RWD154

Using Real World Evidence from the UK MS Register to support optimal healthcare decision making

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BACKGROUND

- The United Kingdom Multiple Sclerosis Register (UKMSR) was established in 2011 by Swansea University Medical School. The UKMSR captures 'real world' data on patients with multiple sclerosis (pwMS) across the UK:
- The UKMSR captures data via two primary methods:
  - Six monthly submissions by pwMS from a 'patient portal': capturing patient reported outcomes (PROs)
  - Medical records via electronic Clinical Report form (eCRF) or directly from clinical systems at hospitals/clinical sites
- Around 20 percent of pwMS have their PRO responses linked with clinical data.
- The application of datasets used within health technology assessment (HTA) submissions to characterise the natural disease course of MS currently utilise London Ontario (1970s) and British Columbia (1980s) datasets. Given the age of these datasets, HTA bodies have questioned their current applicability in light of advancements in treatment options and alignment to current disease course understanding.
- This study aims to provide contemporaneous UK patient characterisation and establish the current treatment paradigm within MS to support healthcare decision-making.

METHODS

- A cross-sectional analysis was conducted to describe demographic, clinical characteristics and treatment aspects. Captured as of September 2023.
- The following key factors have been considered:
  - Phenotypes: geography split
  - Demographics: current age, age at onset, age at diagnosis, gender
  - Symptoms
- Phenotypes were split by:
  - Relapsing-remitting multiple sclerosis (RRMS)
  - Primary progressive multiple sclerosis (PPMS)
  - Secondary progressive multiple sclerosis (SPMS)
  - Other
- Further clinical characteristics investigated:
  - Proportion of patients on highly active disease modifying treatment (DMT)
  - Mean time and proportion of patients who have transitioned to SPMS from diagnosis

RESULTS

Descriptive overview

- Table 1 shows the demographic and phenotypic data for the population.
- Aligned to clinical course of MS, the majority of pwMS within the UKMSR are recorded as RRMS across the UK
  - RRMS: 52%, PPMS: 10%, SPMS: 20%, Benign: 2%, Unknown/ Not recorded: 17% (figure 1)
- Unknown and not recorded have been merged for analysis. This represents 17% proportion of recorded results across all geographies.
- Mean age at diagnosis across portal and clinical entries are 39 and 38 years, respectively.
- Females are more prevalent across both portal (74.2%) and clinical (71.8%) datasets.
- Mean clinical progression from RRMS to SPMS is 16.1% and 10.5% associated with 13.23 years and 14.20 years for portal and clinical datasets, respectively. Time to progression is defined as time from initial RRMS diagnosis to SPMS conversion.
- Participants on a DMT recording highly-active DMTs, as opposed to normally-active DMTs, were: 32.6% (portal) and 34.5% (clinical).

Population Data

Table 1. Demographic data across all four devolved nations of the United Kingdom of Great Britain & Northern Ireland

