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Factors influencing multiple sclerosis disease-modifying treatment prescribing decisions in the United Kingdom: A qualitative interview study



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ABSTRACT

Background: The proportion of people with relapsing-remitting multiple sclerosis prescribed disease modifying treatments (DMTs) in the United Kingdom (UK) is considered low compared with other countries. There are differences in DMT prescription rates between UK nations (England, Wales, Scotland, Northern Ireland). Despite this, there has been little research into decision-making processes and prescribing practices.

Objective: To investigate views and experiences of neurologists prescribing DMTs and MS specialist nurses to identify factors influencing prescribing.

Methods: Semi-structured interviews with 18 consultant neurologists and 16 specialist nurses from diverse settings across the four UK nations. Data were analysed using thematic framework analysis.

Results: Prescribing practices are influenced by organisational prescribing “cultures”, informal “benchmarking” within peer networks, and prior experience with different DMTs. Health professionals differ in their perceptions of benefits and risks of DMTs and personal “thresholds” for discerning relapses and determining eligibility for DMTs. Prescribers in England felt most constrained by guidelines.

Conclusion: To achieve equity in access to DMTs for people with MS eligible for treatment, there is a need for public discussion acknowledging differences in health professionals’ interpretations of “relapses” and guidelines and perceptions of DMTs, variation in organisational prescribing “cultures”, and whether the prevailing culture sufficiently meets patients’ needs.

1. Introduction

Disease-modifying therapies (DMTs) reduce the rate of relapse in relapsing-remitting multiple sclerosis (RRMS) (Oh and O’Connor, 2015), and can therefore improve quality of life and lessen the need for relapse management interventions (e.g. steroids, hospitalisation, neuro-rehabilitation). Accordingly, the Association of British Neurologists (ABN) recommends that DMTs should be considered promptly for all individuals with active RRMS (Scolding et al., 2015). Despite this, people with RRMS in the United Kingdom (UK) are prescribed DMTs considerably less frequently than patients in other European countries. For instance, 59% of people with RRMS in the UK were prescribed DMTs in 2013 while prescribing rates ranged between 75% and 91% in Sweden, Italy, Spain, Germany and France (Wilsson and

Barron, 2014).

Some of this variation could be due to national differences in drug approvals, prescribing guidelines, pharmaceutical funding, availability of neurologists and healthcare infrastructure. However, surveys have found substantial differences between regions within the UK in the proportion of people with a relapsing form of MS who reported taking a DMT (Dorning et al., 2013; Redfern-Tofts and Holloway, 2014). In 2016, 77% of survey respondents were taking a DMT in Northern Ireland, compared to just 49% in Wales, 56% in England and 57% in Scotland (Redfern-Tofts and Holloway, 2014). This wide divergence despite relative similarity in policies and systems suggests variation in prescribing rates may be at least partly due to decisions made by individual prescribing centres.

There is also some evidence that treatment initiation may depend on

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the neurologists' level of MS specialism (Kurtuncu and Tuncer, 2017), but this is poorly understood in the UK context. Studies of clinicians' perceptions of DMTs have not extended to investigating the link between views of these drugs and their propensity to prescribe them (Heesen et al., 2010; Hanson et al., 2014; Heesen et al., 2017). Thus far, no empirical research has been carried out in the UK or internationally investigating factors influencing prescribing rates, and no qualitative research has been conducted with MS health professionals to obtain first-hand accounts of factors affecting their prescribing practice.

The aim of this study was therefore to investigate the views and experiences of neurologists and specialist MS nurses who prescribe or facilitate access to DMTs for people with RRMS, in order to elucidate the range of factors influencing DMT prescribing. Importantly, the present research recruited healthcare professionals from the four nations making up the UK to allow investigation of different experiences around the country of factors influencing prescribing.

2. Materials and methods

Sites were selected purposively to include participants from all four constituent countries of the UK, and a range of specialist and non-specialist services. ABN guidance states individuals working in isolation are likely to experience difficulty maintaining specialist skills (Scolding et al., 2015) therefore a "specialist" service comprised at least two consultant neurologists with expertise or special interest in MS. Sites were identified using MS service maps (Multiple Sclerosis Society, 2018; Multiple Sclerosis Trust, 2018) and discussion with regional clinical research advisors. All consultant neurologists prescribing DMTs at selected sites were invited to participate. Subsequently, snowball sampling was used to identify and invite appropriate MS specialist nurses, who have regular interactions with both prescribing neurologists and patients, and so are often important contributors to prescribing decisions and can provide unique insight into issues affecting patients' access to DMTs and decision-making.

