Understanding the Administration and Monitoring Time Burden of Several Disease-Modifying Therapies for Relapsing Multiple Sclerosis

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CONCLUSIONS

While active HCP time varied across sites, infusion DMTs were projected to require the greatest amount of HCP time associated with administration and monitoring over 4 years versus oral DMTs, with cladribine tablets requiring the lowest amount of time.

Such findings may assist MSSNs and other MS-specific HCPs in planning and delivering the equitable provision of DMT services for patients.

INTRODUCTION

- The evolving disease-modifying therapy (DMT) landscape has changed the role of multiple sclerosis specialist nurses (MSSNs) in the NHS greatly, placing a focus on ensuring the safe and equitable provision of DMT services for patients with multiple sclerosis (MS).
- The increasing range of available DMTs and associated administration and monitoring requirements, has resulted in a situation that is stretching the capacity of already under-resourced MS specialist services in the United Kingdom (UK).[1]
- To enable MSSNs to effectively plan delivery of care, there is a need to better understand the administration and monitoring burden of treatment with high-efficacy DMTs on MS services.

OBJECTIVE

To quantify the administration and monitoring time burden associated with selected high-efficacy* DMTs (alemtuzumab, cladribine tablets, fingolimod, natalizumab, and ocrelizumab) for relapsing MS in the UK.

*High efficacy is defined by the Association of British Neurologists as "DMTs with an average relapse reduction substantially more than 50%".[2]

METHODS

- A time and motion (T & M) study was conducted across four MS centres over 3–4 months per site (Aug 2019–Feb 2021).
- At each site, the monitoring workflow was mapped following a semi-structured interview with a neurologist and/or MSSN; a site-specific activity diary was developed to repeatedly collect active healthcare professional (HCP) time for pre-selected activities (**Table 1**). Even though workflows differed across sites, a core set of tasks could be identified that were generally applicable across all sites (**see Supplementary Figures 1–5**).
- For infused drug administration, active HCP time for pre-specified activities (**Table 1**) was collected using a generic Case Report Form.
- Participating HCPs included, but were not limited to, neurologists, MSSNs, infusion nurses, and healthcare assistants.
- T&M data collected per protocol were extrapolated over 4 years using dosing information from the relevant Summary of Product Characteristics (SmPC)[3-7] and monitoring frequencies obtained from the SmPC, and validated during interviews (local frequencies of blood draws, MRIs, other diagnostic investigations, and neurologist and MSSN clinic visits).
- Descriptive analyses were performed to model active HCP time per patient over 4 years. Minimum and maximum values reflect results for individual sites.

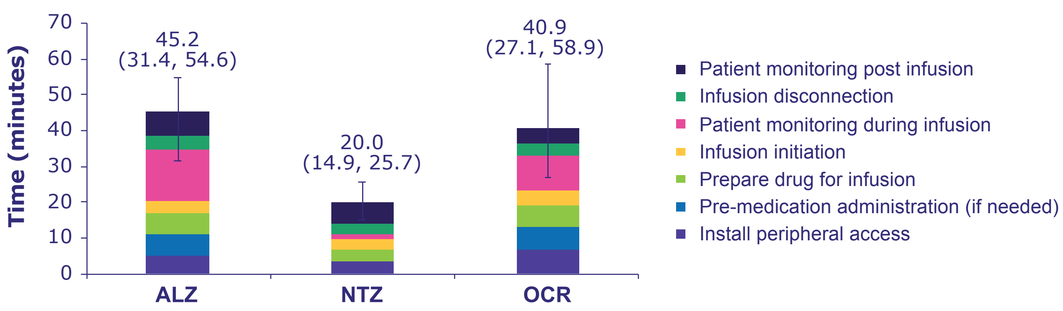
Table 1. Pre-specified Administration and Monitoring Activities

Administration Activities (target samples of 10 observations per infusion DMT per site)	**Monitoring Activities** (target samples of 10 observations per activity; non-drug specific)
Install peripheral access	Blood draw
Pre-medication administration (if needed)	Retrieval and review of blood results
Prepare drug for infusion	Dictate and type blood results letter
Infusion initiation	Review and approve blood results letter
Patient monitoring during infusion	Review of abnormal blood results
Infusion disconnection	Check availability of MRI results
Patient monitoring post infusion	Dictate and type MRI results letter
	Review and approve MRI results letter
	Check patient files prior to clinic visit
	Booking appointments (blood draw, clinic visit, infusion)

