Newsletter Issue 22
June 2019

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1. Message from the Chair

Welcome to the June 2019 EUMDS newsletter

The EUMDS registry is running well with 2,600 patients registered since the start in 2008. In total 17 countries and 146 sites have contributed patients during these 11 years. Four more countries will join us in the near future. The EUMDS Registry contains more than 100 high-risk patients (high and very high-risk according to IPSS-R) and this number is expected to increase rapidly in the next few years, because almost all countries have joined the new extended study protocol. The electronic transfer of EUMDS data from the national registries in Greece and Switzerland will be operational in 2019. Our goal is to extend the electronic transfer from national registries for as many countries as possible.

The number of EUMDS publication is growing rapidly to ten publications in peer-reviewed international journals, including 5 publications in 2018, and 2 in 2019 (recently accepted). This high number of publications reflects the unique data set of the EUMDS Registry, which will become even more attractive after introduction of the new diagnostic molecular and flowcytometric characteristics.

The success of the EUMDS Registry reflects your commitment and dedication throughout all these years. The steering committee is very grateful for all your contributions and we are looking forward to continue the success of the EUMDS Registry.

Theo de Witte
EUMDS Chair

2. Symposium June 12th - celebrating 10 years of the EUMDS Registry

The EUMDS Registry is celebrating its 10th anniversary: since its inception, the Registry has evolved to a successful and unique real world data source, providing results that improve our knowledge of MDS and MDS patient care. The operational team in the Netherlands is organizing a symposium to celebrate this milestone on June 12th, one day before the start of the EHA meeting in Amsterdam. This symposium is open to anyone who is interested in the EUMDS Registry: local investigators, interested potential investigators and those who are interested in MDS in general.

During this symposium investigators will look back to the past 10 years and share results obtained so far. Also, ambitions for the years ahead will be discussed.

Moreover, on June 12th at 14:30, Louise de Swart will defend her PhD thesis entitled: 'Patient with lower-risk myelodysplastic syndromes: in scope of iron related complications' largely based on EUMDS data.

The symposium will be organized in Nijmegen. In case you are interested to join and still have room in your agenda, please, contact Karien Croezen (Karien.Croezen@radboudumc.nl) for the official invitation, including logistical details.

3. Relevance of HRQoL measurements

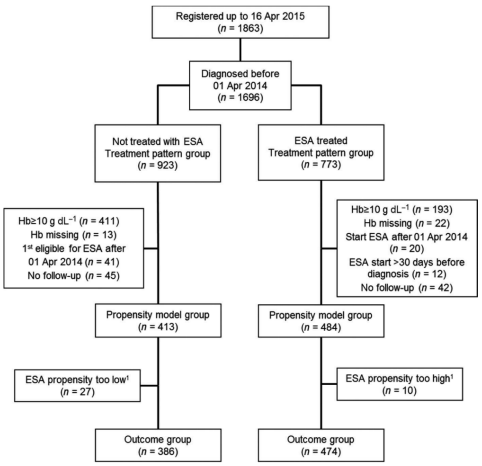
Myelodysplastic syndromes have considerable impact on daily life and social interactions of the patients (Stauder et al. Leukemia 2018), and should therefore not only be judged by its mortality, but also by its social impact and disability. Health related quality of life (HRQoL) measures aim to capture the patients' perception about their illness, their threshold for tolerance of discomfort, or their well-being (or the lack thereof) in more general.

One of the strengths of the EUMDS registry is that we measure quality of life at each subsequent visit using the patient self-reported EuroQol-5D (a general quality of life measure), and since July 2017 also increasingly by the MDS specific quality of life questionnaire QUALMS (see newsletter Issue 19). This allows us to evaluate the impact of disease and treatments on patients quality of life over time.

