Supplementary Materials

Chances and challenges of registry based pharmacovigilance in multiple sclerosis: Lessons learnt from implementation of the multi-center REGIMS registry

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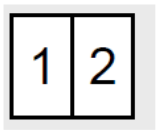
Baseline Questionnaire

(authors' translations)

Multiple Sclerosis Patient Questionnaire

Dear patient,

with this questionnaire we'd like to assess your current health situation and your medical care. The aim of the survey is to improve medical care for people with multiple sclerosis using your experiences and information.
Please use a black or dark blue pencil when filling out the questionnaire. Enter numbers one by one in the large boxes provided and for all other answers, put your cross in the middle of the box that applies to you.

Example: numbers 

correct:  incorrect: 

Please note further instructions for completion or explanations for the individual questions.

Please hand in the completed questionnaire at the outpatient clinic.

Many thanks for your cooperation! Your experiences and specifications are very valuable to us.

1. Year of birth: ____
2. Age at first symptoms of MS?
   Please round to a full year __ years
3. At what age were you diagnosed with MS? __years
4. Who made the diagnosis?
   If you were being treated by more than one doctor or hospital department when the diagnosis was made, please tick all that apply. Treatment for other diseases or syndromes does not count.
   - □ Neurology
   - □ Ophthalmology
   - □ Family doctor
   - □ Pediatrics
   - □ other (specify department: _____)
5. What inital symptoms did you have?
   Please tick all that apply
   - □ Double pictures
   - □ Other visual impairment/blurred vision
   - □ Numbness of the face
   - □ Other numbness
   - □ Facial paralysis
   - □ Other motor disorders (weakness/paralysis in arms/legs)
   - □ Hearing loss/speech disorder/difficulty in swallowing
   - □ Coordination or fine motor skills disorders
   - □ Concentration or memory disorders
   - □ Exhaustibility/reduced resilience
   - □ Euphoric/increased mood
   - □ Depressed mood/increased sadness
   - □ Tremor/showing uncertainty of hands/arms
   - □ Bladder dysfunction (congestion, diarrhoea, incontinence)
   - □ Sexual dysfunction
   - □ Others (if so please specify: _____)
6. Has one or more of the following diagnostic measures been taken, in the last 12 months?
   - □ fMRI brain
   - □ fMRI spinal cord
   - □ Computed tomography image brain
   - □ Spinal fluid examination
   - □ Ultrasound of the heart
   - □ Electrocardiogram
7. Now we want to know how quickly you become exhausted due to your MS?
   a) Exercise brings on my fatigue. strongly disagree □ □ □ □ □ □ □ strongly agree
   b) Fatigue interferes with my work, family, or social life.

strongly disagree ☐ ☐ ☐ ☐ ☐ ☐ ☐ strongly agree

c) Mental activities exhaust me quickly. strongly disagree ☐ ☐ ☐ ☐ ☐ ☐ ☐ strongly agree

8. How often have you been hospitalised for MS?
   - ☐ Never
   - ☐ If so, how often? -__ times
9. Have you been hospitalised for MS in the last 12 months?
   - ☐ No
   - ☐ __ times
10. Have you been treated as an outpatient in a hospital in the last 12 months without staying overnight?
    - ☐ No
    - ☐ Yes, If so, how often: __ times
11. Have you been in inpatient rehabilitation during the last 12 months?
    - ☐ No
    - ☐ Yes, If so, how many days? __ days
12. Have you purchased or received one or more of the following aids in the past because of your MS?
    - ☐ Stick/forearm support
    - ☐ Walking frames
    - ☐ Structural changes to the apartment
    - ☐ Changes to the car
    - ☐ Foot lifter cuff
    - ☐ (electric) wheelchair
    - ☐ Bed lift
    - ☐ Stair lift/ramp
    - ☐ New glasses
    - ☐ Incontinence pads
    - ☐ Other (Please specify: _____)
13. Please indicate whether (1.) you are currently receiving one or more of the following services and if so (2.), whether you pay for them entirely yourself?

