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International consensus on quality standards for brain health-focused care in multiple sclerosis

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Abstract

Background

Time matters in MS. Irreversible neural damage and cell loss occur from disease onset. The MS community has endorsed a management strategy of prompt diagnosis, timely intervention, and regular proactive monitoring of treatment effectiveness and disease activity to improve outcomes in people with MS.

Objectives

We sought to develop internationally applicable quality standards for timely, brain health-focused MS care.

Methods

A panel of MS specialist neurologists participated in an iterative, online, modified Delphi process to define 'core', 'achievable' and 'aspirational' time frames reflecting minimum, good and high care standards, respectively. A multidisciplinary Reviewing Group (MS nurses, people with MS, allied healthcare professionals) provided insights ensuring recommendations reflected perspectives from multiple stakeholders.

Results

Twenty-one MS neurologists from 19 countries reached consensus on most core (25/27), achievable (25/27) and aspirational (22/27) time frames at the end of five rounds. Agreed standards cover six aspects of the care pathway: symptom onset, referral and diagnosis, treatment decisions, lifestyle, disease monitoring, and managing new symptoms.

Conclusion

These quality standards for core, achievable and aspirational care provide MS teams with a three-level framework for service evaluation, benchmarking and improvement. They have the potential to produce a profound change in the care of people with MS.

Introduction

Time matters in multiple sclerosis (MS). Irreversible neural damage and cell loss occur from disease onset when the frequency of inflammatory attacks on the central nervous system is often greatest.[1] Finite neurological reserves and plasticity compensate and maintain normal functioning in early disease. When reserves are exhausted, symptoms typically worsen in a progressive fashion and become irreversible.[2] Manifestations include physical and cognitive decline, fatigue, reduced quality of life, compromised productivity, and impaired functioning.

A policy report, *Brain health: time matters in multiple sclerosis*, the product of an international initiative by MS experts, delineates a strategy for preserving neurological reserve in people with MS.[3] The planks of the strategy are: increase the urgency of MS care; minimise delays in diagnosis and treatment initiation; monitor disease activity closely and proactively; set clear goals for treatment and ongoing management; underpin decision-making with robust up-to-date evidence; implement informed, shared-decision making; address lifestyle choices; collect and consult real world data.[3] The MS community has widely endorsed this evidence-based strategy to reduce delays at all stage of the care pathway.[3]

Time to a diagnosis of MS is often protracted, delaying access to specialist healthcare advice and treatment initiation. Randomised controlled trials in patients with relapsing MS, for example, demonstrate early treatment with a disease-modifying therapy (DMT) produces better outcomes than delayed treatment; specifically, lower relapse rates,[4, 5] reduced disability progression,[6-9] and improved survival.[10, 11] Conversely, unhealthy lifestyle choices and comorbidities can worsen MS outcomes. Smoking is associated with higher relapse rates, increased disability progression, and greater cognitive impairment.[12-15] Obesity is associated with increased lesion volume.[16] Comorbidities can accelerate disability progression, increase

mortality, and reduce quality of life.[17] Therefore, strategies seeking to preserve 'brain health'—a lay term for neurological reserve—should improve MS outcomes.

Quality standards and improvement programmes can improve patient outcomes and experiences. Introduction of the National Surgical Quality Improvement Program was associated with decreases in mortality of 27% and 30-day morbidity of 45%.[18] The *Get With the Guidelines*–Stroke programme was associated with a 1.18-fold yearly increase in the odds of receiving guideline-recommended care.[19] In MS, several national quality standards describe aspects of care, but none comprehensively addresses brain health. Shared benchmarks are needed to formalise care standards and reduce global service provision disparities. We sought to develop internationally applicable quality standards for timely MS care.

Methods

We conducted a modified Delphi consensus process to define timings for key brain health-related MS care milestones (figure 1).[20] The process involved three groups: the Delphi Chairs[a] provided direction and identified potential participants; a Delphi Panel of MS neurologists proposed and agreed timings; a multidisciplinary Reviewing Group of MS nurses, allied healthcare professionals (aHCPs) and people with MS provided a broader perspective on the delivery and experience of MS care. Analysts supported the Chairs by developing surveys, and collating and analysing responses.

[a]Each of the four Chairs represented a different perspective: neurology [G.G.], patient-reported outcomes [J.H.], nursing/policy [A.B.], and the person with MS [G.P.].