Interviews were conducted between November 2016 and March 2017 by the first author. Most took place in participants' usual places of work, typically hospital or primary care settings, and two were conducted by telephone. Interviews were audio-recorded and participants provided written informed consent.

Audio-recordings were transcribed verbatim and identifying information removed. Anonymised, transcribed data were analysed using a thematic framework approach (Gale et al., 2013). A subset of transcripts were coded and indexed by a second researcher to improve research rigour, and findings were discussed by the research team. Ethical approval for this study was received from University of Manchester Research Ethics Committee 4 (Ref. 16413).

3. Results

Thirty-four healthcare professionals participated, including 18 consultant neurologists (ConNs) (5 female) and 16 MS nurses (MSNs) (14 female). Participants were recruited from 15 sites across the UK, including 7 specialist MS services. Eleven interviews were conducted with health professionals working in England, 8 in Scotland, 8 in Northern Ireland, and 7 in Wales. Neurologists had spent between 1 month and 20 years at consultant level (mean = 9.5 years, SD = 6.8). MS nurses had been working in the nursing profession for between 16 and 41 years (mean = 29.9 years, SD = 7.2), and as MS specialist nurses for between 10 months and 22 years (mean = 12.4 years, SD = 6.1). The majority of participants were white British (n = 29), with three identifying as white 'other', and two as Asian or Asian-British.

Interviews lasted 65 min on average (range = 31 to 102 min). Qualitative data analysis resulted in five themes relating to factors influencing prescribing decisions: 1) Prescribing guidelines; 2) Identifying relapses; 3) Perceived risk and readiness to prescribe; 4) Familiarity and

prior experience; and 5) Peer networks and prescribing cultures.

3.1. Theme one: prescribing guidelines

Neurologists working in England described National Institute for Health and Care Excellence (NICE) prescribing guidelines as mandatory criteria which they were "obliged to follow" (P32, ConN, England). This was particularly true given the recent introduction of the 'Blueteq' online system across the National Health Service (NHS) in England for evidencing compliance with clinical commissioning criteria based on NICE guidance and securing prior approval for funding of treatment:

"...we've got the new Blueteq System now which, if we request funding we have to state that they fulfil NICE guidelines, so it's as simple as that." (P39, ConN, England)

Participants in Scotland, Wales and Northern Ireland had knowledge of NICE guidelines and indicated they generally prescribed in line with them. However, while some followed NICE guidelines "quite strictly" (P02, ConN, Wales) others felt they had "a little bit more flexibility to use the medication that you think's most appropriate" (P05, ConN, Wales) as regional regulatory authorities permitted use of DMTs in broader circumstances than in England. Moreover, while interviewees in England were held accountable for prescribing decisions at a national level, those in other regions described justifying decisions instead to local managers and health boards.

Furthermore, some prescribers in Scotland expressed that "guidelines are guidelines, not really more than that" (P41, ConN, Scotland) and instead indicated their priority was the welfare of the patient rather than meeting recommendations based on cost-effectiveness:

"...that almost moral judgment of whether you adhere to the guideline or whether you do the best for the person in front of you... you can't be shackled by worries about whether it's expensive, whether the health board have approved it, whether it's fulfilling X guideline or Y." (P36, ConN, Scotland).

Overall, participants in Scotland, Wales and Northern Ireland identified fewer restrictions on prescribing than their counterparts in England in terms of which guidelines to follow and how restrictive these guidelines were.