	(1)	(2)
Physiotherapy	☐	☐
Massages	☐	☐
Ergotherapy	☐	☐
Speech or language therapy	☐	☐
Sports or exercise therapy	☐	☐
Care by outpatient nursing service	☐	☐

14. Have you received any of the following services in the past 12 months?
    - ☐ Visits by a MS nurse/carer at home
    - ☐ Home assistance
    - ☐ Transport by ambulance
    - ☐ Transport by taxi

- ☐ Social counselling

15. Have you been exempted by your health insurance company from co-payment for medication and treatment last year because you exceeded the maximum limit?
    - ☐ Yes
    - ☐ No
    - ☐ I don't know

16. How satisfied are you with the success of the current MS therapy?
    ☐ Very satisfied, ☐ rather satisfied, ☐ rather dissatisfied,☐ very dissatisfied
17. How satisfied are you with the compatibility of the current MS therapy?
    ☐ Very satisfied, ☐ rather satisfied, ☐ rather dissatisfied, ☐ very dissatisfied

18. Are there people in your family who have MS?
    This is solely a matter of family connections and not of the number of family members affected.
    - ☐ Not
    - ☐ Don't know
    - ☐ Yes
      If yes, who? ☐ mother, ☐ father, ☐ daughter, ☐ son, ☐ sister, ☐ brother, ☐ aunt, ☐ uncle, ☐ other (please specify: _____)
      (Please tick all applicable family members)

19. Have you had one or more of the following complaints in the last 12 months?
    If you answer "Yes" to "Symptoms present" and you believe that this is due to one of your MS medication, please include the following lines.

Symptoms present	No	Yes
shortness of breath or difficulty in breathing/ shortness of breath	☐	☐
Do you believe that this is due to your MS medication	No ☐	Yes ☐ Please specify medication: _____
inflammation of the eyes/lack of vision/eye pain	☐	☐
Do you believe that this is due to your MS medication	No ☐	Yes ☐ Please specify medication: _____
nausea/vomiting	☐	☐
Do you believe that this is due to your MS medication	No ☐	Yes ☐ Please specify medication: _____
diarrhea	☐	☐
Do you believe that this is due to your MS medication	No ☐	Yes ☐ Please specify medication: _____
voiding disorders	☐	☐
Do you believe that this is due to your MS medication	No ☐	Yes ☐ Please specify medication: _____

blistering/burning/itching in the mouth or genital area ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

fever of at least 38° C ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

sore throat ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

joint or limb pain ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

itching or burning skin rash ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

listlessness/depressed mood ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

irregular heartbeat ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

fungal infection ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

dizziness ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

others (Please specify: _____) ☐ ☐
Do you believe that this is due to your MS medication No ☐ Yes ☐ Please specify medication: _____

20. Have you taken any medication during the last 7 days?
☐ Yes, ☐ No – If no, please continue with question 21
If yes, please enter in the list below which medication you have taken in the last seven days. This includes all medications you have taken or received for the treatment of your MS and for other reasons (e.g. headache). Please list all medications - including vitamin tablets, herbal or homeopathic preparations, hormone preparations and infusions.
A. What is the name of the medication?
B. Please indicate the dosage (e.g. 500mg) of the medicine.
C. Did you take this medicine daily? If so, how many times per day did you take this medicine? There is no difference between whole and half tablets. If you are not taking the medicine every day, do not tick the box.
D. Did you have to pay it entirely (i.e. not only the prescription fee) yourself?
Name of the medicine, dosage, medicine daily, How many times per day, payed entirely

yourself

Please write in block letters on the lines.

21. What is your highest general school degree?
    - ☐ grammar school
    - ☐ secondary school
    - ☐ high school
    - ☐ other school-leaving qualifications
    - ☐ no school-leaving qualifications
22. What is your highest professional qualification?
    - ☐ no professional qualifications
    - ☐ training/apprenticeship
    - ☐ technician
    - ☐ polytechnic/engineering school
    - ☐ university
    - ☐ other professional qualifications
23. Are you currently working?
    - ☐ Yes, regularly employed full-time (more than 30h/week)
    - ☐ Yes, regularly employed part-time (more than 15-19h/week)
    - ☐ Yes, marginally or irregularly part-time employed (less than 14h/week)
    - ☐ No
24. Have you been on sick leave in the last 12 months due to an illness?