The longitudinal evaluation of HRQoL and the impact of treatment on HRQoL is currently being analysed as part of the ESA sub study as well as in the HRQoL sub study. Whether or not a patient can be included in the analyses of a sub study depends on the completeness of the data (example in figure). We notice a gradual decline in the proportion of HRQoL questionnaires that are completed over time, as show in table 1 for EQ-5D. This provides a challenge for the analyses.

We would like to emphasize that EQ-5D is part of the mandatory Core data set, and that especially for longitudinal analyses it is important that this is completed at each visit interval. We would like to ask you to motivate the patients to continue to complete the questionnaire(s) at each visit.

Visit	N	Fully completed EQ-5D	
		N	%
1	2602	2057	79.1%
2	2145	1343	62.6%
3	1735	1073	61.8%
4	1382	830	60.1%
5	1105	631	57.1%
6	926	518	55.9%
7	751	432	57.5%
8	615	352	57.2%
9	494	282	57.1%
10	386	224	58.0%
11	293	182	62.1%
12	223	131	58.7%
13	175	105	60.0%
14	131	74	56.5%
15	98	62	63.3%
16	69	41	59.4%
17	44	29	65.9%
18	32	22	68.8%
19	20	10	50.0%
20	10	6	60.0%
21	6	4	66.7%
22	2	1	50.0%
23	1	0	0.0%



4. Missing data

Even a highly active and dedicated Registry, like EUMDS, has to deal with missing data. To minimize the consequences of missing data, data quality control, including monitoring of both clinical execution and data collection, has been implemented since the initiation of the EUMDS Registry. Besides the on-site monitoring in your or other participating hospitals, regular remote monitoring is used to maintain high quality data.

A recent remote monitoring action focussed on the IPSS-R classification, since IPSS-R is a pre-requisite for inclusion in the various study cohorts. Early 2019 we observed that IPSS-R classification was missing for 19% of the patients.

IPSS-R classification (see protocol V5.1 Appendix A.3) requires information on:

1. Cytogenetics
2. Bone marrow blast percentage
3. Hb-level
4. Platelets, and
5. Absolute Neutrophil Counts

All 5 data elements were missing in 2.3% of the patients, but this was restricted to a few sites. Personal contacts with these sites resolved this underreporting. IPSS-R requires exact reporting of the percentage of marrow blasts at the level of 2%. This information cannot be deducted from the WHO classification. Evaluation of information reported in other fields (e.g. text fields) enabled us to retrieve sufficient information to classify the IPSS-R in the majority of the 3.3% patients with missing percentage bone marrow blasts, 1.4% patients with missing absolute neutrophil counts, and most challenging the patients with missing cytogenetic classification. In the remaining patients we have approached the sites again.

So far, the percentage of patients with unknown IPSS-R classification in the database can be reduced to approx. 5-10% due to the dedicated efforts of Peter Karel, our monitor who unfortunately will leave us shortly, Theo de Witte and the York team, as well as the data managers that have already resolved the queries. We will continue our efforts to reduce the missing IPSS-R classification to a minimum. Starting July 1st, we will have a new monitor, who will follow-up on the queries that have been sent to the local sites and who is looking forward to contribute to the quality of the EUMDS Registry data.

We are grateful for your dedication and contribution to the high quality EUMDS data

5. Farewell messages from Karien Croezen and Peter Karel

Karien Croezen

After having worked for four years as a project officer for the EUMDS registry I am leaving the Registry. This means new learning opportunities and challenges ahead, but also leaving a group of people I enjoyed working with. I am very grateful I got the opportunity to work for such an important project and I enjoyed being part of the EUMDS project management team and the Operational Team. I am impressed by the scope of and the amount of cooperation within the project (see 'From the chair'). More than 10 years up and running..., what's more: the registry is growing and expanding to new countries. Compliments to all of you, whether you are a principal investigator or a project assistant at a participating site. I would like to make a special compliment to research staff like research nurses and data managers. Without you, this registry would not be possible! Thank you for your dedication.