3.2. Theme two: identifying relapses

DMT eligibility criteria in prescribing guidelines are based on frequency and severity of relapses, such as 'two clinically significant relapses in the previous two years' (National Institute for Health & Care Excellence, 2014) or 'two or more disabling relapses in one year' (National Institute for Health & Care Excellence, 2007). Participants noted that despite clearly written definitions, distinguishing relapses from pseudo-relapses was not always straightforward:

"...if they've had a recent infection, is it a pseudo worsening or is it a relapse triggered by infection? So yes, I think relapses definitely are a bit of a minefield." (P05, ConN, Wales)

Moreover, interviewees found the language of guidelines "open to interpretation" (P22, ConN, Northern Ireland), particularly in terms of defining a 'disabling relapse':

"What is a disabling relapse? If you're a piano player and your left hand goes numb well that might be disabling for you, but if my left hand went numb for a few days it may well not be at all disabling for me." (P22, ConN, Northern Ireland)

Interviewees felt the imprecise language led to "individual biases" (P25, ConN, England) and personal "thresholds" (P04, ConN, Northern Ireland) in determining relapses, with one participant stating "how you define a relapse... is probably the main driver of individual variation in prescribing" (P30, ConN, Wales).

Specialist nurses in particular emphasised the importance of face-to-face clinical examinations at the time of suspected relapse in order to accurately identify relapses and DMT eligibility:

“To be confident, the person really should be having a neurological examination to see what the differences are between that examination and the previous examination and to get an accurate history as well.” (P10, MSN, Wales)

Many sites offered rapid access clinics or appointments to see these people quickly, however some relied on “a telephone line and we would assess most of it over the phone” (P08, MS Nurse (MSN), Northern Ireland). Despite the relapse reporting routes on offer some patients still reported possible relapses retrospectively during scheduled review appointments, making accurate identification of relapses and DMT eligibility extremely difficult.

3.3. Theme three: perceived risk and readiness to prescribe

Some neurologists described themselves as an “active prescriber” (P36, ConN, Scotland) and “fairly aggressive when it’s needed” (P01, ConN, England), while others “took a more careful approach” (P03, ConN, Northern Ireland), particularly when considering prescribing higher risk DMTs.

Participants’ cautiousness or readiness to prescribe or recommend DMTs to patients were linked to their concerns about the risks associated with DMTs. Major worries were the known risks of serious side-effects, such as progressive multifocal leukoencephalopathy (PML) in patients taking natalizumab, and the unknown long-term effects of these immunosuppressant medications, including potential effects on reproductive health and cancer risk:

“I really have concerns about people being over-treated... and the potential implications for their health in the future. I really have concerns about that.” (P21, MSN, England)

“What are the real risks of giving people these drugs over long periods of time? And we don’t know, do we? We all talk about the higher effect of these drugs. Well, what is the risk of cancer? No one knows.” (P36, ConN, Scotland)

Another concern was lack of evidence about long-term effectiveness of DMTs on disability and disease progression. One neurologist who said they “don’t sell any of these treatments as wonder drugs”, stated:

“All they do is reduce the relapse a bit and I don’t think they do anything else... I don’t believe that we have definite evidence that any of these treatments slow progression of disease.” (P27, ConN, Scotland)

There was consensus that disease course in relapsing MS is highly unpredictable making it “very difficult to prognosticate” (P07, ConN, Scotland) and to base treatment decisions on likely outcomes. Accordingly, more cautious interviewees felt patients might naturally do better than expected and should not be exposed to higher risk treatments if not truly necessary:

“The risks worry me, and the uncertainty about what a particular person’s MS will turn out to be. So I can think of someone who looked like they were going to have awful, awful, awful MS... and actually that person’s done really, really well despite never having had Tysabri, Alemtuzumab or anything else.” (P27, ConN, Scotland)

In contrast, more ‘ready’ prescribers feared patients might do worse than expected if under-treated:

“I don’t want to see them two years down the line to put them on more robust therapy, but by then they’ve had a couple of relapses and they haven’t fully recovered and I’m kicking myself.” (P32, ConN, England)

3.4. Theme four: Familiarity and prior experience

Participants reported the DMTs most commonly prescribed were likely influenced by familiarity, prior experiences and how comfortable they felt prescribing them. Familiarity was attributed to number of patients prescribed the drug so far and whether the individual or service had been involved in clinical trials prior to national licensing:

“You gain confidence, you gain a service that’s structured around the infusions... So, I think that is a natural thing, that if you’re a centre that’s been involved in a phase 3 study, quite often you end up using more of that drug...” (P05, ConN, Wales)

“If it’s just fresh from being licensed and you’re not familiar with it at all, you take a while to build up your experience and you start slowly... You don’t go and put ten people on a new drug that you’ve never used before.” (P02, ConN, Wales)