    ☐ No, ☐ Yes, __ days

    How many days of this due to your MS?

    ☐ No, ☐ Yes, __ days
25. Are you currently …
    - ☐ undergoing vocational training or retraining
    - ☐ housewife/househusband
    - ☐ on maternity/parental leave/ pre-retirement part-time work/other leave
    - ☐ unemployed
    - ☐ pensioner/retired person/early retired

      How old were you when you retired?

      __ years

      Did you retire because of your MS?

      ☐ no ☐ yes
    - ☐ None of this applies to me
26. Your sex/gender

    ☐ female, ☐ male
27. What is your marital status?
    - ☐ Single
    - ☐ Married
    - ☐ Divorced
    - ☐ Widowed

28. Are you living together with a spouse or partner in a common household?
    □ yes, □ no
29. Were you born in the territory of present-day Germany?
    □ yes, □ no
    Since when are you living in present-day Germany? Since ____
    In which country were you born?
    This refers to the current name of the country. Please specify: _____
30. Are you currently smoking cigarettes, pipes, cigars or cigarillos? If yes, what are you smoking?
    Please tick what applies to you
    - □ No, I've never smoked → continue with question 35
    - □ No, but I used to smoke regularly → continue with question 33
    - □ Yes, I smoke occasionally (i.e. less than one cigarette per day)
    - □ Yes, I am currently smoking (i.e. more than one cigarette per day) → continue with question 31
31. What and how much do you smoke?
    Please tick what applies to you
    - □ Cigarettes → about __ times/pieces a day
    - □ Pipe → about __ times/pieces a day
    - □ Cigars/cigarillo → about __ times/pieces a day
32. How many years have you been smoking? since __ years
33. How old were you when you quit smoking? __ years
34. How many years have you been smoking? __ years

35. Please state which of the following physicians you have visited within the last 12 months and how often during this period?

Which physician?	No	Yes	How often?
General practitioner	□	□	_____
Internal medicine specialist	□	□	_____
Gynaecologist	□	□	_____
Urologist	□	□	_____
Ophthalmologist	□	□	_____
Orthopaedics	□	□	_____
Neurologist	□	□	_____
dentist/jaw surgeon	□	□	_____
psychotherapist/psychiatrist	□	□	_____
pain specialist	□	□	_____
non-medical practitioner	□	□	_____
other doctors please write down all „other:			
please specify: _____	□	□	_____
please specify: _____	□	□	_____

36. We would like to know how good or bad your health is TODAY.
    This scale is numbered from 0 to 100.
    100 means the best health you can imagine.
    0 means the worst health you can imagine.
    Mark an X on the scale to indicate how your health is TODAY.
    Now, please write the number you marked on the scale in the box below: ___

37. Do you have a disabled pass?
    □ Yes, □ No
    If yes : Please indicate the severity of your disability.
    Degree of disability: __

38. Have you ever applied for payments from the German nursing care insurance?
    □ No, □ Yes
    If yes, was the application successful?
    □ No, □ Yes, □ Not yet decided
    If so, to what level of care were you classified?
    Level of care □ 1 □ 2 □ 3 □ 5 □ 6
    a) Since when are you getting payments from the nursing care insurance? ____
    b) Which main benefit do you currently receive from nursing care insurance?
        □ Cash benefits
        □ benefits in kind (e.g. by outpatient nursing service)
        □ combination of both (benefits in kind and cash benefits)
        □ no benefits any more

At the end of the questionnaire we would like to ask some questions about well-being, in short quality of life.

[Here, the following scales are implemented: Short Form 36 (SF-36, quality of life), Patient Health Questionnaire Depression Scale (PHQ-9), and Patient Health Questionnaire Anxiety Scale (GAD-7)]

You did it! Thanks for your patience! On the following lines you have the possibility to write down comments and suggestions. Please use block letters for better readibility:

_____

_____

_____

Finally, we would like to thank you very much for filling out the questionnaire! Your detailed experience with your MS disease is very important for us.