Title research proposal:

Level of implementation of the new Standards of Care for management of Rheumatoid Arthritis across Europe – the patient perspective

Applicants:

Researchers and supervisor

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1. Background and rationale for the study

Rheumatoid arthritis (RA) has an important impact on patients and society. Fortunately, timely diagnosis, changes in the treatment paradigm and development of innovative treatments substantially improved outcome. However, inequities in care and disease outcome persist across European countries [1]. To raise and harmonize quality of care and enable equity of care for rheumatic diseases and other musculoskeletal conditions across Europe, the European Musculoskeletal Conditions Surveillance and Information Network (eumusc.net) was initiated as a project co-founded by EULAR and the EU [2].

As part of this initiative, eumusc.net developed a set of documents to support harmonization of RA and osteoarthritis care across Europe.

1. *The professional version of the Standards of Care (SOC)* which aim to ensure that health care professionals know the recommended treatment strategies for RA patients across Europe [3].
2. *Health Care Quality Indicators (HCQI)* that were formulated to operationalize the SOC, and which aim to measure and compare the quality of health service provision that should be available for people with RA across Europe [4].

The patient-centered SOCs specifically developed for RA patients to strengthen the patients' voice in the management of their disease but also to empower (individual) patients to gain responsibility for their disease [3]. The *patient-centred standards of care* summarize in plain language several aspects of RA care a patient should receive or should be educated about. To our knowledge this type of document is quite innovative in RA care (and even in the care of patients with chronic diseases). It allows for the first time to investigate the quality of RA care across Europe from the perspective of the patient (audit tool).

Beyond auditing quality of care and assessment of relative importance of the different aspects of care, the SOC could be used to develop a tool that supports patients to become active partners in clinical care. Patient-centeredness became increasingly important not only in rheumatology. A wide range of studies confirmed the need and positive effects of patient centered care and shared decision making in rheumatoid arthritis and other disease areas [5, 6]. With an educational tool that helps patients to (1) get an overview on the most relevant aspects of RA care and (2) assess the quality of care they are receiving, patients could become more actively involved in the management of their disease and as a result contribute to improvement of health outcomes for all patients.

With the present research project we primarily aim to investigate the current level of RA care across 47 European countries from the perspective of the patient. We expect to gain insights into the inequalities in care across Europe and thus create awareness on inequalities/inequities that still exist. The results are expected to support discussions on a national level as well as for the European Rheumatology community on possible barriers and challenges to improve quality of care and equity in care for patients.

Further we would like to understand which recommendations listed in the SOC are most important to patients to better understand the patient´s needs and how the patient´s needs change dependent on disease status or socio-demographic factors like education, economic or cultural background.

Finally, we want to explore how patients think the SOCs could be used to support active involvement of patients in the management of their disease. In this context the study will provide insights on stated usefulness and readiness to self-manage RA in different European countries.

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2. Objectives

Primary objectives

1. Gain insight into the level of implementation of the SOC for management of RA across Europe from the perspective of the patient
2. Understand which recommendations listed in the SOC are most important to patients across Europe and whether these differ according to patient characteristics

Secondary objective

4. Explore to what extent patients would find a supportive patient tool based on standards of care useful to self-manage their disease

3. Methodological approach

3.1. Design

The proposed study is a cross-sectional observational study, involving all European countries.

3.2. *Framework to explore level of RA care across Europe*

Two questionnaires have been developed.

The questionnaire for patients (appendix A) will address the patient perspective on

1. The perceived level of care received for each of the 16 core recommendations of the SOC.
2. The perceived importance of each of the 16 core recommendations of the SOC.
3. The usefulness of a supportive patient tool based on standards of care to self-manage the patient´s disease

The short additional questionnaire (appendix B) will address the rheumatologist’s perspective on

1. The perceived level of care received for each of the 16 core recommendations of the SoC.
2. The perceived importance of each of the 16 core recommendations of the SOC.

The rheumatologist´s perspective will be assessed in order to primarily gain insights into differences in the perception of rheumatologists compared to patients and thus contribute to the discussion on potential barriers for implementation of SOC across Europe [7].

Both questionnaires will ask respondents to provide socio-demographic background information needed for data analysis and interpretation (e.g. age, gender, education, disease characteristics (patients) or work environment and experience (rheumatologists)). Both questionnaires will be piloted in 2-3 countries. Further PIs will be requested to confirm applicability of questionnaires in their country in parallel to the pilot studies.

All patients will be asked to sign an informed consent before participation in the study (Appendix C). Patient questionnaire will be translated into local language by the country PI. Validated translations of the SOC into European languages already exist at www.eumusc.net and will be used to support translation.

Timeline of the project is presented in the Appendix D.

3.3. Participants(subjects)

All European countries (target 47 countries), not limited to EU-member states, will be invited to participate. For each country will a principal investigator (PI) will be nominated. The national PI will be responsible for recruitment of RA patients and rheumatologists in his/her country.

PIs will be recruited using an existing network established during earlier research projects investigating equity in RA care [1, 8].

