCP, who was empathetic about the short-term challenges of MRD testing commented that if a patient has a negative result and they can discontinue treatment, side effects can be avoided altogether. This can be a significant improvement in quality of life.

THE FOLLOWING STRATEGIES MAY ASSIST PATIENTS IN MANAGING THE EMOTIONAL IMPACTS OF MRD TESTING:



I think that with every examination, it's crucial that there's a good conversation and good dialogue with the doctor. Does the patient understand why we're doing this examination? And what are the results? And what do we do with the results? How do the doctors consider the results?"

MYELOMA PATIENT

Discuss the purpose of MRD testing and how the results may or may not guide treatment decisions:

Patients and haematologists emphasised the importance of dialogue about what MRD testing is, what the individual's results are and how the results will factor into treatment decision-making.

What to expect during MRD testing: Patients should be aware of what to expect, the timeline for testing and potential hurdles. For example, it would be useful for patients to be aware that multiple samples might be needed.

Information about how to interpret the results in the context of other lab results:

Patient participants commented that they would appreciate it if their haematologists explained or provided a resource outlining the correlation between traditional blood tests and MRD results.

Delivering the results through a telephone call or during a visit allows patients and haematologists to discuss them and plan the next steps. Receiving the results electronically may make patients feel less supported. It also does not provide a clear opportunity for patients and haematologists to discuss the results.

Provide timely and convenient emotional support, including patient-to-patient support: Many patients benefit from opportunities to discuss myeloma treatment and MRD testing with other patients. One patient stated that peer-to-peer discussions are particularly helpful if patients are similar in age or share other demographic characteristics. Online or in-person opportunities are both valuable.

Support from professional counsellors: If patients learn they have residual disease, they may require emotional support. It would be helpful for haematologists to offer help or resources as soon as possible. For example, one participant stated that at their hospital, they could walk downstairs and talk with someone who was there to provide emotional support.

EDUCATIONAL RESOURCES ABOUT MRD TESTING

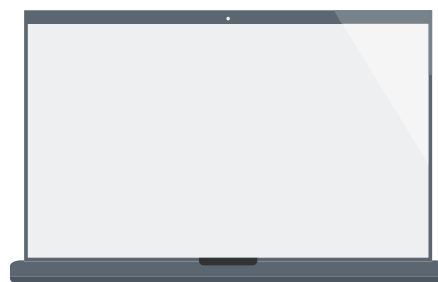
Patients and haematologists noted that MRD testing is a complicated topic, and haematologists may not always have the time or tools to communicate it to patients in a way that is easy to understand. Patient groups are an important resource for simplifying complex topics, such as MRD testing. Patients and haematologists offered additional suggestions related to educational resources:

CREATE PLAIN LANGUAGE INFORMATION FROM A VARIETY OF FORMATS

Patients noted that information about MRD testing should come from a variety of sources, including patient organisations, healthcare professionals and take-home guides. Materials that can be taken home are helpful not only for patients but also for their family members

Patients and haematologists suggested a variety of formats, including written guides, simple videos and patient-to-patient discussions

Participants noted that while English-language resources are often accessible to younger patients, older patients may not read or understand English as well or at all



PARTICIPANTS NOTED SEVERAL SPECIFIC TOPICS THAT SHOULD BE ADDRESSED IN FUTURE MATERIALS:

- ☒ Introductory guide to MRD testing, including what the test is, how the sample is collected, why it is done and how it can guide decisions
- ☒ A simple guide to “What does ‘MRD negative’ mean?”
- ☒ Information about the use of MRD testing in different countries

PERSPECTIVES ON MRD STATUS AS A SURROGATE ENDPOINT

PATIENT PERSPECTIVES

If researchers demonstrate that MRD status is a reliable surrogate endpoint for survival outcomes, most patient participants stated that it would be an important advancement. However, some patient participants emphasised that they saw it as valuable additional information, not as a replacement for other lab tests.

Several patient participants expressed concern that if MRD status becomes a common outcome measure in clinical trials, it could also be prematurely adopted by government agencies and insurers to deny maintenance treatment or withhold new and potentially expensive treatments.

