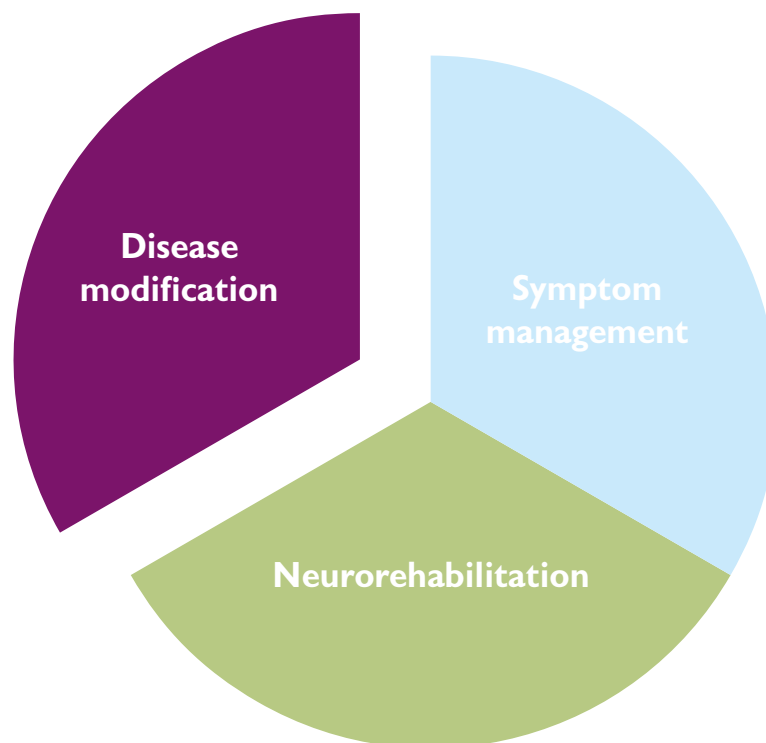




Improving the efficiency of disease modifying drug provision

November 2016

Authors: Geraldine Mynors[†], Megan Roberts^{*}, Amy Bowen[‡]



[†] GEMSS programme manager, MS Trust

^{*} MS Specialist Nurse and Advanced Practice advisor, MS Trust

[‡] Director of service development, MS Trust



Contents

1 Introduction: why focus on DMD provision?	3
2 What we did	4
3 Where DMDs are currently prescribed	5
4 Overview of the DMD pathway and associated workload	6
5 Barriers to efficient practice within current DMD services	10
6 Towards more efficient DMD services	13
7 Conclusions and recommendations	23
Appendix 1: DMDs available in the UK and their monitoring requirements	25
Appendix 2: The functional mapping approach	27
Appendix 3: Outputs of the functional mapping workshop	28
References	35

Figures

Figure 1: Number of DMD prescribing and monitoring centres by country of the UK	5
Figure 2: Summary of the DMD pathway	6
Figure 3: Assumptions in our model of future DMD activity	7
Figure 4: Projected growth and change in treatment rates within a caseload of 358 people with MS in 2016	8
Figure 5: Increasing workload across an MSSN caseload associated with increased DMD provision	9
Figure 6: Example of a new DMD: Introduction of fingolimod	10
Figure 7: Case study - DMD coordinator	14
Figure 8: Roles currently played by pharmacists within MS teams	16
Figure 9: Extent of direct pharmacist involvement with people with MS	16
Figure 10: Discussion point - role of pharmacists	17
Figure 11: Discussion point - MSSN prescribing	19
Figure 12: Case study - DMD monitoring without face to face consultation	20
Figure 13: Discussion point - GP monitoring of DMDs	21



I Introduction: why focus on DMD provision?

Disease modifying drugs (DMDs) have changed the face of treatment for people with relapsing forms of multiple sclerosis (MS) over the past 20 years. They reduce the frequency of relapses and the accumulation of lesions in the brain detectable by MRI scanning, and some studies suggest that they can slow disability progression and improve long term outcomes^{1, 2}. The Association of British Neurologists (ABN) now recommends that treatment with DMDs should be started as soon as possible in eligible patients³.

DMDs vary significantly in terms of their benefit-risk profiles (see [Appendix I](#)), but all carry risks and need to be prescribed and monitored (for both safety and efficacy) by an MS specialist team including an MS neurologist and MS specialist nurse³. There are four drivers that are increasing the burden associated with the provision of DMDs:

- ▶ The overall number of people with MS is estimated to be growing each year by around 2.4%, due to increasing life expectancy⁴.
- ▶ The proportion of people with MS who are taking DMDs in the UK is growing, from around 7% in 2005⁵ to 21% in 2013⁶ and 27% in 2015⁷. A recent survey of over 11,000 people with MS showed that, in England, treatment rates amongst those who could benefit^{iv} increased from 40% to 56% between 2013 and 2016⁸. However, treatment rates in the UK remain among the lowest in Europe⁶, so this trend is set to continue.
- ▶ The number of DMD treatment options available on the NHS has grown from four in 2002 to 11 today (see [Appendix I](#)), with more likely to be licensed and then appraised by NICE in the next 12-24 months, including, for the first time, one for the treatment of primary progressive MS (ocrelizumab). MS teams now manage patients on a wide range of monitoring regimes involving different tests and test intervals, requiring the development of new protocols and a high degree of organisation to ensure adherence to these. MS specialist nurses currently shoulder most of the monitoring workload. Furthermore, advising and supporting people with MS to choose a DMD has become more complex, necessitating extra time for information provision and shared decision making early in the pathway.
- ▶ DMD monitoring regimes have become more intensive. The newer, 'highly effective' DMDs (shown in [Appendix I](#)) come with greater efficacy and are used for treating more highly active MS, but also carry risks of potentially life threatening complications such as progressive multifocal leukoencephalopathy (PML). There is also an increasing recognition of the value of using MRI scanning to detect disease activity and monitor treatment effectiveness³, and 69% of MS specialist neurologists responding to the MS Forward View survey of neurologists told us that they now use MRIs routinely to judge treatment response^v.

As a result of these drivers, MS teams have become increasingly overwhelmed by the workload associated with DMD provision and MS specialist nurses (MSSNs) in particular are struggling with the monitoring requirements. Both the MS Trust GEMSS programme⁷ and recent MS Trust research with people with MS⁹ have identified that this is compromising the ability of teams to meet the needs of people with progressive forms of MS, for whom there are currently no DMDs available, and to meet the non-DMD-related needs of people with relapsing MS.

For this reason, within the MS Forward View project, we chose to look in depth at the provision of DMDs, and to explore the potential for improving the efficiency of DMD prescribing and monitoring.

iv Defined as those with relapsing forms of MS and/or taking a DMD

v A further 14% said that they 'sometimes' used MRI to judge treatment response.



2 What we did

As part of the MS Forward View project, we explored DMD provision in a number of ways.

- ▶ Our survey of all MS specialist nurse teams in the UK (described in detail in a separate report¹⁰) enabled us to map prescribing and monitoring centres and ask about the use of innovative practices.
- ▶ Our survey of consultant neurologists across the UK, answered by 118 consultants who see people with MS regularly (around a third of all such consultants in the UK) enabled us to ascertain the views of neurologists about problems and opportunities around DMD prescribing.
- ▶ We held a one-day workshop attended by clinicians and lay members of our MS Forward View advisory group (in consultation with the wider MS Forward View lay forum). This workshop analysed the DMD pathway using a functional mapping approach (described in [Appendix 2](#)) focusing mainly on initiation of prescriptions and monitoring, to identify who is best placed to deliver these elements of care.
- ▶ Our survey of hospital pharmacists working in MS, carried out in collaboration with the UK Clinical Pharmacy Association Neurosciences Group, was answered by 23 pharmacists and explored the scope for pharmacists to play a greater role in this area.
- ▶ We modeled different scenarios over the years 2016 to 2020 to identify the inputs required by an MS caseload under different assumptions about treatment rates going forward, and the associated workforce requirements.

This report is a synthesis of the findings from these activities.



3 Where DMDs are currently prescribed

The heatmap of MS services developed through the MS Forward View MS nurse survey identifies 107 centres in the UK where neurologists prescribe DMDs. Around three quarters of these centres offer the full range of DMDs and the remainder offer a more limited range (typically, though not always, excluding the ‘highly effective’ category DMDs administered by IV infusion). The map identifies a further 47 MS specialist nurse teams (mostly small or single handed community-based teams) who carry out DMD monitoring in conjunction with a prescribing centre elsewhere. Figure 1 breaks down the number of MS teams involved in DMD prescribing or monitoring.