Confidence in prescribing and recommending DMTs was also said to be influenced by the positive and negative outcomes of patients taking the drugs:

“I was aware that one of the patients died. So when you see that sort of thing, you’re a bit more hesitant about using it.” (P09, ConN, England)

“It can be very possible so patients come back and say this drug’s been fantastic, it’s really well tolerated and that’ll sway us in a particular way.” (P01, ConN, England)

3.5. Theme five: Peer networks and prescribing cultures

Interviewees discussed the importance of having access to a network of peers prescribing DMTs, either within organisations or across regions, for shared learning and achieving consensus on best approaches to prescribing:

“We meet regularly once a year across [region] where we discuss all of the MS treatments and things to make sure that we are quite similar in our approaches.” (P02, ConN, Wales)

These networks seemed especially valuable to prescribers who worked apart from other MS specialists:

“I didn’t want to be out on a limb doing my own thing, I wanted to be in with the group and I wanted to be able to benchmark myself against the group.” (P04, ConN, Northern Ireland)

Peers influenced prescribing decisions at a local level through shared practices and organisational ‘prescribing cultures’. In some places, neurologists intentionally took a team approach as “you need to make sure that you have a demonstrably standardised way of managing your patients” (P32, ConN, England). In these organisations, multi-disciplinary team meetings functioned to generate and maintain this standardised practice and prescribing culture, as well as providing reassurance and alleviating concerns about prescribing ‘riskier’ DMTs:

“I feel reassured by the multidisciplinary thing, I think if I was working in isolation I’d have more concerns about that [PML risk].” (P05, CN, Wales)

However, at centres where prescribers considered themselves to be a collection of individuals, neurologists were less influenced by their peers:

“[Dr A] doesn’t know what [Dr B] does in clinic. [Dr B] doesn’t know what [Dr C] does in clinic... Nobody really knows what other people do.” (P41, ConN, Scotland)

One participant noted that shared prescribing practices came about through local ‘habits’ and infrastructure:

“It’s just what you become familiar with and if everybody else is doing it,

the nurses are familiar with it, that's what you just end up using... It's just what a centre is familiar with, and just habit. Learning from your peers.” (P05, ConN, Wales)

Another clinician described how organisational prescribing cultures could be driven by local opinion leaders:

“...you tend to have certain neurologists who are more dominant and who influence the department, and if that neurologist or group of neurologists have a certain view then that tends to purvey the department.” (P36, ConN, Scotland)

4. Discussion

Interviews with neurologists and MS specialist nurses revealed a number of factors influencing DMT prescribing decisions. The importance of peer networks and prescribing cultures were emphasised, with neurologists eager to position their decision-making in comparison to local and national peers, often with the aim of aligning prescribing practice. Neurologists reported prescribing more readily when they were familiar with a particular drug and had positive experiences with it in the past. However, some health professionals were more cautious in prescribing or recommending DMTs due to uncertainty over long-term benefits and risks of DMTs, and uncertainty over necessity of treatment given the unpredictable nature of the disease.

Prescribers found DMT eligibility criteria in national prescribing guidelines open to interpretation, particularly in terms of deciding what constitutes a disabling relapse, and some neurologists and nurses reported difficulties in distinguishing new MS activity from pseudo-relapses. Generally, neurologists in England felt most constrained by guidelines. Prescribers in the other three UK nations had greater flexibility in the circumstances under which some DMTs can be prescribed and experienced oversight by local rather than national regulatory bodies, with which they had greater opportunity for dialogue.

The relative restriction in prescribing perceived by neurologists in England could partly explain lower DMT prescribing rates in this UK nation. However, this does not account for similarly low rates in Scotland and Wales. It is possible that prescribing rates in the other nations reflect shared attitudes within regional peer networks as prescribing centres are few and largely interconnected, particularly in Wales and Northern Ireland, resulting in a very small number of dominant prescribing cultures.

There is some evidence from other fields of medicine that prescribers' personal beliefs about medicines predict prescribing practice (Walker et al., 2001; Hutchinson et al., 2007). However, this requires further exploration in multiple sclerosis care to quantify the extent to which neurologists' treatment perceptions influence their prescribing practice.