Thirty-nine MS neurologists were invited by email to participate in the Delphi Panel. They were chosen to represent seven regions of high MS prevalence (North America, Northern Europe, Western Europe, Southern Europe, Eastern Europe and Russia, Australia and New Zealand, the Middle East and North Africa).[21] Twenty-nine of the 39 (74%) agreed to participate and confirmed they were based in MS clinics and spending at least half of their clinical time seeing people with MS; six did not respond, three declined because they did not meet the criteria, and one did not have time to participate. Thirty-one of 39 (79%) invited individuals from the same regions agreed to participate in the Reviewing Group. Participants were contacted by email. Responses were collected between March and October 2017 via online surveys (SurveyMonkey Inc., San Mateo, California, USA).

In brief, the Delphi process had three stages, each of which could have multiple rounds until considered complete. First, the scope was defined and agreed. Delphi Chairs and analysts derived, from *Brain health: time matters in multiple sclerosis*,[3] principles of timely care. These were presented to the Delphi Panel to agree the content areas. Second, each Delphi participant independently proposed initial standards for the timing of key events in the MS care pathway and an iterative process was used to refine the timings. Third, consensus was reached via voting. Delphi panellists were required to participate in each round and, as standard for a Delphi process, remained anonymous throughout to analysts, Chairs, and other participants.

Round 1: establishing principles of timely care

The Delphi Chairs and analysts derived 21 time-related principles from the evidence-based recommendations of *Brain health: time matters in multiple sclerosis* (supplementary table 1).[3] The principles were grouped into five domains: onset of symptoms; referral and diagnosis; lifestyle and comorbidities; initiating DMT; monitoring. These were presented to

the Delphi Panel who were asked if each was '*an appropriate and accurate description of a good standard when considering brain health in people with MS*'. Panellists had the opportunity to explain their opinions and/or propose additional principles. Responses were summarised and presented to the Reviewing Group for evaluation. The Chairs agreed several principles did not require defined timings, for example '*Regular inclusion of patient data in MS database*'. These were noted for inclusion later.

Rounds 2 and 3: setting time frames

In Round 2, Delphi Chairs derived variables reflecting timings of MS care pathway events from the principles (25 variables from 21 principles; supplementary table 2). For example, the variable '*Frequency of MRI scans*' was derived from the principle '*Regular MRI scans*'. Each Delphi panellist was asked to assign (1) core, (2) achievable, and (3) aspirational time frames for each variable using free text (table 1). Analysts summarised the suggested timings as box plots showing the maximum, minimum, median, and interquartile range. The Chairs developed multiple-choice options based on the grouped data.

In Round 3, Delphi panellists were presented with the box plots and multiple-choice options and asked to select core, achievable and aspirational time frames. Subsequently, the Chairs requested two new variables be included. These concerned timings of events following new or worsened symptoms and were intended to supplement timings for routine monitoring. Multiple-choice options for the two new variables were derived from clinical guidelines.[22]

Time frames for the final consensus rounds were determined based on the 75th percentile values achieved for each core, achievable and aspirational standard in the Round 3 voting. Four additional statements were derived from principles brought forward from Round 1 that did not require defined timings, for example '*The MS team should regularly enter patient data into an MS database'*.

Rounds 4 and 5: achieving consensus

In Round 4, the Delphi Panel was asked to indicate their level of agreement with the core, achievable and aspirational timings associated with each statement on a five-point scale (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree). Data were analysed to quantify consensus. The threshold for Delphi Panel consensus was agreement (agree, strongly agree) by ≥ 75% of panellists. For valid consensus, ≥ 66% of panellists who completed Round 1 had to respond to all surveys. These percentages were predefined by the Chairs, based on a literature search.

In Round 5, statements for which consensus on time frame was not reached in Round 4 were shown alongside the associated voting results. The panellists were asked to vote again and to give an explanation if they still did not agree.

Reviewing Group opinion on consensus timings

The Reviewing Group was given the statements from Round 4 defining timings of MS care pathway events. Participants were asked to grade the ambition of each statement using a three-point scale (not ambitious enough, about right, too ambitious). Results will be presented elsewhere.

Post-Delphi feedback

After the Delphi process was completed the full results were circulated to the unblinded panel. Two teleconferences were held in December 2017 to gain further insights into the thinking underlying panellists' choices. Panellists unable to attend teleconferences were invited to provide feedback via email.