Portal					
	Overall	**England**	**Wales**	**Scotland**	**Northern Ireland**
n	23520	18924	1476	2230	890
Age (mean (SD))	55.37 (12.75)	55.51 (12.75)	56.56 (12.66)	54.59 (12.82)	52.23 (12.22)
OnsetAge (mean (SD))	34.39 (10.71)	34.57 (10.77)	34.59 (10.68)	33.34 (10.52)	32.88 (9.71)
DiagnosisAge (mean (SD))	39.26 (10.75)	39.41 (10.81)	39.89 (10.61)	38.28 (10.49)	37.38 (9.99)
Gender, female (%)	17434 (74.2)	14006 (74.1)	1071 (72.6)	1690 (75.8)	667 (75.2)
MSTypeNow (%)					
RRMS	11280 (48.0)	9118 (48.2)	586 (39.7)	1015 (45.5)	561 (63.0)
PPMS	2510 (10.7)	2029 (10.7)	171 (11.6)	251 (11.3)	59 (6.6)
SPMS	4992 (21.2)	4067 (21.5)	352 (23.8)	470 (21.1)	103 (11.6)
Benign	469 (2.0)	381 (2.0)	32 (2.2)	48 (2.2)	8 (0.9)
Unknown/Not recorded	4269 (18.2)	3329 (17.6)	335 (22.7)	446 (20.0)	159 (17.9)
DMT, highly active (%)	2399 (32.6)	1994 (33.8)	131 (35.9)	177 (24.8)	97 (25.0)
ConvertedToSPMS (%)	3389 (16.1)	2767 (16.3)	219 (16.9)	340 (17.2)	63 (8.0)
TimeToSPMS (mean years (SD))	13.23 (8.08)	13.31 (8.14)	12.80 (8.02)	13.19 (7.87)	10.94 (6.31)
Clinical					
	Overall	**England**	**Wales**	**Scotland**	**Northern Ireland**
n	14492	8618	307	<5	119
Age (mean (SD))	54.17 (13.00)	54.57 (12.97)	52.90 (12.61)	-	51.67 (12.99)
OnsetAge (mean (SD))	35.06 (11.08)	35.14 (11.08)	33.64 (10.09)	-	-
DiagnosisAge (mean (SD))	38.49 (11.47)	38.53 (11.46)	37.25 (11.46)	-	-
Gender, female (%)	9837 (71.8)	6190 (72.1)	229 (74.6)	-	80 (72.7)
MSTypeNow (%)					
RRMS	7065 (48.8)	5509 (63.9)	146 (47.6)	-	-
PPMS	939 (6.5)	767 (8.9)	13 (4.2)	-	-
SPMS	1713 (11.8)	1375 (16.0)	21 (6.8)	-	-
Benign	40 (0.3)	33 (0.4)	<5	-	-
Not recorded	4735 (32.7)	934 (10.8)	126 (41.0)	-	119 (100.0)
DMT, highly active (%)	1647 (34.5)	1074 (30.2)	45 (46.4)	-	-
ConvertedToSPMS (%)	1527 (10.5)	1224 (14.2)	-	-	8 (2.6)
TimeToSPMS (mean years(SD))	14.20 (9.98)	14.41 (10.00)	-	-	12.78 (8.35)

Figure 1. Proportion of patients within the UKMSR by recorded phenotype across each geography

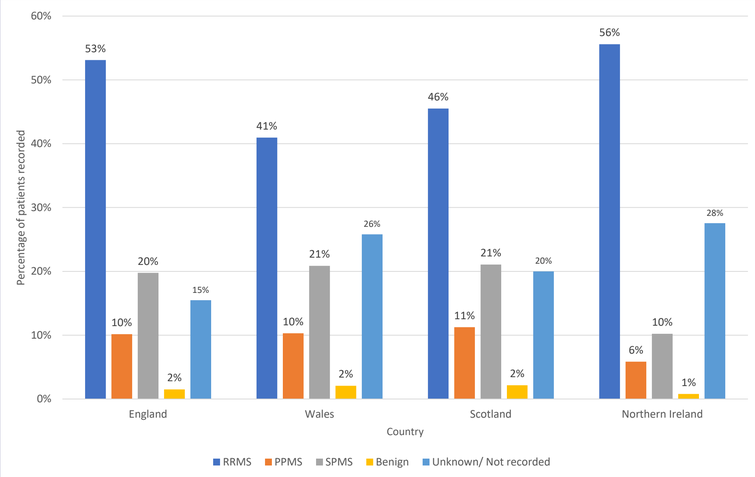
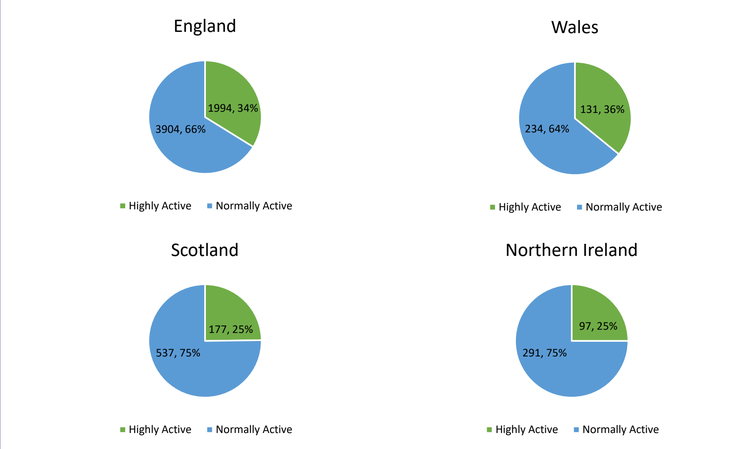