Each country PI will be responsible for

- Translation of the patient questionnaire (and if necessary the rheumatologist´s questionnaire) into the local language of the country.
- Recruitment of patients and rheumatologists in the country
- Support of data interpretation, revision and approval of the manuscript
- If necessary according to local regulations, the local Ethics Approval will be a responsibility of the PI

All participating country PIs will be rewarded with co-authorship in resulting publications.

3.2.1 Recruitment of patients

Patients will be invited to complete a questionnaire to assess a) the perceived level of RA care stated in the SOC and b) the perceived importance of the recommendations listed in the SOC. Further patients will be invited to complete an additional questionnaire to gain insights on patient tools that potentially support patient centered care and involvement of patients in the management of their disease.

The recruitment target per country will be at least 50 RA patients. For recruitment of patients, we will instruct PIs to ensure a representative sample of RA patients in each country. However, no strict selection procedure will be given to PIs since we want to allow participating countries to have some flexibility. To ensure that major care settings are reflected in the study, the country PI (mostly academic setting) will be encouraged to recruit patients in at least one academic and one non-academic setting (local hospital or private practice).

Patient recruitment will be performed through rheumatologists only to ensure that patients actually have the disease and are diagnosed by experts. Country specific patient recruitment scenarios can be allowed on the condition that recruitment is random and the diagnosis RA is ascertained by the rheumatologist.

Patients that are interested to participate in the survey will receive the study information and questionnaire either as email (link to survey attached to email) or paper based. Paper based surveys will be collected by the attending rheumatologist and returned to the study team in a pre-stamped envelope.

3.2.2 Recruitment of rheumatologists

Furthermore, 50 rheumatologists per country will be recruited to complete a short questionnaire limited to assessment of a) perceived level of implementation of each of the SOC and b) perceived importance of the recommendations listed in the SOC.

PIs should reassure that a representative sample of rheumatologists will be included.

Rheumatologists will be invited to participate through email. A link to the survey will be attached to the email. Paper based surveys will not be distributed among rheumatologists as we expect that rheumatologists across Europe are familiar with online systems. The PI of each country will decide if translation of the rheumatologist´s questionnaire is required. If needed, the PI will be in charge of the translation. Validated translations of the standards of care into European languages already exist at www.eumusc.net and will be used to support translation.

4. Intervention

The current study is an observational, non-interventional study that evaluates care in different European countries. Patients will receive a questionnaire that will mainly contain questions about their perceptions and experiences with RA care they receive (full text of the questionnaires can be found in the appendices).

5. Analyses

Descriptive statistics will be used to compare per country and for patients and rheumatologists separately (a) level of implementation per SOC and average of all SOC, (b) importance per SOC and average of all SOCs (c) importance weighted implementation per SOC and average of all SOC and (d) stated usefulness and readiness to self-manage disease based on a checklist. In addition, for each country, the gap in perceived level of implementation and importance according to patients and rheumatologists will be calculated per SOC and for the average of all SOCs and will be compared across countries.

Linear regression will be applied to understand country differences in the main outcomes (level of implementation, importance, implementation importance gap and readiness to self-manage based on the checklist for the average score across SOC, and where applicable each SOC separately) in addition to the influence of age, gender, education, disease duration, disease severity, type of medication, literacy, setting of recruitment (academic/peripheral centre). Further also evaluation of potentially influencing country characteristics like Gross Domestic Product (GDP)/Human Development Index (HDI) could be considered.

6. Anticipated results

Implementation

Level of implementation of SOC (overall) according to patients is expected to vary significantly across countries. Higher level of implementation is expected for high GDP countries and countries with high health care standards.

Lack of implementation for individual SOC is in particular expected for recommendations asking for (early) involvement of experts (early diagnosis) or involvement of a multidisciplinary team (involvement of dietician, occupational therapist or physiotherapist) and recommendations asking for extensive patient education.

We expect that rheumatologists differ in their perception on level of implementation (e.g. on recommendations involving patient education); however we expect the same trends for high vs low GDP countries or countries with high vs low health care standards.

Importance

The relative importance of the 16 recommendations of SOCs from the patient´s perspective is expected to largely overlap across countries, however differences may be observed among different subgroups (e.g. younger patients or patients with higher education may consider items on patient education more relevant). We further expect that rheumatologists partly deprioritize patient education, however this may vary dependent on age, gender or work setting.

SOC as instrument/tool for patients

For the majority of patients knowing the SOC is considered useful and most patients wants to get actively involved in the management of their disease.

7. Handling and storage of data

The investigator assures that in subject’s (either patient or rheumatologist) anonymity will be maintained. On documents, subjects will not be identified with their names, i.e. questionnaires will be kept totally anonymous. The investigator will maintain the data in strict confidence. The data will be kept for 5 years and can be used for follow up research in line of this research.