Figure 1: Number of DMD prescribing and monitoring centres by country of the UK

	Full range of DMDs prescribed	Limited range of DMDs prescribed	Monitoring only (prescribing elsewhere)
England	60	27	43
Northern Ireland	1	2	1
Scotland	9	4	3
Wales	4		
Grand Total	74	33	47

This pattern of provision highlights four issues which we heard about during the project:

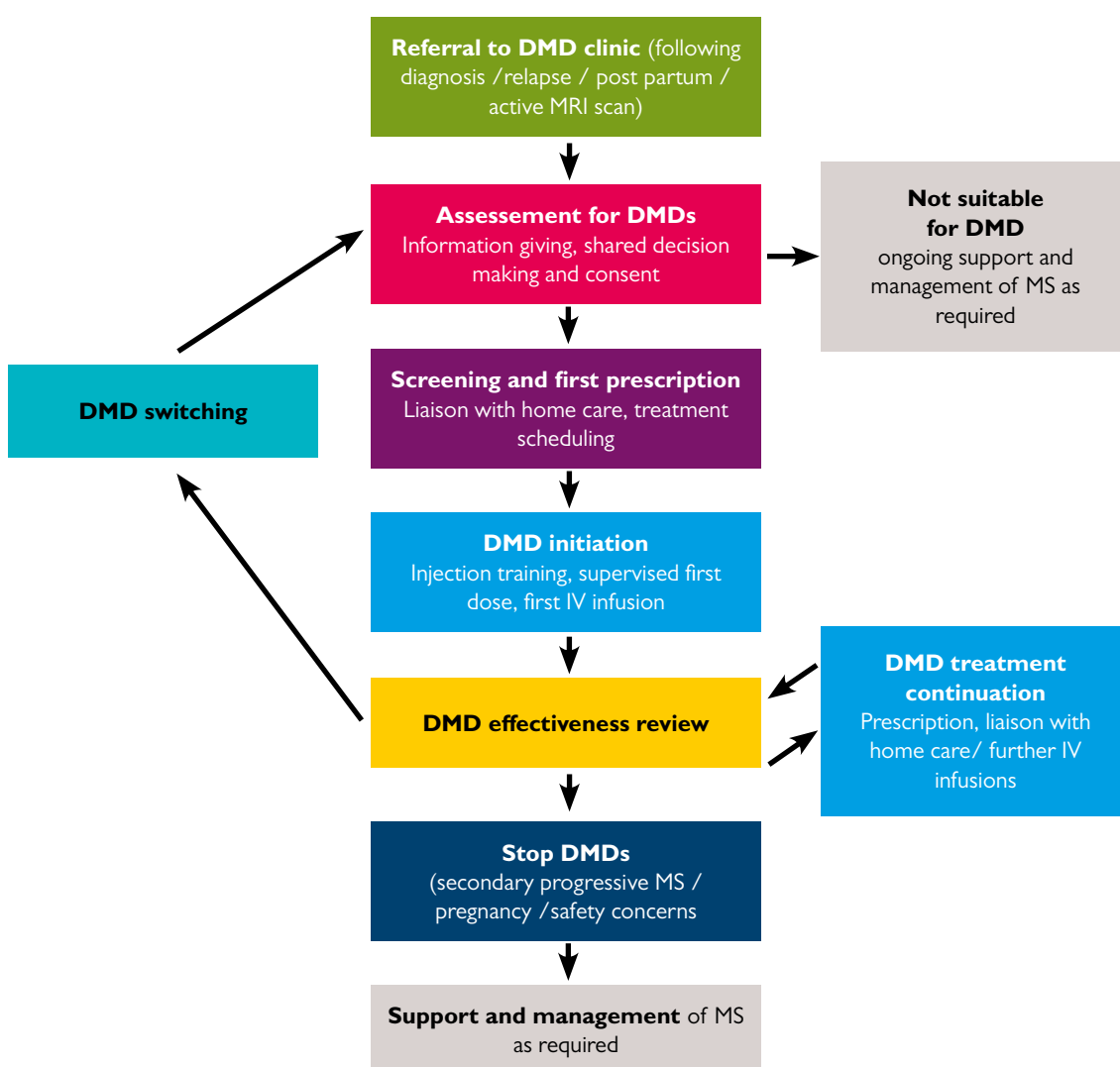
- Whilst the majority of centres offer the full range of DMDs, others offer only a limited range. Most of these centres operate as ‘spokes’ of larger specialist centres, sharing consultant neurologists. However, in a number of cases it is unclear whether people with MS are being offered the full range of DMD treatments, and this is a cause for concern.
- Linked to this, our neurologist survey showed that, in some centres, ‘moderately effective’ DMDs are being prescribed by neurologists who do not define themselves as MS specialists or run MS clinics. 31% of non-MS specialist neurologist respondents said they prescribed DMDs, though none prescribed the ‘more effective’ or ‘highly effective’ options. Different views exist about this, with some neurologists highlighting concerns that limiting prescribing to ‘scarce’ MS specialists could restrict access to DMDs, while others state that DMDs should only be prescribed by a neurologist with an interest in MS and access to the full range. This issue needs to be resolved.
- The relative concentration of prescribing in specialist centres means, in some parts of the country, people with MS must travel long distances to their nearest centre. If they require frequent blood monitoring (as with alemtuzumab for example) and need to travel to the prescribing centre for blood to be taken, this can be very onerous and interfere with work and other activities. In some instances, specialist centres have asked primary care to undertake blood monitoring on their behalf, but this is problematic for reasons described in [Figure 13](#) below.
- Where DMDs are being monitored by MS specialist nurses outside the prescribing centre, there are clear benefits to people with MS in terms of care being offered closer to where they live. However, there are real challenges to ensure that lines of communication between the prescribing centre and the peripheral nurses work well in both directions – and if not managed well, shared care arrangements carry clinical risk. In some instances, funding arrangements (in England) again create a barrier to community-based MS nurses being commissioned to deliver blood monitoring.



4 Overview of the DMD pathway and associated workload

As shown in [Appendix I](#), the 11 DMDs currently available in the UK differ in their risk-efficacy profiles, routes of administration (self-injected, oral or given by IV infusion in hospital), frequency of administration and monitoring requirements. However, the process has a number of common features and [Figure 2](#) shows a simplified outline of the DMD pathway which applies across all DMDs.

Figure 2: Summary of the DMD pathway



Based on this pathway, we used the DMD SmPCs^{vi} (summarised in [Appendix I](#)) to identify the activity that MS teams need to undertake for all of the currently available DMDs.

We then built a model to look at how the workload of MS teams could increase over the next five years as the proportion of people on DMDs increases. The main assumptions used in the model are summarised in [Figure 3](#) below and are based on an analysis of data from the 15 teams who took part in the MS Trust GEMSS programme⁷ and two other large teams who made their data available to us, and the results of

vi Summary of medicinal Product Characteristics



the MS Society My MS My Needs survey 2016⁸. There is inevitably a large degree of uncertainty around these assumptions but the results show one plausible view of how workloads could increase, holding the current mix of DMDs and indications for prescribing constant. The introduction of new DMDs for progressive forms of MS, or any further significant shift from the 'moderately' and 'more effective' DMDs to the 'highly effective' DMDs would increase workload further. Further work is required to predict how treatment patterns will actually evolve in the light of consensus on prescribing, monitoring and stopping, as discussed in the recommendations in this report.

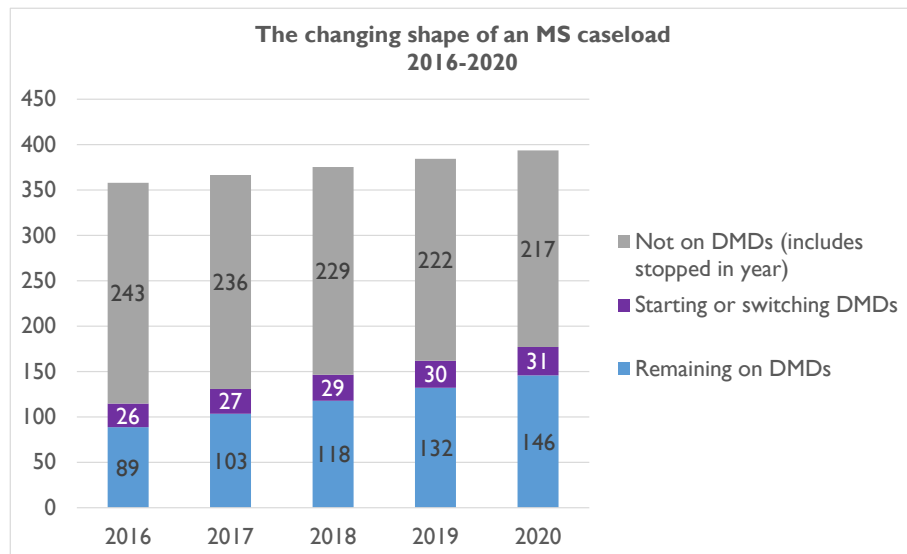
Figure 3: Assumptions in our model of future DMD activity

- ▶ 52% of people on the caseload have relapsing forms of MS (relapsing remitting, or secondary progressive with relapses) and are potentially eligible for DMDs if they meet the relevant criteria and there are no contraindications. This is based on the analysis of the GEMSS combined caseload⁷.
- ▶ 54% of people with relapsing forms of MS are on DMDs in 2016. This is based on the MS Society My MS My Needs survey 2016⁸.
- ▶ Of people taking DMDs, 42% are on self-injected drugs, 39% are on orals and 19% on DMDs given by infusion. This is based on the MS Society My MS My Needs survey 2016⁸. It is assumed that these proportions do not change across the five year period.
- ▶ The underlying prevalence of MS is increasing by 2.4% per year, as people with MS live for longer⁴.
- ▶ 7% of people on DMDs switch between DMDs each year in response to concerns about efficacy or adverse effects. This is based on data from two large teams.
- ▶ 3.5% of people on DMDs stop taking them each year. This low level of stopping reflects current practice and is driven by two factors. First, the fact that treatment rates have increased sharply means that most people currently taking DMDs are relatively near the start of their treatment journey. Second, there is growing evidence that DMD treatment is postponing progression from relapsing MS to secondary progressive MS¹¹, which would mean that people remain eligible for treatment for longer. Over future years, as the system reaches 'steady state' and with the introduction of more formally defined stopping criteria, we could expect the proportion of people stopping DMDs each year to increase.
- ▶ By 2020, the proportion of people with relapsing forms of MS on DMDs will be 75%. The My MS My Needs survey shows that 74% of people with relapsing MS diagnosed in the past year in 2016 are on a DMD⁸. Amongst the teams who took part in GEMSS, the team with the highest treatment rate had 74% of people with relapsing MS on DMDs¹.
- ▶ In terms of nurse input, each person newly diagnosed, starting or switching DMDs will have two MSSN consultations to support decision making and two DMD monitoring reviews in the first year. People stable on DMDs will need one DMD review each year. Everyone with MS will also need one annual holistic review with an MS specialist nurse, and half will need a second appointment in the year for symptom or relapse management. These assumptions are in line with the MS Trust sustainable caseload model¹².
- ▶ In terms of neurologist input, each person on DMDs will need a weighted average of 1.1 neurologist reviews each year. People not on DMDs will need 0.5 neurologist reviews per year (or in other words half will need a neurology review, the remainder will have nurse led care).