Results

Delphi Panel consensus

Twenty-one MS neurologists from 19 countries completed the modified Delphi process (78% of the 27 panellists from Round 1, figure 1). Consensus was reached on the majority of core (25/27), achievable (25/27) and aspirational (22/27) time frames for events spanning the MS care pathway (figure 2), thus defining a timeline for MS care (figure 3).

The Delphi Panel agreed that uncomplicated MS ought to be diagnosed in all clinics within 3 months of symptoms first being reported to a healthcare professional, and that diagnosis within 1 month would be expected of the best clinics (figure 2a). These time frames include referral and completion of diagnostic workup (figure 2a). There was consensus that all clinics should as a minimum standard assess DMT eligibility within 6 weeks of diagnosis (figure 2b), and then offer an appropriate DMT within 2 months (figure 2d). Consensus was that routine check-ups to assess MS status, review treatment plans and discuss lifestyle issues ought to take place at least annually, with 6-monthly check-ups being an achievable target for most MS teams (figure 2c). The Delphi Panel also agreed that offering a routine annual MRI scan was achievable for most clinics (figure 2c). In addition, there was consensus that all patients should be seen by a member of the MS team within 7 days of reporting new or worsened symptoms, or within 2 days in leading centres (figure 2e). Supplementary table 3 shows the nine statements for which consensus was not reached on time frames.

The Panel also reached agreement on four statements that were not time limited (figure 2f). Applying the latest MS diagnostic criteria and offering all people with MS the opportunity to participate in informed, shared decision-making were agreed to be minimum standards of good care. There was consensus that routine entry of patient data into an MS database was

achievable for most MS teams. Offering regular cognitive screening to all patients with MS was agreed to be an aspirational target.

Post-Delphi agreement

All 21 Delphi panellists fed back on the results (12 via teleconference; 9 via email). Reasons for non-agreement with suggested time frames included impact on healthcare costs and potential inconvenience to patients (supplementary table 3). Panellists agreed a time frame for one further core statement: when the response to a DMT is suboptimal an appropriate alternative DMT should be offered within 3 months. In the Delphi process, the panel had been offered a time frame of 4 months; 6/21 considered this time frame too long.

Discussion

A modified Delphi process has established a comprehensive set of globally applicable quality standards for timely MS care. This is the first time a multinational group of neurologists has reached consensus on the timing of events across the MS care pathway. Given that participants practise in a wide range of countries with differing healthcare systems, it is reassuring that consensus was reached. The standards defined here provide benchmarks for MS services, while the three levels—core, achievable and aspirational—offer all clinics a standard to aim for. Taken together, the standards outline a practical and reasonable timeline for brain health-focused MS care.

The Delphi Panel agreed that MS teams should provide prompt diagnosis and treatment of MS, followed by regular monitoring, regardless of the local healthcare system. Across the standards, there is a focus on MS teams engaging patients in informed, shared decision-making and offering services promptly. This is particularly important when discussing DMTs, where each person has unique circumstances, needs and attitudes to risk.[23] Healthcare

professionals with expertise in MS are best placed to explain the pros and cons of various treatment options, given the increasing number of DMTs available.[24] The panel agreed alternative DMTs should be offered and provided promptly when a treatment response is suboptimal. Naturally, some people with MS may require a longer time for decision-making and the standards allow for this. Informing, encouraging and empowering people to lead a brain-healthy lifestyle was regarded as a priority following diagnosis and regularly thereafter, with face-to-face discussions considered more effective and less intrusive than written reminders. MS nurses are well-placed to lead these discussions, so this does not necessitate longer consultations with a neurologist, which may be challenging in many centres.

Routine, 6-monthly appointments were agreed to reflect high-quality care, providing that MS teams respond quickly to patients reporting new or worsened symptoms. Annual MRI was considered a realistic target. More frequent 'routine' MRI was not recommended, owing to concerns regarding lack of proven added benefit, expense, and inconvenience to people with MS. Naturally, this guidance does not apply to ad hoc scanning for new or worsening symptom evaluation, which should be conducted as needed. Contrast enhanced scanning was not specified because of recent concerns around gadolinium accumulation.[25]

The panel agreed that regular cognitive screening was an aspirational, rather than core, standard, with participants noting that emotions immediately post-diagnosis can affect results. In general, cognitive screening is not routine, which may be a consequence of healthcare costs and limited availability of neuropsychologists. There are several rapid, inexpensive, effective cognitive screening tests,[26-28] but none are used as standard. Agreement among the MS community on a test to measure and monitor longitudinal cognitive changes would encourage acceptance of cognitive screening as a standard of MS care.