My contribution to the Registry is coming to an end now, but I hope the Registry keeps growing and study results will find their way to clinical practice. In the end, it is about the MDS patient that should benefit from all our joined efforts.

I wish you all a very good summer with your loved ones. On my side, I will take the time to enjoy the summer with my family, before starting a new job. Wishing you a good summer, and all the best!

Kind regards, Karien

Peter Karel

After 2.5 beautiful years, I will soon be leaving as the EUMDS monitor. Starting on June 17th, I will start a new challenge focusing on my long-term ambition of becoming a clinical chemist by starting a 4 year specialization program.

I joined the EUMDS in December 2016 and since then I have enjoyed providing my contribution to increase the quality of the data. I visited several of you in your home countries, and was always welcomed with open arms and warm smiles. I also met many of you at different meetings throughout the continent. It has always been a pleasure working with you, all of you are highly motivated to make the best of the Registry.

During my time as monitor I have seen the Registry grow, not only in the number of patients entered into the database, but also the number of sub-studies conducted and the number of (potentially field changing) scientific publications these studies have produced. I can only hope that the Registry keeps growing in my absence for many years to come.

I wish you all the best

Cheers

Peter

6. 2019 publications

Recently, two more papers have been accepted for publication in Haematologica. These will soon become available online:

- de Swart et al. Impact of red blood cell transfusion dose density on progression-free survival in lower-risk myelodysplastic syndromes patients. Haematologica 2019
- Hoeks et al. Impact of treatment with iron chelation therapy in patients with lower-risk myelodysplastic syndromes participating in the European MDS registry. Haematologica 2019

Other publications

- de Swart, L. Patient with lower-risk myelodysplastic syndromes: in scope of iron related complications. PhD thesis 2019 (12 June) https://www.globalacademicpress.com/ebooks/louise_de_swart/mobile/index.html

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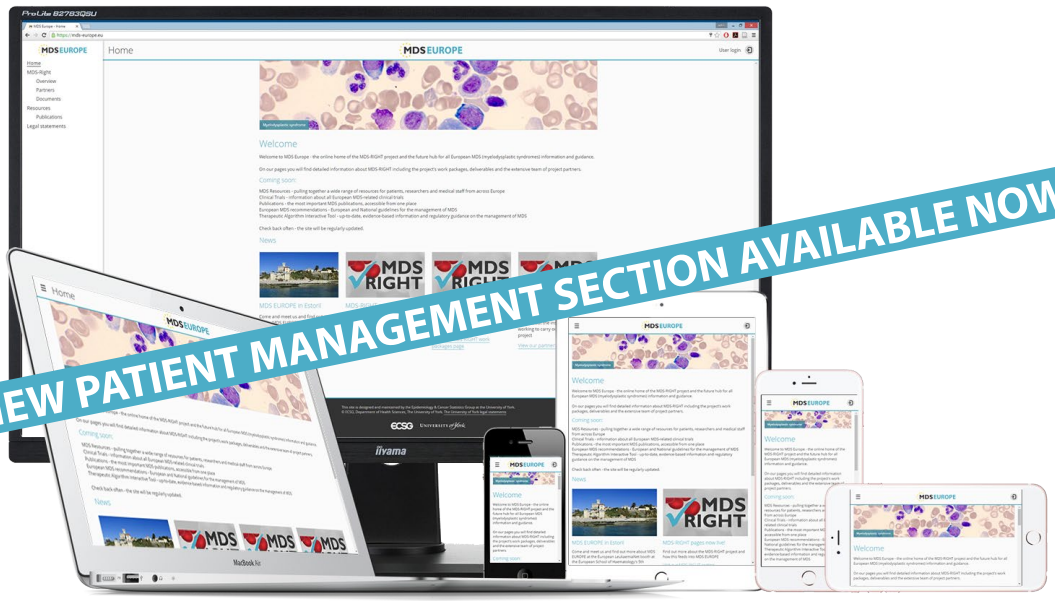

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