Figure 4 shows how, under these assumptions and starting with a caseload of 358 people with MS in 2016 (the caseload defined as 'sustainable' for one whole time MS specialist nurse¹¹), the size and shape of the caseload could change by 2020, even with the existing DMD range and indications.

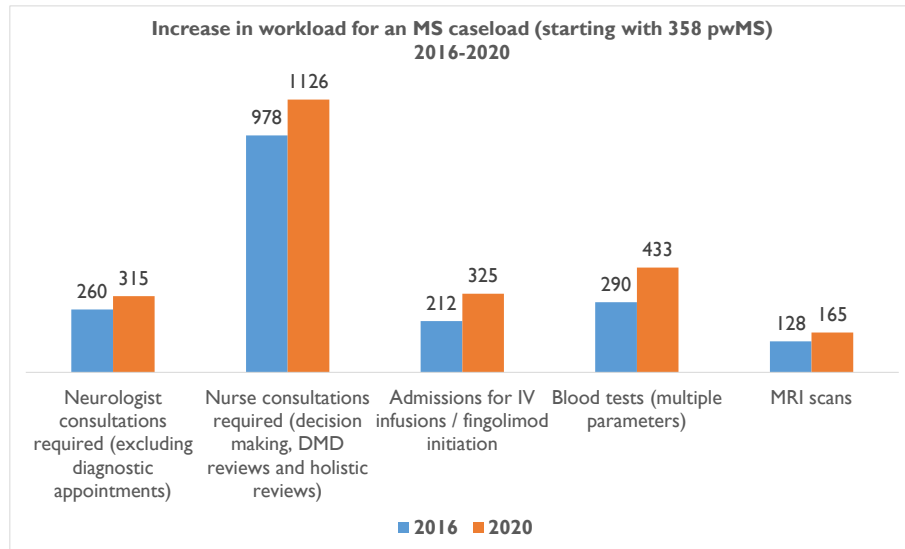
Figure 4: Projected growth and change in treatment rates within a caseload of 358 people with MS in 2016



The increase in the proportion of people within the caseload on DMDs will have an associated increase in the workload to administer and monitor these treatments, including expert interpretation of neurological MRI scans. Figure 5 shows how the work would increase in the next five years for the whole caseload, including both those on DMDs and not.



Figure 5: Increasing workload across an MSSN caseload associated with increased DMD provision



This increase in workload will be challenging or impossible for MS teams to deal with unless they work differently – particularly given that research by the MS Trust shows that the majority of teams are starting with caseloads well in excess of the recommended ‘sustainable’ level¹⁰. As [section 6](#) below shows, there is scope for MSSNs to work at a more specialist level, in line with their pay grade, enabling them to free up neurologist time – but critically, this depends on them being able to delegate routine and non-clinical aspects of DMD care to other members of the team.



5 Barriers to efficient practice within current DMD services

The expansion in DMD treatment options has led MS teams to adapt and expand their DMD service each time a new DMD is approved for use^{vii} (see figure 6 for an example of what this can require). As a result, many services are structured less efficiently than if they had been designed from scratch.

Figure 6: Example of a new DMD: Introduction of fingolimod

When fingolimod was granted reimbursement approval MS teams had to establish links with both cardiology and ophthalmology. The risk management plan for fingolimod mandates that people should have a 12 lead electrocardiogram (ECG) performed prior to and six hours after taking their first dose and recommends continuous ECG monitoring for a minimum of six hours following their first dose of fingolimod. An optical coherence tomography test (OCT) is also mandated for people who have been taking fingolimod for 3-4 months as there is a risk of macula oedema. Neurologists and MS nurses do not have the expertise to routinely monitor and read ECG recordings or OCTs and so inter-departmental pathways had to be set up before DMD services could prescribe fingolimod. Provision is needed to be made for a daycase admission for initiation to take place, and staff to supervise this made available. The process for planning the initiation of fingolimod therefore requires liaison with a number of departments, and unless carried out systematically can be very time consuming.

Our work has highlighted four main sources of inefficiency associated with the increased number of DMDs and their ongoing monitoring.

5.1 Undifferentiated roles: MS specialist nurses doing 'everything'

Many elements of DMD coordination and monitoring involve repetitive tasks such as scheduling review appointments with people with MS, booking daycase chairs, reviewing routine results to ensure that they are within acceptable limits and liaising with home care companies. MS specialist nurses have led the establishment of DMD services, but much of the work now does not require their level of skill and the volume of work involved means that it is not cost effective for them to deliver it all. Despite this, MS nurses have retained responsibility for delivering the vast majority of care required along the DMD pathway, because of a lack of other staff, including non-clinical admin staff, to take it on. The report of our MS nurse team survey¹⁰ quantifies the huge range of non-clinical, DMD-related tasks which specialist nurses are currently undertaking, including scheduling monitoring appointments, booking chairs for IV infusions and much more besides.

5.2 Lack of enabling information systems for planning and monitoring care

As **figure 3** shows, running a DMD service involves scheduling hundreds of review appointments, blood tests, scans and infusions every year and checking that they have taken place as planned. However, many MS teams currently have no access to a database or information system to help them with this task. Our nurse survey showed that only 28 out of 107 prescribing centres (26%) use an IT system or database to keep track of DMD monitoring. In most centres, care is planned on an individual patient basis during appointments using individual patient records, and there is nothing to prompt necessary actions or flag when monitoring and care has departed from the pathway. Problems are compounded by a lack of clear pathways and unified systems for monitoring. Pharmacists responding to our survey commented:

“There is a lot of duplication of effort and no clear processes defined.”

“In our service there are multiple systems of handling prescriptions and monitoring in place. We have a mix of paper and electronic systems which are standalone and don't integrate.”

vii NICE mandates that new medications granted approval should be available to prescribe by services within three months of the final decision.



5.3 Systems are not integrated between providers

Where care is shared between more than one MS team: for example with a neuroscience centre prescribing DMDs and monitoring undertaken by MS nurses in the community, communication of test results is frequently done by email or even fax because access to patient information and pathology systems is not shared between providers. Similarly, whilst some GPs are happy to take on responsibility for phlebotomy for blood monitoring within their surgeries, many MS centres are unable to view the results if the surgery is outside their local area and uses a different laboratory. MS teams at prescribing centres therefore spend a huge amount of time chasing up results from other teams and professionals, with increased clinical risk that monitoring will be missed. In many cases, the informatics-related barriers to phlebotomy being available locally are so insurmountable that people with MS have to travel many miles to a neuroscience centre simply to have blood taken.

Comments from the MS Forward View lay forum reinforce these points:

“My GP surgery is less than a mile from my home but won’t do monthly bloods so I attend neuro clinic ten miles away. Reasons are a mix of not being paid to monitor them and being afraid of the results of a red listed drug like Tysabri.”

Similarly, pharmacists responding to our survey said:

“The biggest challenge is meeting the regulatory requirements for appropriate blood monitoring for DMDs in terms of infrastructure to support coordination and ease of patient access to phlebotomy.”

“The greatest challenge is in liaising with primary care to arrange bloods and in getting these transferred across the primary / secondary care IT interface.”

And some comments from the lay forum highlighted that, when systems are properly integrated, there are major payoffs in convenience for people with MS:

“The MS nurse sends me a request form when my test is due which I can take to either my GP practice or my local hospital. The hospital is easiest for me as I can just turn up without needing to make an appointment.”

5.4 Difficulties with home care delivery

People with MS on self-injected and oral medications (over 80% of those currently on DMDs⁷) usually have these delivered by home care delivery companies. The choice of company is limited by the arrangements put in place by the five pharmaceutical companies which supply these drugs. People with MS told us that they often find home care delivery companies frustrating to deal with and rely on their MS specialist nurse to resolve issues. Similarly, MSSNs told us that they spend a great deal of time liaising with home care companies to ensure that people with MS get the right medication at the right time. The ability of hospitals to explore different delivery options (such as patients collecting their medication from a local community pharmacy) is limited by VAT regulations, which mean that delivery via home care costs less to the NHS.

Some of the issues were highlighted by pharmacists responding to our survey:

“There are great difficulties in joining up systems; we generate prescriptions using Word templates and have to move bits of paper round the hospital and off to the homecare providers. GP practices seem to cope more efficiently with much larger volumes of repeat prescribing!”