MRI, magnetic resonance imaging

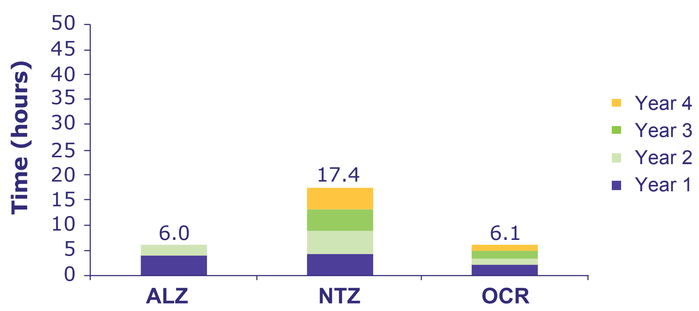
RESULTS

Figure 1. Mean active HCP Time per Infusion by DMT



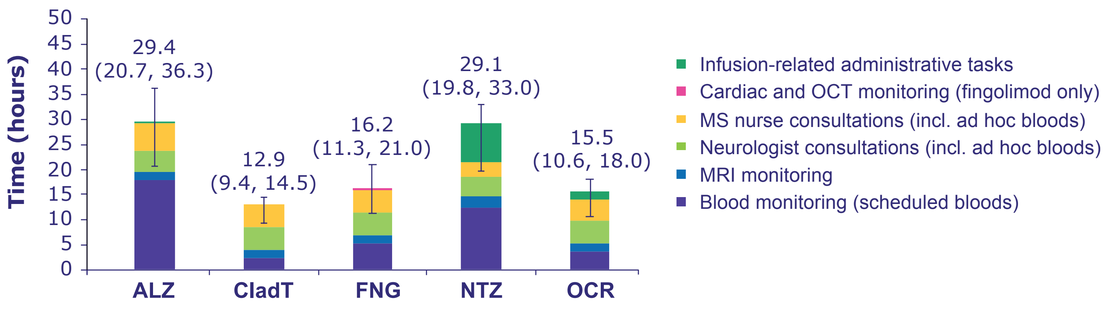
Data labels show mean (minimum, maximum) active HCP time per infusion by DMT.

Figure 2. Estimated Infusion-related Active HCP Time per Patient Over 4 Years, by DMT



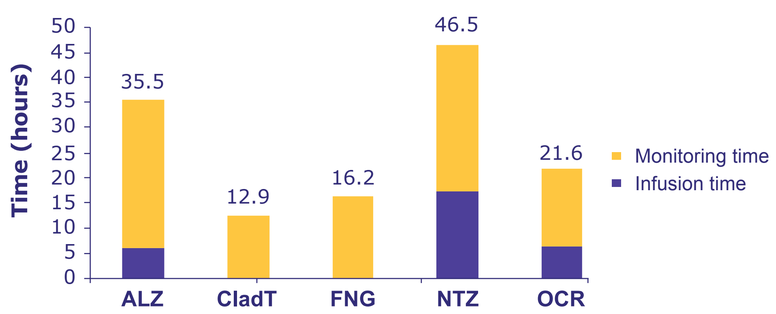
Data labels show estimated infusion-related active HCP time per patient over 4 years, by DMT

Figure 3. Estimated Monitoring-related Active HCP Time per Patient Over 4 Years, by DMT



Data labels show estimated mean (minimum, maximum) monitoring-related active HCP time per patient over 4 years, by DMT.

Figure 4. Estimated Total Active HCP Time per Patient Over 4 Years, by DMT



Data labels show estimated total active HCP time per patient over 4 years, by DMT

ALZ, alemtuzumab, **CladT**, cladribine tablets; **DMT**, disease-modifying therapy; **FNG**, fingolimod; **HCP**, healthcare professional; **MRI**, magnetic resonance imaging; **MS**, multiple sclerosis; **NTZ**, natalizumab; **OCR**, ocrelizumab; **OCT**, optical coherence tomography

Limitations

- The results are based on a T & M model that was subject to multiple assumptions.
- The results may not be generalisable to the entire UK due to the small number of sites included in the study.
- For some core tasks, data could be collected at some sites but not others; this was in part influenced by the COVID-19 pandemic.

SUPPLEMENTARY MATERIALS
Figures 1 - 5: Monitoring Workflows

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