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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Follow-up Questionnaire

(authors' translations)

Multiple Sclerosis Questionnaire

Please enter today's date: __ __ ____

1. Compared to six months ago, how would you rate your health in general now?
   - ☐ Much better now than six months ago
   - ☐ Somewhat better now than six months ago
   - ☐ About the same
   - ☐ Somewhat worse now than six months ago
   - ☐ Much worse now than six months ago
2. How quickly do 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
3. Have you been hospitalised for in-patient treatment in the last 6 months? If so, how many days in total?
   ☐ No ☐ Yes
   If yes, was your MS the reason for hospitalisation? ☐ No ☐ Yes
   If not, which other reason? Please specify: _____
4. Have you been treated as an outpatient in a hospital in the last 6 months without staying overnight?
   ☐ No ☐ Yes If yes, how often: ___ times
5. Have you been inpatient rehabilitation during the last 6 months?
   ☐ No ☐ Yes If yes, how many days: ___
6. Have you purchased or received one or more of the following aids because of your MS in the past six months?
   - ☐ 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: _____)

7. 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	☐	☐

8. Have you received any of the following services in the past six months?
   - ☐ Visits by a MS nurse/carer at home
   - ☐ home assistance
   - ☐ transport by ambulance
   - ☐ transport by taxi
   - ☐ social counselling
9. Has one or more of the following diagnostic measures been taken, in the last six months?
   - ☐ fMRI brain
   - ☐ fMRI spinal cord
   - ☐ Computed tomography image brain
   - ☐ Spinal fluid examination
   - ☐ Ultrasound of the heart
   - ☐ Electrocardiogram
10. Have you had one or more of the following complaints in the last six 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: _____

11. How satisfied are you with the success of the current MS-Therapy?
    ☐ Very satisfied, ☐ rather satisfied, ☐ rather dissatisfied,☐ very dissatisfied
12. How satisfied are you with the compatibility of the current MS-Therapy?
    ☐ Very satisfied, ☐ rather satisfied, ☐ rather dissatisfied,☐ very dissatisfied
13. Please state which of the following physicians you have visited within the last six 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: _____	☐	☐	_____

14. 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: ___
15. For each category, please tick the ONE box that best describes your health today.
    Mobility:
    - ☐ I have no problems in walking around.
    - ☐ I have moderate problems in walking around.
    - ☐ I am unable to walk around.

    Selfcare:
    - ☐ I have no problems washing or dressing myself.
    - ☐ I have moderate problems washing or dressing myself.
    - ☐ I am unable to wash or dress myself.

    Usual Activities (e.g. work, study, housework, family or leisure activities):
    - ☐ I have no problems doing my usual activities.
    - ☐ I have moderate problems doing my usual activities.
    - ☐ I am unable to do my usual activities.

    Pain/Discomfort:
    - ☐ I have no pain or discomfort.
    - ☐ I have moderate pain or discomfort.
    - ☐ I have extreme pain or discomfort.

    Anxiety/Depression:
    - ☐ I am not anxious or depressed.
    - ☐ I am moderately anxious or depressed.
    - ☐ I am extremely anxious or depressed.
16. Have you taken medication in the last seven days?
    ☐ Yes ☐ No
    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.

17. Over the last 2 weeks, how often have you been bothered by any of the following problems?

[Here, the following scales are implemented: Patient Health Questionnaire Depression Scale (PHQ-9), and Patient Health Questionnaire Anxiety Scale (GAD-7)]