“[There are] multiple models of supply (different home care schemes and drug access arrangements). Prescription management is led by home care companies, not the service and patient.”



“Home care is currently cumbersome and time-consuming with variable service both within and between home care companies, eg prescriptions accidentally cancelled/lost by home care or not requested in time with others requested before they are due.”

“Home care has a huge amount of inefficiencies. Medicines should be supplied via community pharmacy.”

In the next section, we describe some of the ways in which the barriers to efficient DMD management may be overcome.



6 Towards more efficient DMD services

Our work has identified three main ways in which DMD services can become more efficient.

6.1 Greater role diversity for economies of scale

MS specialist nurses, most of whom are employed at band 7 or 8, are an expensive resource and it is not cost effective or a good use of their expertise for them to be undertaking all tasks along the DMD pathway. Our functional mapping work has identified a number of other staff groups who could provide elements of the work, as shown in [Appendix 3](#). Freeing up time for MS specialist nurses will enable them to provide leadership for the whole DMD pathway and give time to other activities such as symptom and relapse management and the care of people with advanced MS. Freeing up MS nurse time could also enable them to take over some DMD-related functions from neurologists, such as repeat prescribing, providing appropriate local protocols exist and caseloads are sustainable.

Clearly there is a trade-off between carrying out tasks at the most cost effective skill level and ensuring that care is not fragmented to the point that handoffs create more work. It would make no sense, for example, for a person with MS to have an annual review consultation with an MS specialist nurse to talk about symptoms and other issues, and soon afterwards to have to have a separate consultation with a less specialist DMD nurse who can only review DMDs. Smaller teams also have less scope to diversify their teams. The size of the service therefore needs to be taken into account when planning skillmix, but suggestions for using different roles within the MS team are as follows.

6.1.1 Role of the DMD coordinator

Every MS team that is prescribing or monitoring DMDs should include a non-clinical DMD coordinator to manage the process. In smaller teams, this function could be combined with the wider administration role which is required by all MS teams. Our recommendation is that there should be at least 0.6 whole time administrative staff for each whole time MS nurse, to include time for DMD coordination and other non-clinical administration¹⁰. Alternatively, the DMD coordinator role could be played by a member of pharmacy staff (see the section on pharmacy below), with a corresponding reduction in the administrative time needed within the MS team. A list of DMD coordinator functions is given in [Appendix 3](#).



Figure 7: Case study - DMD coordinator

Case study – the Leeds MS Service DMD coordinator

The MS service in Leeds has a coordinator dedicated to managing the administration of DMDs. She is a band 4 administrator, working 20 hours per week, coordinating care for approximately 350 people with MS taking DMDs. Leeds is a regional prescribing centre for DMDs and manages treatment not only for people within Leeds but also outlying areas such as Calderdale and Huddersfield where there are locally based MSSNs undertaking some of the blood monitoring. The coordinator is responsible for liaising with consultant neurologists, pharmacists and home delivery services to ensure the timely renewal of DMD prescriptions, and operates a helpline for people with MS with non-clinical DMD queries that receives between 10 and 20 calls per week. The coordinator is also responsible for managing clinic lists for people with MS in order to best utilise clinic capacity, and produces patient pathways for new DMDs based on pharmaceutical guidelines. The main benefits of the DMD coordinator role are:

- ▶ People with MS on DMDs have a direct point of contact for non-clinical issues and an advocate to deal with problems involving home delivery companies and monitoring appointments.
- ▶ Non-clinical yet complex administration tasks are relieved from clinical staff.
- ▶ Individuals on DMDs are effectively tracked - the DMD coordinator maintains a database detailing monitoring events and alerts that are followed up if missed, ensuring that monitoring is effective and timely.

6.1.2 Role of a DMD or therapies nurse

In larger teams, efficiencies can be gained by including a DMD or therapies nurse within the team who can do the DMD reviews required outside the comprehensive reviews offered by an MS specialist nurse, review blood test results to ensure that they are within normal parameters and undertake injection training and supervised first-dose appointments for oral therapies. These roles (which of themselves are unlikely to be sufficient to add up to a whole post in all but the very largest centres) can be combined with a responsibility for administering IV DMDs on an infusion suite or ward, as shown in [Appendix 3](#). Our MS nurse team survey showed that six DMD prescribing centres currently employ one or more MS DMD or therapies nurses, but in other teams these roles may be played by a support nurse with particular responsibility for DMD monitoring.

Modelling the workload required for the DMD pathway shows that in a service with around 350 people with MS on DMDs, there would be enough work to employ a full time therapies nurse (spending around half their week on IV infusions and the other half on other elements of the DMD pathway), and this could free up half a whole time MS specialist nurse post to provide new services, potentially taking on some roles from neurologists by offering nurse-led care to people on the caseload with MS who do not routinely need to see a neurologist. However in smaller services, the workload will not be sufficient for a whole time DMD nurse post.

6.1.3 Role of pharmacists

Neurospecialist pharmacists and pharmacy technicians could be playing a greater role within the DMD pathway. Pharmacists are expert on all aspects of medication management including prescription screening, interactions, side effects, adherence and establishing pathways and protocols for prescribing and dispensing drugs. Aside from this expertise, other benefits of using pharmacists and pharmacy technicians to deliver elements of the DMD pathway are that they typically have cross-cover arrangements within their departments to allow for absences, which small MS teams may not, and they can spread learning and innovation from other specialties. 91% of pharmacists responding to our survey agreed that ‘pharmacists are well placed to play a greater role in the management of DMDs in MS than they do now.’



50 out of 107 DMD prescribing teams told us that they had access to a neurospecialist pharmacist within their service. [Figure 8](#) shows the roles currently played by pharmacists within the DMD pathway who responded to our survey. [Figure 9](#) shows that 74% of pharmacists answering the survey are involved in direct interaction with people with MS, usually on an ad hoc basis to resolve issues rather than in a formal clinic setting.

Our recommendation is that all MS teams who prescribe DMDs should include a pharmacist within the multidisciplinary team (MDT) and involve them as much as possible in the development and design of processes and pathways for DMD care, including setting up and managing agreements with home care companies. Teams could also consider assigning a pharmacist, working with a technician, to undertake the DMD coordination and some DMD nurse roles around scheduling and checking monitoring results, and making the pharmacy department the first point of contact for people with MS with DMD-related queries. Whether they can play an even wider role is considered in [Figure 10](#) below.



Figure 8: Roles currently played by pharmacists within MS teams

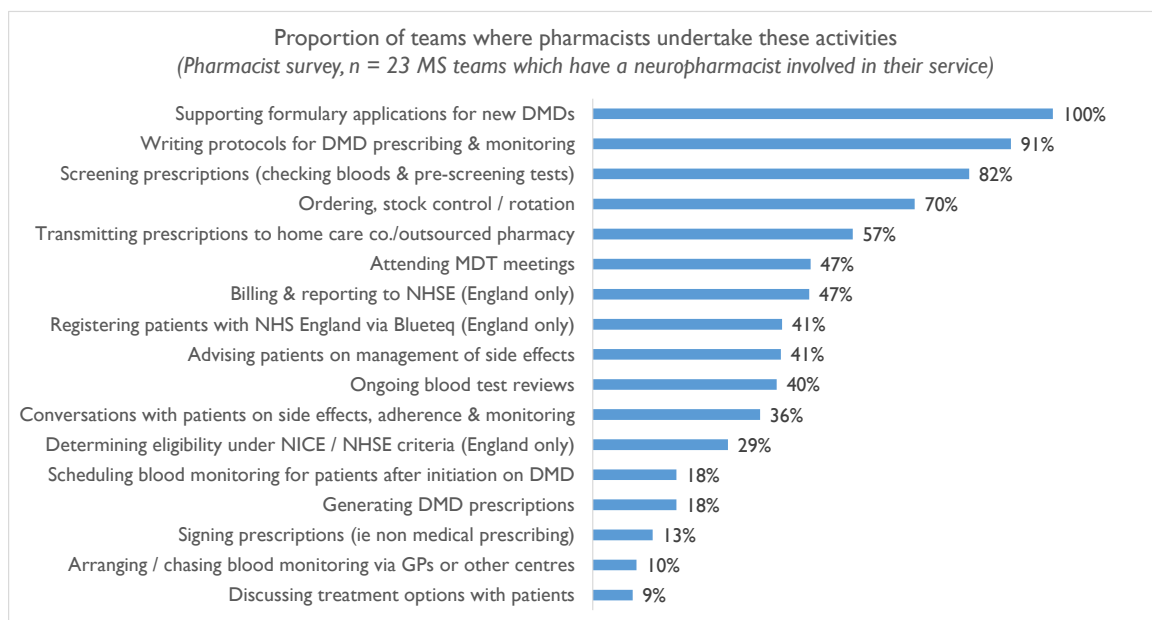


Figure 9: Extent of direct pharmacist involvement with people with MS

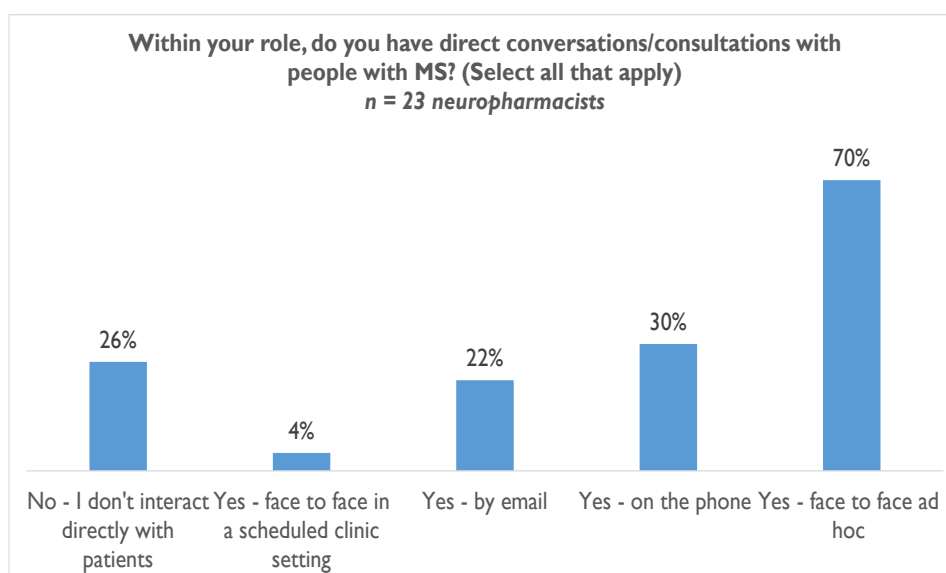




Figure 10: Discussion point - role of pharmacists

Discussion point – Should pharmacists undertake DMD-related consultations with people with MS and non-medical prescribing?

