

JUNE 2021

Does early treatment with highly effective DMT improve prognosis for people with MS?

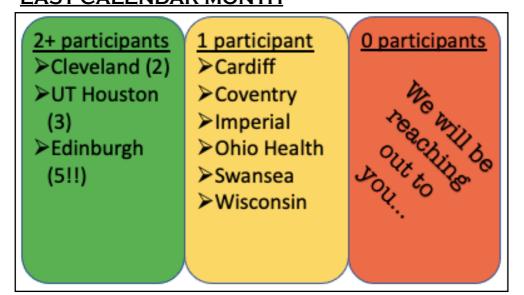
WELCOME TO THE DELIVER-MS NEWSLETTER

This month has seen steady recruitment in some sites and enrolment in some sites that had been inactive for a while. Less good news was that our funder, PCORI, delayed their decision to extend our study, pending more evidence of enrolment. As you know, enrolment to DELIVER (and many other trials) has been considerably set back by COVID. While PCORI are sympathetic to this, they require evidence that the study can consistently enrol in order for them to award an extension that will allow full study enrolment. Now, more than ever, we must ask ourselves: "Is DELIVER-MS still relevant?" (see below) and "Can I recruit one or two more?". We hope you agree.

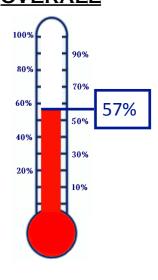




DELIVER-MS ENROLLMENT: LAST CALENDAR MONTH

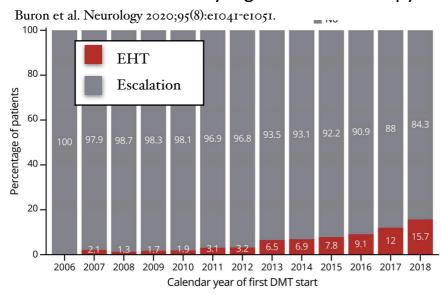


OVERALL



DELIVER-MS FOCUS: IS DELIVER-MS STILL RELEVANT?

Clinicians we have faced many challenges during the COVID pandemic, and research has often had to take a backseat. But we are also acutely aware that COVID has amplified the safety concerns of patients around DMT, especially when to use high efficacy drugs. Here we consider whether Escalation vs Highly Effective DMT remains an area of equipoise. People sometimes feel confused about the aim of DELIVER-MS: "Why are we testing moderate vs high efficacy DMT, when we already know from studies like CARE-MS and OPERA that high efficacy DMT is better?" Although we have some head-to-head trials, the field is still split on whether to use early high effective therapy or escalation:

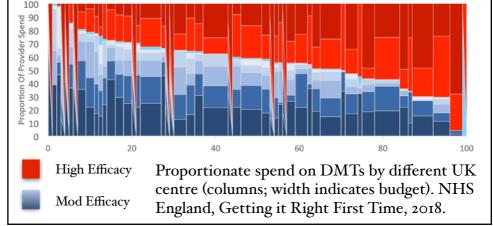


Explanations may include local approvals for DMTs, but are also likely to include patient or clinician concerns over safety / convenience.
We also know that in the

UK, different centres differ widely in their practice, highlighting a degree of subjectivity or personal preference:

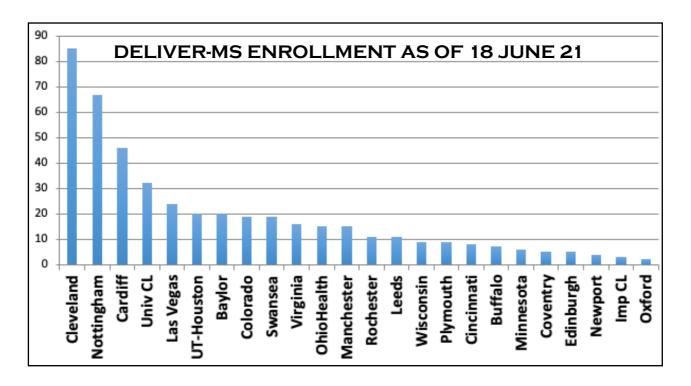
The current split of ESC vs EHT amongst people in DELIVER's observational arm (people who are uncomfortable with randomisation) is:

- 40% Escalation
- 60% High Efficacy



This further highlights ongoing equipoise over the optimal DMT strategy.

DELIVER-MS tests whether moderate efficacy <u>can</u> be a valid first-line strategy, when it is used early, and combined with monitoring that allows transition to heDMT in those people who demonstrate breakthrough activity. We would love to hear your thoughts at our next PI meeting.



FINAL THOUGHTS

The DELIVER MS trial has enrolled well over half the study population. Although we know that enrolling patients into the study is not easy, we are entering the final straight. We really need to collectively push enrollment in the coming months, so we can demonstrate to our funders that study enrollment can be completed over the next year. We rely on you to help answer this important question and to keep our study going strong!

Relevant Links

Our website is:

www.deliver-ms.com

Our mailing address is:

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