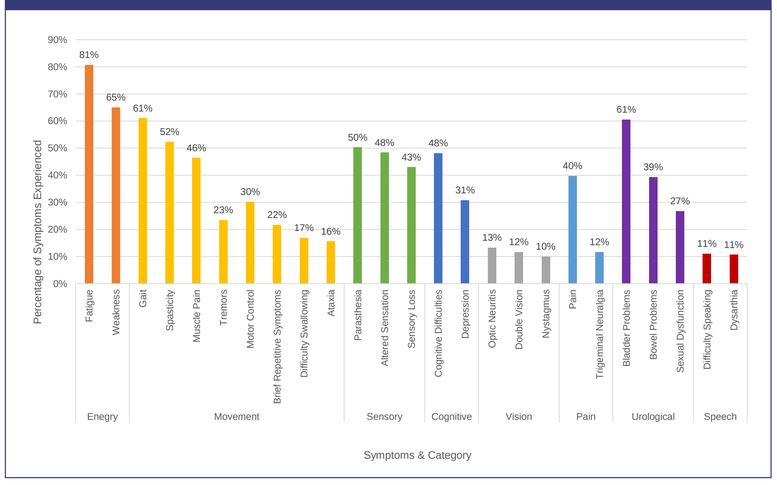
Figure 2. Proportion of population reporting highly active DMT prescription by geography



Presentation of symptoms

- Figure 3 illustrates recorded symptoms, highlighting patients experience a magnitude of symptoms.
- Fatigue and weakness are the most frequently recorded symptoms amongst pwMS on the UKMSR.
- Movement related symptoms represent the second largest group, with gait (61%) and ataxia (16%) recorded. These can impact on the assessment of the expanded disability status scale (EDSS), utilised to capture disability progression and can also impact quality of life (QoL)
- Cognitive and mental health symptoms captured include cognitive difficulties (48%) and depression (31%), Both of which are impactful on overall QoL. They should be considered for incorporation within economic models.
- Vision and speech categories were reported least frequently by pwMS, nystagmus (10%), difficulty speaking (11%), dysarthria (11%), double vision (12%) and optic neuritis (13%).

Figure 3. Symptoms experienced by pwMS recorded within the UKMSR



LIMITATIONS

- Real world data may be inconsistently supplied, meaning there can be inconsistencies in available data at a given time. However, there are a number of approaches to account for 'sparse' data.
- Recorded MS phenotype 'Unknown/Not recorded' could highlight an issue with pwMS not agreeing with their disease classification or their preferred option not being available to them: 'rapidly evolving MS' for example. Only patients who have been diagnosed with MS can enter the UKMSR.
- EDSS scores are traditionally assessed by clinicians directly, the UKMSR has these clinical assessments and webEDSS PRO based assessments. The impacts of this and symptomatology on QoL may form part of future work.

CONCLUSIONS

- **General distribution across the UK represents a consistent split per phenotype, highlighting RRMS as the most common type of MS.**
- **A large proportion of pwMS have recorded their current MS phenotype as either unknown or not recorded indicating further investigation is required into what people with MS think their MS type is, or what their clinician tell them it is. Evolution of categories such as rapidly evolving MS are not selectable within the UKMSR data dictionary.**
- **Of pwMS reporting to currently be taking a DMT, more than 30% are categorised as being on 'highly-active' treatment, potentially indicating that a more aggressive treatment rationale is being embedded within the current clinical landscape.**
- **A higher proportion of patients recorded RRMS as their phenotype across all geographies, aligning with published literature on phenotype split.**
- **Utilising up-to-date real world evidence highlights current patient characterisation and, DMT prescribing pattern to support optimal treatment positioning and healthcare decision-making.**

REFERENCES

1. Overview: MS Register. Available: About Us | UK MS Register
2. Scenario: Managing complications: NICE Multiple Sclerosis. Available: Scenario: Managing complications | Management | Multiple sclerosis | CKS | NICE

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DISCLOSURES

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