Some of the pharmacists who took part in our survey thought that pharmacists could be even more involved in the DMD pathway, taking on face to face reviews with people with MS and prescribing DMDs. Comments included the following:

“We know that DMDs for MS are highly costly and come with significant risks of adverse events. We also know that people who do not adhere to their treatment end up costing the healthcare system more, and doing less well in the longer term. Individualised targeted adherence support could help address this (and with measurable outcomes).”

“[I see the main opportunities for pharmacists to improve DMD care as] monitoring concordance and prescription management, patient and service monitoring and supply processes to minimise waste and oversupply.”

“I see a pharmacist’s role alongside the MS nurse’s role - I would like to see a pharmacist included in the MDT.”

“[I see the main opportunities for pharmacists to improve DMD care as] utilisation of pharmacists’ prescribing qualifications to prescribe DMDs. Pharmacists have a wider drug knowledge and are able to advise patients about DMDs in the context of their concomitant medication.”

“In a clinic setting, [we could be] discussing options for DMDs with patients including side effect profiles and dosing schedules for each drug. Also to ensure that monitoring is carried out and advise on dosage reductions and stopping treatment.”

“As medicines experts we could play a greater role in supporting the MS nurses in counselling patients about potential treatment options, monitoring and side effects.”

MS teams, however, expressed some concern about pharmacists taking on direct consultations with people with MS for two reasons:

- ▶ Hospital pharmacists are typically employed at a higher pay grade to MS specialist nurses (more than 80% of pharmacists responding to our survey were at band 8). In addition, pharmacists do not currently report spare capacity; 87% responding to our survey said that they would need more pharmacy staff in order to play a greater role. Hence substituting pharmacist time for MS specialist nurse time could cost more to the NHS, unless band 6/ 7 pharmacists were trained up to be involved.
- ▶ Pharmacists’ focus is on medication-related issues, and they will not be able to address the full range of other neurological symptoms and MS-related issues that may come up in consultations. The broader counselling role that is needed to guide someone with MS through the DMD decision process includes things like helping someone overcome denial of their disease and think through the wider aspects of MS in their lives – areas that MS specialist nurses have unique training and experience to be able to do. For this reason, consultations with pharmacists could not substitute for consultations with MS specialist nurses (although they could potentially substitute for DMD nurse consultations).

There was consensus within the workshop group that pharmacists could play a much greater role in designing the DMD pathway and DMD monitoring, and that further work was required to see whether it is cost effective for them to take on additional roles such as face to face reviews with people with MS or prescribing.



6.2 Enablers for efficient DMD management

Dividing the workload around more staff groups offers efficiency benefits, but four essential requirements for this to work well are:

6.2.1 Leadership of the DMD service

There should be a named clinical lead for DMD management within the MS service who will be responsible for coordinating the delivery of the whole DMD pathway and ensuring people with MS receive a consistent service. This includes:

- ▶ allocating clear responsibilities across the MDT, including the neuropharmacist, and defining supporting role descriptions
- ▶ developing pathways, processes and efficient use of skill mix
- ▶ ensuring an experience for people with MS that supports shared decisions and maximises convenience as well as safety
- ▶ undertaking audit and quality assurance
- ▶ providing continuous quality improvement, using team suggestions, feedback from people with MS and problems / near miss incidents as a spur to update systems and processes

The clinical lead could be an MS neurologist or an MS specialist nurse or potentially a neurospecialist pharmacist, but it is critical that this individual is recognised by the service as whole and has time built into their job plan to do this work effectively.

6.2.2 Clearly defined pathways and processes for DMD prescribing and monitoring

Every DMD prescribing centre should have a clear set of standard operating procedures, agreed and shared by the centre and any peripheral MS services undertaking monitoring, specifying:

- ▶ Patient pathways and protocols for each DMD type and the overall system of working
- ▶ Roles and responsibilities of each team member (both at the prescribing centre and the periphery)

Visual displays (such as posters) can be a useful way of clarifying roles and responsibilities.

6.2.3 An information system for tracking monitoring across the caseload

It is essential that the DMD coordinator has access to a system for tracking everyone on the caseload taking a DMD, enabling them to see who is due for monitoring and who has had this. Systems do not necessarily need to be high-tech and a good Excel database can be a very effective tool. Examples are:

- ▶ Many hospital information systems which now allow for scheduling of planned monitoring and flag anomalies
- ▶ MS Specific database systems, such as iMed^{viii} and DAWN^{ix}
- ▶ Excel databases incorporating monitoring review dates

6.2.4 Regular MDT meetings of everyone involved in the DMD process

There should be regular MDT meetings involving, at a minimum, a neurologist, MS specialist nurse, pharmacist and DMD coordinator to discuss the overall functioning of the service and review complex or

viii iMed is currently in use within around 30 MS centres in the UK as a patient database. It doesn't currently prompt monitoring or enable users to see outstanding monitoring across the caseload, but this may be developed in future releases. For details of iMed see http://www.imed.org/en/about_imed/about_imed.html

ix DAWN is a system originally developed for rheumatology which integrates an MS patient database with local pathology systems to track monitoring. It is currently up and running in two MS teams in the UK (with initial fees paid for by Genzyme pharmaceuticals), although through this project we heard of difficulties in getting it adopted in the NHS because of the move away from standalone databases. See <http://www.4s-dawn.com/>



challenging cases and adverse events in order to continually improve the protocols and pathways in place. Where outlying MS nurses are involved in monitoring, they should be invited to participate periodically.

Figure 11: Discussion point - MSSN prescribing

Discussion point – Should MS specialist nurses undertake non-medical prescribing of repeat DMDs?

Our nurse survey revealed that there are 19 MS specialist nurse prescribers who currently prescribe repeat DMDs¹⁰ – around 7% of all MS specialist nurses and one third of MS nurse prescribers. The issue of whether this should become more widespread has been explored through MS Forward View.

Our neurologist survey revealed that 70% of MS specialist neurologists ‘agreed’ or ‘strongly agreed’ with the statement that MS nurses, with appropriate training, could undertake repeat DMD prescribing. However, 17% disagreed. Comments from MS specialist neurologists included:

“I think specialist nurses may be able take on some elements of renewal prescribing, but not for all DMDs, and this would be subject to sufficient training and oversight.”

“I think the key to nurse (and neurologist) prescribing is an MDT.”

“MS Nurse might prescribe the first line DMDs in future following adequate training.”

“Need a collaboration of nurses and neurologists. It is a complex issue.”

“Prescribing - yes. Decision about whether ongoing treatment or a switch is advisable is more complex.”

“This depends on the DMD. First line injectables OK.”

“Strict guidelines would need to be in place.”

A benefit of MS nurses prescribing repeat ‘moderate efficacy’ DMDs would be a recognition that in many cases, MS nurses are effectively taking on prescribing responsibility anyway given that they monitor results and generate repeat scripts for neurologists to sign. The scale of prescribing in larger centres means that neurologists have to sign large batches of prescriptions, and pharmacists provide a valuable check by screening prescriptions for appropriate monitoring tests. Hence introducing nurse prescribing for straightforward renewal scripts, with agreed protocols, could be a sensible development. However, it will require careful planning, close working between MSSNs and neurologists, sufficient staffing by experienced and highly competent MSSNs, and clarity about the intervals for neurologist review to assess sub-clinical as well as clinical disease activity, informed by MRI scanning.

6.3 Reduce unnecessary face to face appointments

Our analysis has shown that there may be scope to cut down on routine face to face appointments with people on DMDs without compromising safety.

6.3.1 Phlebotomy-related appointments

Our nurse team survey showed that only 32 out of 148 prescribing and monitoring centres reported that they were able to schedule blood tests without the need for an MS specialist nurse or neurologist appointment (with the results available at a later date). The result is that people on more intensive monitoring by default have more appointments with MS nurses, leaving fewer for others. We also heard about innovations which would reduce these unnecessary appointments, including:

- Open access monitoring clinics without a nurse consultation (see figure 12 below)
- People with MS being given a clear schedule of monitoring dates and pathology request forms during their DMD review, and asked to take responsibility for getting blood tests done on the required date



either at the hospital or at a local GP surgery (if agreed with primary care), with interpretation and monitoring still undertaken by the prescribing team.