The findings suggest a need to acknowledge individual differences in health professionals' attitudes to prescribing DMTs, and the impact of these attitudes on patients' access to treatment. While there is continuing debate around the long-term risks and benefits of these drugs, there is also consensus that these decisions should ultimately be weighed up by the person with MS, as long as they fulfil the prescribing eligibility criteria. Research into patients' decision preferences indicates that most people with MS prefer an active role in treatment decisions, and advocate shared decision-making and informed choice (Heesen et al., 2004). A substantial proportion may prefer a passive role in decision-making, while very few would choose entirely autonomous decision-making (Deber and Kraetschmer, 2007). However, preferences may vary by nationality, age, level of education, and familiarity with the condition (Deber and Kraetschmer, 2007; Solari et al., 2013).

Further work should be carried out to support MS health professionals to support informed patient decision-making according to patients' preferences, regardless of their personal views on the risks and benefits of treatment. Moreover, there is a need for more nuanced

definitions in guidelines for phenomena such as 'disabling relapses' and observable standards by which to recognise them, to ensure their usefulness and practicability as eligibility criteria.

Existing prescriber networks could be strengthened and their utility maximised through shared learning and experiences of DMTs in order to increase prescribing confidence across the network, as well as consensus building, standardising practice and advocating for local service provision. This might particularly benefit those in smaller centres and DMT-prescribing general neurologists who do not have ready access to other prescribers or specialist MS knowledge.

Finally, it is important there is ongoing explicit and public discussion acknowledging differences in organisational prescribing 'cultures' and habits, the impact of these on equitable access to DMTs regardless of location, and the need to regularly query whether the local 'culture' sufficiently meets patients' needs. This may involve evaluating the impact of multidisciplinary team meetings which have been advocated in DMT prescribing guidelines for multiple sclerosis (Scolding et al., 2015) and which are likely to drive shared thinking and practice. Systematic reviews investigating oncology treatment have found that over a fifth of cases discussed at multidisciplinary team meetings subsequently undergo changes in treatment plans, suggesting these forums are key factors in therapeutic decision-making (Pillay et al., 2016; Basta et al., 2017).

The present study has a number of strengths. Most importantly, it is the first to investigate influences on neurologists' prescribing decisions in the UK or internationally, and the first to use qualitative methods with MS health professionals to obtain first-hand accounts of factors affecting DMT practices. The sample was large in size for a thematic interview study (Braun and Clarke, 2013) and included MS specialist nurses who are significant contributors to prescribing decisions and decision-making contexts. Further, interviews were carried out with neurologists and nurses from each of the four nations of the UK, facilitating understanding of factors influencing prescribing across the UK and differentially between areas of the UK. Some health professionals may have been wary of disclosing views that conflicted with guidelines or prescribing norms, but the frank and open responses obtained in the interviews suggest this was not a major limitation. Future research could expand on the present findings by quantifying the presence of the identified factors influencing prescribing in representative samples of DMT prescribers in the UK and in other nations with comparable healthcare systems.

This research has shed light on the impact of individual health professionals' interpretations and perceptions and organisational prescribing cultures on whether people with relapsing-remitting MS in the UK are offered DMT prescriptions. There is now a need to use this knowledge to ensure equitable access to DMTs for all people with MS who are eligible for treatment.

Declaration of conflicting interests

E. Cameron, G. McDonnell, and D. French declare no conflicts of interest.

D. Rog has served on advisory boards and/or received speaking fees from Biogen, Sanofi Genzyme, MedDay, Merck, Roche, Novartis and Teva Pharmaceuticals, and has had research support to an institutionally-managed fund from: Biogen, GW Pharma, Sanofi Genzyme, Merck, Mitsubishi, Novartis and Teva Pharmaceuticals.

J. Overell has received honoraria for speaking engagements and attendance at advisory boards from Teva, Novartis, Merck-Serono, Genzyme, Roche, Allergan and Biogen. Additionally his department has received educational grants, research funding and funds to provide nursing and administrative staff from these companies.

O. Pearson served on the scientific advisory boards for Biogen, Novartis, Roche, Merck, UK MS Register and has received travel funding and/or speaker honoraria from Biogen, Roche, Merck, Novartis, Teva, Genzyme Sanofi.

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