We recognise the limitations of this work. The standards are not exhaustive – we have not been explicit about what constitutes shared decision-making, MRI sequences, and the extent of diagnostic testing, for example – because our focus was on timing. The strengths of the Delphi method include the anonymity of respondents and the equal weight given to all opinions, but because it can be difficult to reconcile widely varying opinions, it is recommended that panellists have similar backgrounds and experience.[20] Hence, only practising MS neurologists were invited to participate in the panel. Improving MS care involves multiple stakeholders; so, the Delphi process was modified to include a Reviewing Group of MS nurses, aHCPs, and people with MS. Subgroup analysis could provide additional insights into geographical or stakeholder group differences in expectations.

Many healthcare systems are now focusing on quality and improving patient care and so we developed these standards to facilitate formal care quality improvement. Other standards for MS care exist, including local clinical guidelines, treatment algorithms and recommendations on MRI use.[22, 24, 29-33] Our quality standards differ in that they focus on timings rather than specific treatment strategies; as such, they should be considered in conjunction with existing local guidance. We have defined global standards that are not specific to any one country. To ensure these standards were relevant in a range of healthcare systems, we agreed upon three levels. MS clinics therefore have the flexibility to work towards standards that are realistic within the constraints of their systems. The National Institute for Health and Care Excellence quality standards, for example, recommend annual clinical evaluations;[34] this is consistent with the core standard in the present study, but we have gone further and defined an achievable standard of 6-monthly evaluations and hope that MS clinics will strive for this higher standard.

Implementing the quality standards first requires individual MS centres to evaluate their service. A quality improvement tool – which helps MS clinics to compare their current

practice with the standards – is in development and will be piloted in several international sites. Given the number of standards, a key action is to identify a representative subgroup of standards, allowing refinement of the tool to make it brief enough for easy use in routine clinical practice. The final tool will be available for interested MS teams to use locally. MS clinics could use this as an opportunity for patient engagement by asking patients to complete a survey about their experiences, complementing a formal review of patient records. We encourage centres to seek specific funding, where needed, to carry out an assessment. Following service evaluation, MS teams should analyse their integrated care pathways to understand the processes underpinning any delays identified and have targeted discussions with local development teams to identify solutions.

Using a quality improvement cycle, MS clinics will be able to demonstrate service improvement. We encourage MS teams to incorporate data collection into routine care to support re-evaluation, and to share examples of best practice. In some countries, local budget holders may want further evidence of the clinical benefit of timely care – as described by the quality standards. To generate evidence, MS clinics will need to link results from routine service evaluations with long-term clinical outcomes. MS clinics could collaborate with other centres to allow comparisons and, in the future, MS databases could enable large-scale analysis by adding relevant data fields.

Other stakeholders will contribute to improving care. MS neurologists and MS nurses should educate colleagues – including general neurologists and primary care practitioners – on the importance of timely, specialist MS care, and highlight best practice examples to local budget holders, managers and service providers. Professional organizations could promote the standards by incorporating the ‘time matters’ message into training programmes. Charities representing people with MS could use the quality standards in advocacy work with decision makers, to demonstrate the care people with MS should be receiving. If accompanying data

show that standards are not being met, this could be a powerful motivator for increased resources, particularly if the standards are met in comparable countries. The standards also present an opportunity for empowering individuals to ask for high-quality care. We encourage stakeholders to collaborate nationally and speak to decision makers with a united voice.

We know these standards will be challenging for all of us to meet, particularly within current healthcare climates. However, we believe this is no justification for disregarding timely care. These standards provide an opportunity to identify strengths and weaknesses, focus problem-solving, and highlight areas requiring investment.

Conclusions

Multinational MS neurologists have used a Delphi process to agree quality standards for timely MS care focused on preserving brain health. These new global benchmarks have the potential to help individual clinics and national healthcare systems maximise outcomes for people with MS. We anticipate vigorous debate of these standards in the wider MS care community.

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Declaration of Conflicting Interests

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