Figure 12: Case study - DMD monitoring without face to face consultation

Case study – DMD monitoring clinics at St George’s Hospital

The MS service at St George’s Hospital in south London has established a weekly DMD monitoring clinic in two locations (the main hospital and a nearby community hospital) where people with MS can come to have their blood tests done without needing to see an MS nurse.

People with MS are given a treatment agreement when they start on DMDs, including a schedule of monitoring visits. Each patient has an A4 card detailing the schedule, which is used as a low-tech system for monitoring adherence to the schedule. The monitoring clinic is organised by the MS team coordinator working closely with one MS specialist nurse who has responsibility for therapies. Patients are booked into a ‘drop in’ clinic and can attend the outpatient department any time they choose during that day (appointment times are allocated on the system but do not need to be adhered to). The day before the clinic, the MS coordinator orders relevant blood tests for patients due to attend for monitoring the following day and places these at neurology outpatients clinic reception along with a monitoring card for each person. On the day of the clinic, the receptionist retrieves the patients’ order form(s) when they arrive and the patient takes them to phlebotomy to have blood taken, after which they can simply leave. A healthcare assistant helps with urine tests where necessary and MSSNs are available nearby for ad hoc questions.

The day after the clinic, the MS coordinator and MS nurse review the results. If normal, no further action is taken. If abnormal, time is set aside to discuss this with other nurses and the neurologist the same day. Patients and GPs are notified by telephone about abnormal results and the plan of action. The coordinator books in the next appointment dates and keeps patients updated.

Benefits of the system have been:

- ▶ A reduction in unnecessary face to face appointments for monitoring: if a consultation with the MS nurse is necessary, this happens by phone when the monitoring results are already available and form part of the discussion.
- ▶ By having a weekly cycle for scheduling monitoring and reviewing results, and concentrating this function in a dedicated team with a batch processing approach ensures that tasks are carried out systematically and more quickly than would be possible if monitoring was dispersed amongst different MS nurses and across the week.



Figure 13: Discussion point - GP monitoring of DMDs

Discussion point - Should GPs be asked to take over monitoring DMDs?

At our DMD workforce mapping day, some teams reported that a few GPs had agreed to take over the monitoring of DMDs for selected patients, including the interpretation of test results. However, difficulties with monitoring in primary care are:

- ▶ GPs have limited experience of DMDs in MS and may therefore not feel confident to make judgments about DMD blood monitoring results. There is a risk that treatment could be stopped unnecessarily or, conversely, that adverse incidents might be missed.
- ▶ DMDs can only be prescribed in secondary care, and the prescriber needs to take responsibility for reviewing the monitoring results as part of this process.
- ▶ GPs are not funded to undertake this monitoring, which forms part of the DMD treatment pathway which is funded (in England) under specialised commissioning. As a result, GP monitoring is usually done under an informal arrangement which applies in some practices but not all, meaning a patchwork of monitoring arrangements which is difficult to manage.

For this reason, the consensus was that GPs should only be asked to undertake monitoring (including reviewing results) under defined shared care agreements which they can opt in to. However, where possible, phlebotomy should take place as close to home as possible, provided that the DMD prescribing team is able to access, interpret and act on the results at the prescribing centre. GPs' willingness to undertake this within their practices will depend to some extent on goodwill, given the current funding arrangements for MS services which have been highlighted by the related MS Forward View report on this topic¹³.

6.3.2 Ordering MRIs

There was consensus that monitoring could be made more efficient if MS nurses were empowered to order MRI scans in advance of neurology reviews so that these could be ready and available for the consultation. This would apply both to routine monitoring MRIs, and for people whom they suspect may have increased activity and who therefore need a neurology review. There is a need for teams to develop protocols to enable this to happen.

6.4 Involving people with MS in their care

There is scope for people with MS to be more informed about the monitoring requirements for DMDs when they make the decision with their neurologist or MSSN to start treatment, and to take greater ownership for ensuring that monitoring happens when needed. Many teams operate with a 'no bloods, no drugs' mantra, but we heard from many teams that non-adherence to monitoring regimes remains a time-consuming problem (and may be no fault of the person with MS if they are not fully aware of when monitoring is required).

6.4.1 Treatment agreements

Treatment agreements are used by some teams to ensure that people with MS sign up to their part of the responsibility for ensuring that DMDs are used safely and effectively. We would recommend that these are more widely used, but importantly:

- ▶ They must be written in non-technical, non-threatening and accessible language.
- ▶ The contents of the agreement should be discussed and agreed with the person with MS through a collaborative process.
- ▶ The person with MS must be given a copy of the agreement.



- The agreement should include details of the DMD coordinator for the person with MS to contact with queries and issues.
- The agreement should be accompanied by written information about the medication and its associated monitoring.
- The agreement should make clear that monitoring requirements may change, and explain how the person with MS will be told if this happens.

Further work is warranted to develop and test a 'model' treatment agreement for wider use.

6.4.2 Group information sessions

Group information sessions may be used to impart information about DMDs more efficiently and comprehensively than would be possible within individual consultations in larger centres, although they cannot substitute for one to one shared decision making appointments. Further work is warranted to test this model^x.

6.4.3 Informing people that their bloods have been monitored

We heard from people with MS that, for the most part, they would like to be informed of both normal and abnormal results, not least so that they can be sure that the results of their monitoring have been reviewed. We would recommend that people with MS are routinely kept informed of the outcome of monitoring tests, and this can be done efficiently (for normal results) via email or text message, with appropriate agreement in advance. Most hospital information systems now have systems in place to facilitate this.

^x The Queen Elizabeth Hospital in Birmingham have piloted and evaluated this approach and the results will be published shortly.



7 Conclusions and recommendations

Commissioners should:

- ▶ Recognise that the DMD pathway is complex and resource intensive and ensure that services they commission providing DMDs are clearly specified and underpinned by protocols, particularly when prescribing and monitoring are carried out by separate teams.
- ▶ Engage with MS teams and people living with MS to identify how DMD service provision can be improved by:
 - ▶ Determining the total number of people with MS and the proportion of these who may be eligible for DMD treatment.
 - ▶ Identifying the number of people with MS currently on DMDs and estimate extent of unmet need (if any).
 - ▶ Agreeing an action plan for ensuring that all those who could benefit from DMDs are offered the full range of treatment options.

Managers should:

- ▶ Ensure the MS team is resourced appropriately with the skillmix to ensure efficient and effective delivery of care along the whole DMD pathway and that team members have sustainable caseloads.
- ▶ Ensure that MS teams have access to information systems to support DMD monitoring.
- ▶ Work with the MS team to help them establish links and arrangements with other providers when required for joint monitoring of DMDs.

Every DMD service should:

- ▶ Be supported by a DMD coordinator. We recommend that there should be at least 0.6 WTE administrative staff per whole time MS nurse (with a 'sustainable caseload' of 358 people with MS) to ensure that specialist nurses can focus on clinical tasks.
- ▶ Have clear protocols and pathways in place to underpin effective delivery of the DMD service. These should:
 - ▶ be developed by the DMD lead for the service (an MS specialist nurse, neurologist or neuropharmacist) with input from other neurologists and other DMD team members
 - ▶ clarify the monitoring requirements for each of the DMDs and set out the responsibilities of each team member and of the person with MS for ensuring safe and effective prescribing and that monitoring takes place
- ▶ Include a pharmacist within the MDT and involve them in the design of the service. Explore delegating elements of the pathway, such as liaising with home care delivery companies and scheduling monitoring, to pharmacy.
- ▶ Identify facilities for people with MS who need regular blood tests to have phlebotomy near to home if pathology systems allow for results to be viewed. If people with MS can have phlebotomy for blood monitoring carried out in primary care, this is welcome, but interpretation of blood results should not be delegated to GPs unless there are clear shared protocols which they can opt in to.
- ▶ Set up systems so that people with MS can have blood taken without needing an outpatient consultation (though may be undertaken at the same time if there are other reasons for the appointment).
- ▶ Ensure their systems for keeping track of monitoring appointments and results for each person with MS on a DMD are fit for purpose and efficient.
- ▶ Support MS nurses to request routine MRIs as part of the regular monitoring requirements and



non-routine MRIs if increased disease activity is suspected prior to referral to the DMD clinic for (re) assessment.

- ▶ Support people with MS to take more responsibility for their own DMD treatment by providing written information and treatment agreements.
- ▶ Ensure that everyone who is taking a DMD has a point of contact for DMD-related enquiries who is able to respond in a timely way.
- ▶ Refer people who stop DMDs to appropriate services to ensure they can continue to access the care they need. These may be delivered by the same MS team that provides DMD care or by other local services with expertise in MS.
- ▶ Ensure that GPs of people on DMDs know who they should contact within the team if they have any queries, before treatment starts. GPs should be asked to include the details of the treatment on their own prescribing records.
- ▶ Provide training to other members of the MS team who require it.

Larger prescribing centres should:

- ▶ Facilitate greater diversity of roles within their DMD service. Services treating more than c. 350 people with MS on DMDs should consider employing a DMD nurse to release MS specialist nurse time.
- ▶ Consider extending and integrating the role of neuropharmacists to include more responsibility for DMD prescription management and monitoring.

