

# Lymphocyte counts in patients treated with dimethyl fumarate and implications for patient monitoring

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## Introduction

- The Multiple Sclerosis (MS) teams at Imperial & Hillingdon NHS Trusts work collaboratively as a hub & spoke model looking after 1750 MS patients on disease modifying therapies (DMT's).
- Between the 2 trusts more than 500 patients are being treated with dimethyl fumarate (DMF). These patients require 3 monthly blood tests to monitor for lymphopenia & changes in LFTs.
- This is a considerable monitoring burden for the MS services involved equating to the organisation and interpretation of more than 40 blood tests per week for DMF alone
- In 2016 Fox *et al* . showed that mean lymphocyte counts of dimethyl patients decreased by 30% in the first year of treatment and plateaued above the lower limit of normal.
- It would be an advantage to MS services to be able to predict trends in lymphocyte counts within their local population and thereby identify those groups of patients that may be at greater risk of lymphopenia and require more careful monitoring.

## Aim

- To analyse lymphocyte counts in a group of patients being treated with DMF and identify any trends in lymphopenia over time
- To identify those groups of patients most at risk of lymphopenia

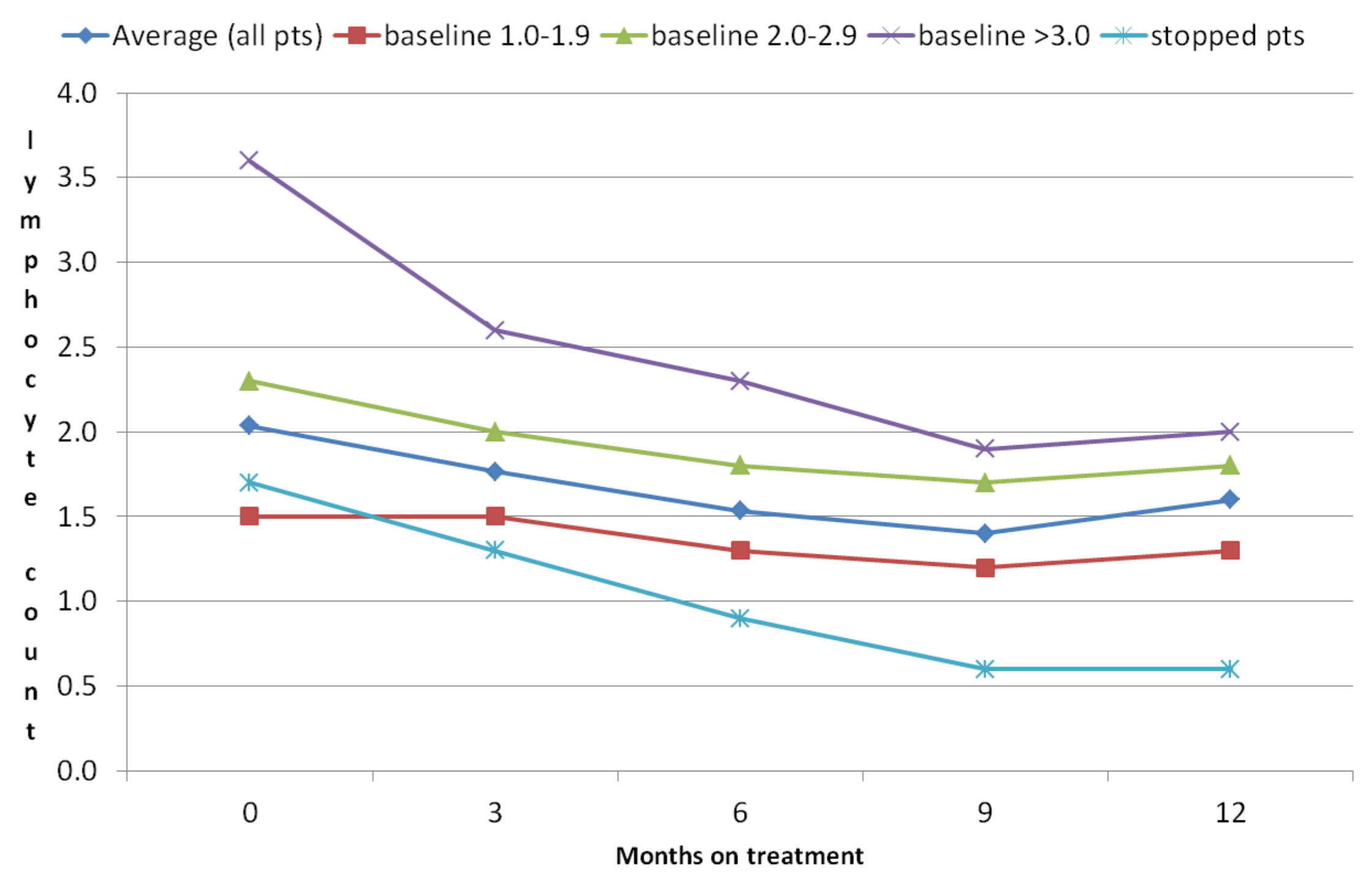
## Method

- We used local patient records at each trust to identify those patients on dimethyl fumarate between Jan 2013 and July 2018
- The start date for each patient treatment was noted
- We used local pathology reporting systems to obtain a retrospective record of lymphocyte counts over the first 12 months of treatment starting from the baseline prior to DMF initiation.
- We also identified a group of patients who had stopped DMF due to lymphopenia and recorded their baseline and subsequent lymphocyte counts over 12 months
- We excluded any patients for whom a baseline or full set of lymphocyte counts were not available

## Results

- We identified 505 patients on DMF. 362 patients were excluded due to incomplete data.
- 143 patients were included in the analysis
- Baseline lymphocyte counts in the population on DMF ranged from 0.7 to 4.3 with a mean count of 2.0
- Lymphocyte counts dropped on average by 25% at 6 months and by 21% at 12 months.
- Patients with a higher starting count (>3.0) had the greatest drop at 12 months (average 44%).
- Lymphopenia requiring cessation of DMF (0.5 or less) took on average 13 months to occur (range 3-36 months).

Average Lymphocyte Count Over 12 Months



% Drop in Lymphocyte Count

	% drop at 6m	% drop at 12m
Average (all pts)	25	21
Baseline 1.0-1.9	13	13
Baseline 2.0-2.9	22	22
Baseline >3.0	36	44
Stopped pts	47	64

## Conclusions

- An average 21% drop in lymphocyte count is to be expected in patients on DMF at 12 months .
- Patients who have a greater than average 25% drop at 6 months may be more likely to go on to develop lymphopenia requiring treatment to be stopped.
- Lymphopenia requiring treatment cessation took on average more than 12 months to develop.
- These results demonstrate the importance of ongoing monitoring of lymphocyte counts in our patients on DMF & that it is not possible to identify those at greater risk from a baseline lymphocyte count.