HAEMATOLOGISTS' PERSPECTIVES

Haematologists also saw a role for MRD testing in clinical trials, especially as an opportunity to make new treatments available sooner, but offered the following caveats:

- 1 MRD testing should be a co-primary endpoint, or to support conditional approvals. Although the trend is for smaller, shorter clinical trials, in the context of validating MRD as a surrogate endpoint, larger and longer trials are required
- 2 Consensus is needed regarding the cadence or milestones at which MRD testing should be conducted. Haematologists' confidence about the efficacy of treatments approved based on MRD status as a surrogate outcome would hinge on trust and comfort with the frequency of MRD testing
- 3 Research is needed to understand minimal clinically relevant differences in test results between 'negative' and 'positive'. Haematologists need to see how MRD status correlates with the longer-term effects of relapses
- 4 MRD testing is useful for many patients, but there appears to be a percentage of patients for whom it does not seem to work as well. It is important to understand why and how genetic profiles may contribute to this discordance

Haematologists stated that exposure to MRD testing through implementation in clinical practice would build trust in its use as an outcome measure over time. In addition, one haematologist suggested that it could be useful in a value-based payment model. For example, an outcome-based contract, which ties reimbursement to patients achieving certain pre-defined outcomes.

RECOMMENDATIONS

CONDUCT ADDITIONAL RESEARCH ABOUT MRD TESTING AND COMMUNICATE THE FINDINGS TO PATIENTS

- ✓ **Patients and haematologists require clarity about how frequently MRD status should be tested and how the results should guide treatment decisions.** Despite enthusiasm from patients and haematologists about the potential role of MRD testing to guide treatment decisions, there are several questions that require additional research. For example, the cadence of MRD testing
- ✓ **Clarify why negative MRD testing appears predictive of improved survival outcomes among certain patients, but not others.** During the interviews, two haematologists mentioned that MRD status appears useful in guiding treatment decisions among many, but not in all myeloma patient subgroups. One haematologist mentioned that this is likely due to genetic risk profiles. Researchers must elucidate for which subgroups MRD status is and is not a good predictor of survival before MRD testing is implemented in routine care for myeloma patients

PLACE PATIENT NEEDS AT THE CENTRE OF MRD TESTING IMPLEMENTATION

- ✓ **Provide timely and convenient emotional support for patients and their families:** Support can be provided through peer-to-peer opportunities (e.g., patient support groups) or via professional counsellors within hospitals or clinics
- ✓ **Deliver MRD results via telephone or in-person appointments:** MRD test results should be delivered via telephone or in-person discussions. This allows patients to ask questions about the results, including what they mean and how they will impact care decisions

DEVELOP TRAINING AND RESOURCES FOR PATIENTS AND HEALTHCARE PROFESSIONALS

- ✓ **Introductory materials for patients and their families:** Patient education materials, including written guides, simple video, and patient-to-patient discussions, are necessary to better inform patients about MRD and its potential implications for the future of treatment decision-making
- ✓ **Develop information for healthcare professionals about when and how MRD results should guide treatment decisions:** Healthcare professionals training on when and how to use MRD testing and how to apply findings to guide decisions would allow patients and clinicians to incorporate MRD testing in clinical practice during a patients' treatment journey
- ✓ **Develop and implement training for laboratory staff to ensure consistency and reliability:** Patients should expect high-quality lab results across Europe, irrespective of which country they live in, or their proximity to a university hospital. Laboratory staff should undergo training across Europe to ensure MRD testing is reliable and consistent

CONCLUSION

Patients and haematologists find MRD testing compelling and are enthusiastic about ongoing research to identify how MRD status can guide individual treatment decisions for people with myeloma. While research is ongoing, patients and haematologists suggest that traditional lab tests, such as m-protein testing, will continue to play a primary role in treatment decision-making. Participants stated that the emotional impact of MRD testing can be significant. Patient participants offered several strategies for managing the burden, including delivering the results via telephone or in-person, and offering peer-to-peer and professional counselling support. Patient and haematologist participants largely agreed with the European Medicine Agency's reflection paper on MRD status as a surrogate endpoint in clinical trials. There is great promise, but details (e.g., milestones at which testing is completed) require additional research. Finally, patients and haematologists noted that MRD testing is a complicated topic and resources are needed to help patients and their families understand what MRD testing is and its potential implications for the future of treatment decision-making.

APPENDICES

- [Appendix 1: Patient discussion group guide](#)
- [Appendix 2: Haematologist interview guide](#)

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CONTACT US

Myeloma Patients Europe AISBL
Avenue Louise 143/4
1050 Brussels - Belgium



info@mpeurope.org



www.mpeurope.org



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