Opportunities for UK wide developments

- ▶ Choice of home care delivery companies are currently defined by the pharmaceutical companies. Choice of which home care delivery company(ies) and/or community pharmacies to use should be left to the MS team/NHS Trust.
- ▶ Monitoring requirements of different DMDs are currently set by pharmaceutical companies based on clinical trial protocols. A consensus view of MS neurologists is needed to establish monitoring regimes for each DMD which are safe but practical within a real-world clinical environment.
- ▶ There is a need for national consensus on who can prescribe DMDs, incorporating both specialist and non-specialist neurologists and also the circumstances in which MS specialist nurses and pharmacists might undertake repeat prescribing. This consensus should include the intervals for neurologist review, informed by MRI scanning.
- ▶ NHS IT systems should facilitate results and records of people with MS being accessed by all the appropriate members of their healthcare team. This would make monitoring and review much more convenient and efficient for both the person with MS and the MS team, and reduce unnecessary journeys by people with MS to centres simply for phlebotomy.

Areas for further work

- ▶ There is a need for further analysis of current MS caseloads to establish what proportion of people with MS are eligible for DMDs with the current criteria and how this might change with the approval of new drugs and changes to criteria (both for starting and stopping DMDs), to enable more accurate workload modelling.
- ▶ Pharmacist-led DMD clinics and prescribing should be piloted and evaluated for cost effectiveness and clinical effectiveness for people with MS.
- ▶ Model treatment agreements with people with MS who have been prescribed DMDs should be developed and evaluated.



Appendix I: DMDs available in the UK and their monitoring requirements

Summary of available DMDs

The following DMDs are currently available on the NHS in the UK. They have been grouped into categories in line with the ABN prescribing guidelines³.

	Name	Route	Frequency of administration	Year approved in UK ^{xi}
Moderately effective	beta interferon 1a (Avonex®)	Self-injected	Weekly	2002
	beta interferon 1a (Rebif®)	Self-injected	Three times a week	2002
	beta interferon 1b (Betaferon®)	Self-injected	Every other day	2002
	beta interferon 1b (Extavia®)	Self-injected	Every other day	2009
	peginterferon beta 1a (Plegridy®)	Self-injected	Fortnightly	2015
	glatiramer acetate (Copaxone®)	Self-injected	Daily or three times a week	2002
More effective	fingolimod (Gilenya®)	Oral tablet	Daily	2012
	teriflunomide (Aubagio®)	Oral tablet	Daily	2014
	dimethyl fumarate (Tecfidera®)	Oral tablet	Daily	2014
Highly effective	natalizumab (Tysabri®)	IV infusion	4 weekly	2006
	alemtuzumab (Lemtrada®)	IV infusion	Two courses: 5-day admission for 5 infusions, then one year later a 3-day admission for 3 infusions	2014

^{xi} Year approved refers to when the DMDs were approved by NICE for use in England. The original injectable DMDs - Avonex, Rebif, Betaferon and Copaxone - were not approved by NICE but were prescribed from 2002 under the Department of Health Risk-sharing Scheme.



Monitoring requirements of DMDs

The following summary is taken from the summary of product characteristics for each DMD (www.medicines.org.uk/emc/ [accessed 22 August 2016]). Details of the specific blood testing required can also be found within SmPCs.

Name	Year 1		Year 2 onwards
	Special requirements	Frequency of blood testing p.a.	Frequency of blood testing p.a.
beta interferon	Self injection training prior to starting	5	2
glatiramer acetate	Self injection training prior to starting	0	0
fingolimod	First dose taken in hospital with 6 hour cardiac monitoring, ophthalmic monitoring required 3-4 months after starting treatment	5	2
teriflunomide		16	6.5
dimethyl fumarate		3	2
natalizumab	JC virus testing as part of routine monitoring requires specialist offsite lab analysis. (JC virus testing is now being extended to some of the other 'more' and 'highly' effective DMDs in some centres.)	2	2
alemtuzumab		12	12 (For four years after the last course of treatment)

In addition to the above, MRI scanning may be used to monitor treatment response. The SmPC for natalizumab mandates MRI scanning at least yearly, and more frequently for patients at high risk of PML. For other DMDs, our survey of MS specialist neurologists showed that around half used MRI to monitor treatment response annually, and the remainder 'as required'.



Appendix 2: The functional mapping approach

Functional mapping is a process for working with clinicians and practitioners to identify all the tasks or 'functions' needed to deliver a patient pathway. It uses a 'functional map' originally developed by Skills for Health to ascribe a skill level to each function (or task) and think about the workforce needed to deliver that pathway in a much more creative way; one that is less bounded by a specific professional role or pay band. The MS Trust brought together a group of clinicians and people with MS in March 2016 to carry out a functional mapping process with the DMD pathway, facilitated by Sheila Hawkins, functional mapping advisor at Health Education England.

The functional mapping process had three main stages. In stage one, the group considered each stage in the patient pathway and identified all the functions/tasks that need to be carried out from the patient's perspective (using the Skills for Health manual), as well as other functions that are underpinning principles or need to be done by the whole organisations (corporate functions). In stage two, the group allocated each function to one of three levels:

Skill level	Type of tasks	Could be done by (examples)
Specialist	Tasks that require specialist knowledge of direct relevance to the pathway(s)	Neurologist, MS specialist nurse, neurospecialist pharmacist
Enhanced	Tasks requiring enhanced competence that might be typical of a qualified member of staff	An appropriately trained DMD nurse or pharmacist
Generic	Care or support not requiring training at a qualified or specialist level; could be achieved through a short course or on the job experience	An appropriately trained Healthcare Assistant, administrator or support worker

In stage three, the group identified who currently provides each function, and who could provide the function in future given the skill level identified.

The group also considered some other important questions about the DMD process, such as the role of GPs and of people with MS themselves in the process.

Following the day, the MS Forward view team analysed the results to develop the grid shown in [Appendix 3](#).



Appendix 3: Outputs of the functional mapping workshop

The following grid represents the output of the functional mapping workshop and shows who could undertake tasks at each stage of the DMD pathway for an individual with MS (as shown in figure 2 in this report), balancing competence/skill level with the need to deliver services cost-effectively and free up scarce specialist time. It is assumed that all DMD teams include a neurologist, an MS specialist nurse and a DMD coordinator. Some services will also have a 'DMD nurse' role at band 5 or 6, although some of the functions of the DMD nurse could be provided by nurses based in an infusion suite, and in smaller centres (as explained in the report above), there is unlikely to be sufficient activity to warrant a separate DMD nurse function. Some services may also have pharmacists playing active roles within the DMD service, and the range of activities that a pharmacist could undertake is also shown.

In practice, it is important that each MS team defines who will actually deliver each element of the pathway. A Word version of this grid is available from the MS Trust GEMSS team and could be adapted and used by teams to plan to help decide and record this.

The grid does not show leadership functions which will need to be undertaken by the DMD lead for the service with the support of other senior neurologist, MSSN and pharmacist staff such as:

- establishing pathways and protocols for new DMDs
- submitting formulary applications for new DMDs
- establishing service level agreements with home care companies
- auditing care and undertaking continuous quality improvement
- training more junior members of the team in the roles that they will undertake

Updating patient records and communication between team members is not shown as a separate activity as it is assumed that this is an integral part of every task.

Pathway elements	Neurologist	MSSN (usually band 7)	Pharmacist (band 7/8)	DMD nurse (band 5/6)	DMD coordinator (band 4)	Pharmacy technician (band 4)	Phlebotomist/ HCA (band 3/4)
Referral to DMD clinic							
Refer people on DMDs who show signs of increased disease activity to DMD clinic for assessment	⊙	⊙		⊙			
Refer treatment naïve people with MS to DMD clinic for assessment	⊙	⊙					
Assessment for DMDs							
Review medical history and undertake clinical assessment	⊙						
Provide written (or online) information for people with MS about options	⊙	⊙	⊙	⊙			
Discuss pros and cons of DMDs (consider doing in groups)	⊙	⊙	⊙	⊙			
Shared decision making with person with MS about DMD choice	⊙	⊙	⊙				
Complete treatment agreement / consent with person with MS and provide written information about chosen DMD and its monitoring	⊙	⊙	⊙				
Enter information on DMD information systems and request funding via Blueteq (England)			⊙	⊙	⊙	⊙	
Screening and first prescription							
Provide information to person with MS about screening	⊙	⊙		⊙			
Request screening tests	⊙	⊙		⊙			
Schedule test appointments (involving people with MS)				⊙	⊙		
Obtain samples for testing							⊙
Review results against normal parameters and escalate if abnormal		⊙	⊙	⊙			

Pathway elements	Neurologist	MSSN (usually band 7)	Pharmacist (band 7/8)	DMD nurse (band 5/6)	DMD coordinator (band 4)	Pharmacy technician (band 4)	Phlebotomist/ HCA (band 3/4)
Act on abnormal results	⊙	⊙		⊙			
Generate DMD prescriptions (first time)	⊙	⊙	⊙	⊙			
Sign first time DMD prescription (prescribe)	⊙						
Receive and process prescriptions			⊙			⊙	
Screen prescription			⊙				
Set up home care delivery for people with MS				⊙	⊙	⊙	
Agree start date with person with MS		⊙		⊙	⊙		
Book infusion suite /clinic appointment /day ward					⊙		
Check the person with MS's understanding /anxieties		⊙	⊙	⊙			
Maintain DMD information system(s)		⊙	⊙	⊙	⊙	⊙	
Unsuitable for treatment: support and ongoing management	⊙	⊙					
DMD initiation							
Check results of screening tests prior to starting treatment		⊙	⊙	⊙			
Check understanding of person with MS and consent to treatment and monitoring		⊙	⊙	⊙			
Take baseline readings on day of initiation (eg blood pressure, pregnancy test) if applicable		⊙		⊙			⊙
Administer medication (oversee first self-injection or first tablet)		⊙		⊙			
Deal with any adverse reactions	⊙	⊙		⊙			

Pathway elements	Neurologist	MSSN (usually band 7)	Pharmacist (band 7/8)	DMD nurse (band 5/6)	DMD coordinator (band 4)	Pharmacy technician (band 4)	Phlebotomist/ HCA (band 3/4)
Support individual to self medicate (injection training) (This is often outsourced to home care delivery company nurses.)				⊙			
Maintain DMD information system(s)		⊙	⊙	⊙	⊙	⊙	
Book follow up appointments					⊙		
IV administration-related tasks (may be undertaken by infusion suite nurses outside the MS team)							
Check screening / monitoring results fall within normal ranges prior to infusion and adherence to monitoring regime				⊙			
Act on abnormal results	⊙	⊙					
Check understanding of person with MS prior to administering treatment				⊙			
Prepare IV medication if required			⊙	⊙		⊙	
Administer IV medication				⊙			
Manage stocks of medication				⊙		⊙	
Record any PROMs (Patient Reported Outcome Measures) and vital signs during infusion				⊙			
Assess and manage any infusion-related reactions and escalate as appropriate	⊙	⊙		⊙			
Provide support to people with MS during their infusion				⊙			
Refer any MS-related issues identified during infusions back to the MS team				⊙			

Pathway elements	Neurologist	MSSN (usually band 7)	Pharmacist (band 7/8)	DMD nurse (band 5/6)	DMD coordinator (band 4)	Pharmacy technician (band 4)	Phlebotomist/ HCA (band 3/4)
Check the person with MS is aware of their next infusion and monitoring requirements				⊙	⊙		
Safety monitoring (as per DMD protocol)							
Plan monitoring regime as per protocol		⊙	⊙	⊙	⊙		
Book appointments for monitoring tests					⊙	⊙	
Request monitoring tests		⊙	⊙	⊙			
Book appointments for review with MSSN and neurologist (holistic reviews) and with DMD nurse / pharmacist in between holistic reviews					⊙	⊙	
Obtain specimens (blood)							⊙
Obtain readings (pulse / blood pressure)				⊙			⊙
Review results from monitoring against normal parameters and escalate if abnormal			⊙	⊙		⊙	
Manage abnormal results	⊙	⊙	⊙	⊙			
Inform person with MS of abnormal monitoring results or that results were normal		⊙	⊙	⊙	⊙ (normal only)		
Monitor adherence to monitoring regime and report non-adherence		⊙	⊙	⊙	⊙	⊙	
Discuss reasons for non-adherence to monitoring with person with MS		⊙	⊙	⊙			
Maintain DMD information system(s)		⊙	⊙	⊙	⊙	⊙	

Pathway elements	Neurologist	MSSN (usually band 7)	Pharmacist (band 7/8)	DMD nurse (band 5/6)	DMD coordinator (band 4)	Pharmacy technician (band 4)	Phlebotomist/ HCA (band 3/4)
DMD effectiveness review (monitoring results / disease activity / adherence and adverse events)							
Identify people with MS at risk of complications from DMD treatment	⊙	⊙	⊙	⊙			
Implement interventions to reduce risk of complications (eg injection site reactions, JC virus screening)	⊙	⊙	⊙	⊙			
Book comprehensive review appointments					⊙		
Assess significance of findings from safety monitoring results	⊙	⊙	⊙	⊙			
Request routine MRIs as per protocols		⊙	⊙	⊙			
Assess presence /extent of disease activity (eg at comprehensive review or following relapse)	⊙						
Revise treatment plan on basis of full assessment	⊙						
Agree courses of action with the person with MS	⊙	⊙	⊙				
Manage stocks of medication						⊙	
Treatment continuation							
Generate routine renewal prescriptions		⊙	⊙	⊙	⊙		
Sign routine renewal prescriptions	⊙	⊙ (if a prescriber)	⊙ (if a prescriber)				
Liaise with home care delivery company				⊙	⊙	⊙	
Deal with complaints or queries in relation to home care delivery		⊙	⊙	⊙			

Pathway elements	Neurologist	MSSN (usually band 7)	Pharmacist (band 7/8)	DMD nurse (band 5/6)	DMD coordinator (band 4)	Pharmacy technician (band 4)	Phlebotomist/ HCA (band 3/4)
Support people with MS to maintain adherence and self medicate		⊙		⊙			
Manage stocks of medication						⊙	
Prepare IV medication		⊙		⊙		⊙	
Administer IV medication				⊙			
Manage ongoing monitoring appointment bookings					⊙	⊙	
Maintain DMD information system(s)		⊙	⊙	⊙	⊙	⊙	
DMD switching (following review) - see DMD assessment; screening and start DMD							
Stop treatment (following review)							
Liaise with home care delivery company			⊙	⊙	⊙	⊙	
Manage medication stocks				⊙		⊙	
Assess revised health needs and implement revised treatment plan in discussion with person with MS	⊙	⊙					
Maintain DMD information system(s)		⊙	⊙	⊙	⊙	⊙	



References

1. Rice CM. Disease modification in multiple sclerosis: an update. *Practical Neurology*. 2014;14(1):6-13.
2. Palace J, Duddy M, Bregenzer T, Lawton M, Zhu F, Boggild M, et al. Effectiveness and cost-effectiveness of interferon beta and glatiramer acetate in the UK Multiple Sclerosis Risk Sharing Scheme at 6 years: a clinical cohort study with natural history comparator. *The Lancet Neurology*. 2015;14(5):497-505.
3. Scolding N, Barnes D, Cader S, Chataway J, Chaudhuri A, Coles A, et al. Association of British Neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. *Practical Neurology*. 2015;15(4):273-9.
4. Mackenzie IS, Morant SV, Bloomfield GA, MacDonald TM, O'Riordan J. Incidence and prevalence of multiple sclerosis in the UK 1990-2010: a descriptive study in the General Practice Research Database. *Journal of Neurology, Neurosurgery, and Psychiatry*. 2014;85(1):76-84.
5. Kobelt G, Kasteng F. Access to innovative treatments in multiple sclerosis in Europe. European Federation of Pharmaceutical Industry Associations (EFPIA), 2009.
6. Access to medicines for multiple sclerosis: Challenges and opportunities. London: Charles River Associates, 2014.
7. Mynors G, Suppiah J, Bowen A. Evidence for MS Specialist Services: Findings from the MS Trust GEMSS MS specialist nurse evaluation project. Letchworth: MS Trust, 2015.
8. Redfern Tofts D, Wallace L, McDougal A. My MS My Needs 2016: access to treatment and health care - Technical report. Edgware: MS Society, 2016.
9. Is MS Care Fair? Key findings from the MS Trust's survey into the experiences of people living with MS. Letchworth: MS Trust, 2016.
10. Mynors G, Bowen A, Doncaster D. MS Specialist Nursing in the UK 2016: report on progress towards equitable provision. Letchworth: MS Trust, 2016.
11. Cree BA, Gourraud PA, Oksenberg JR, Bevan C, Crabtree-Hartman E, Gelfand JM, et al. Long-term evolution of multiple sclerosis disability in the treatment era. *Annals of Neurology*. 2016;80(4):499-510.
12. Mynors G, Bowen A. Modelling sustainable caseloads for MS specialist nurses: Report on a consensus process led by the MS Trust. *British Journal of Neuroscience Nursing*. 2014;10(6):274-80.
13. Croft A, Mynors G, Bowen A. Funding for MS services in England: a practical guide. Letchworth: MS Trust, 2016.



Acknowledgements

We would like to thank all the MS specialist nurses, neurologists and neuropharmacists who responded to the MS Forward View surveys in 2016 and those who attended the workforce mapping day on DMDs.

About MS Forward View

MS Forward View is a one year project, launched in November 2015, to identify the priority actions needed across the MS sector to enable MS services to deliver efficient, effective and equitable services for everyone with MS, in the context of changing treatment paradigms. MS Forward View is looking at how MS services can make better use of current resources and skills, and how best to measure the quality and equity of access to services for everyone with a diagnosis of MS. We are bringing together clinicians, specialised and local commissioners, professional bodies, experts in workforce planning, multidisciplinary educators, people with MS and patient organisations, to produce a sector-wide consensus on how to optimise the provision of equitable, evidence-based care for everyone with MS. This plan will also help define future education programmes for health professionals working in MS.



About the MS Trust

The MS Trust is a charity which works to make a difference today for the more than 100,000 people living with MS in the UK.

We work to make sure everyone affected by MS can access good quality, specialist care. We do this by providing high quality education and professional development support to MS specialist health professionals so they can deliver an even better service. We support health professionals with online information, publications and updates on the latest research.

Through our innovative GEMSS programme, we support evidence-based service improvement in MS care. Our approach is always to work in partnership with health professionals to improve MS services now and in the future.

We also produce practical, reliable information for people living with MS. Our information is available online and in print, and we offer a telephone and email enquiry service to anyone who needs to know more about MS. Our materials are widely used by MS services across the UK.

We receive no government funding so we rely on donations to fund our vital services.

To find out more about our work, how we can help you and how you can get involved

Visit www.mstrust.org.uk

Call 01462 476700

Or email info@mstrust.org.uk