References

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Appendix A

Patients' questionnaire (English)

Appendix B

Questionnaire for Rheumatologist (English)

Appendix C

Informed consent form (English)

Appendix A – Patient Questionnaire

Evaluation of care for Rheumatoid Arthritis patients accros Europe

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Introduction

Dear Madam/Sir,

European experts in the field of rheumatology agreed recently on a set of patient-centred Standards of Care for the management of Rheumatoid Arthritis (RA). These Standards of Care consist of 16 recommendations that reflect the most relevant aspects of care all RA patients in Europe should receive. The standards of care have been developed to improve and harmonize RA care across Europe. Also the agreed standards of care should enable patients to understand which type of care they should receive and thus play a more active role in the management of their disease. For this purpose, the Standards have been formulated as questions.

In this survey, we aim to understand first to what extent patients in different European countries receive already care according to the standards. Further we would like to gain insight whether the Standards of Care can support you, as a patient, to become more actively involved in the management of your disease

We prepared two questionnaires. In the first (main) questionnaire, we want to understand

1. to what extent you personally received RA care as described in the recommended standards of care and
2. how important the recommendation is in your opinion

In the second questionnaire we aim:

3. to explore how much you want to be involved in the management of your disease and how the recommended standards of care could support you as patient to become actively involved in the management of your disease

It will take approximately 20 minutes to complete the main questionnaire, the optional second questionnaire will take another 5 minutes. If possible, we would highly appreciate if you can fill in both.

Your participation in the survey is entirely voluntary. Your responses will be anonymized, treated strictly confidential and used for the purpose of this study only. Please be reassured that your doctor will not be informed about your responses. There will be no right or wrong answers as we are solely interested in your personal experience and opinion as patient.

In case of questions please do not hesitate and contact the research team at Maastricht University coordinating the study (contact person: Monika Hifinger, m.hifinger@maastrichtuniversity.nl, phone: +31 433 875 026) and/or PI.

Thank you very much for the time you dedicate to the questionnaire.

Yours sincerely,

Annelies Boonen, MD, PhD
Professor of Rheumatology
Monika Hifinger,
Investigator and PhD student
Department of Internal Medicine
Maastricht University Hospital
NL-6202 AZ Maastricht

the PI/will be individualized per country

Questionnaire Part I – What do patients with Rheumatoid Arthritis think about the Standards of Care

In the following task, we would like to learn about **your personal experiences with Rheumatoid Arthritis (RA) care**.

We will present you each of the 16 questions from the Patient-Version of the “Standards of Care” and will ask you to answer two questions:

- **To what extent you** currently **receive** the care as described
- **How important** this particular aspect of RA care is for you

Please note that in the Patient-Version of the Standards of Care, the recommendations on RA care are formulated as a question to enable patients to understand which type of care they should receive and actively monitor the care they receive.

To answer the two questions, please simply mark your personal opinion on a 0 (not at all received/not at all important) to 10 (fully received/very important) scale.

In case a particular standard of care does not apply to you, or in case you have no opinion on the importance, you can cross the filed “not applicable” or “no opinion’”.
In case you do not understand the meaning of the question, you can cross “I do not understand” and move to the next question.
At the end of each set of questions, you will have the opportunity to share your personal comments.

1. Was my RA diagnosed by a specialized health professional within 6 weeks of onset of symptoms?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

☐

2. Do I understand my disease, my role in its management and the role of health professionals?

2.1. Have I been given information in different formats and/ or education about my disease?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

2.2. Have I been given information and / or education about treatments, their benefits and risks?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

2.3. Have I been given information and education relevant to my needs i.e. pain/flare management, drug reactions?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

2.4. Have I been given information about, and given contact details of, relevant patient charities and organisations which are considered to be trusted sources of evidence based Information

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

3. Have I received a treatment plan which includes explanation of my management, expected goals and outcomes and important contact details?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

4. Was I informed about expected benefits and potential risks of treatment?

4.1. Was I assessed for clinical status and safety before the treatment was started?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

4.2. Was I informed about vaccination?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

5. Have I received a schedule of regular assessments of my disease – The symptoms, disease activity and of what I can do?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

6. Have I been informed when, how, and who I can contact in case my disease is worsening?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

7. **Am I receiving a disease modifying anti-rheumatic drug, and if not, do I understand why not?**

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

8. **If my target of low disease activity or remission is not achieved, is my treatment reappraised at least every 3 months?**

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

9. **Do I know how to control pain associated with my RA?**

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

10. Have I been informed about the options of surgery and have the benefits and risks been explained?

No, not at all										Yes, fully	Not applicable	I do not understand
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										Very important	No opinion
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

11. Do I have access to pharmacological and non-pharmacological treatments according to my clinical need?

No, not at all										Yes, fully	Not applicable	I do not understand
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										Very important	No opinion
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

12. Do I have the opportunity to receive support if needed from health professionals such as rheumatologist, dietician, general practitioner, nurse, occupational therapist, physiotherapist, psychologist and social worker?

12. 1. Have I been offered information about how, why and when to contact different members of the multi-disciplinary team as soon as possible after my diagnosis was made?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

13. Have I been informed about physical activity and exercises specific for me?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

14. Have I received information and if necessary advice and trainings on aids, devices and ergonomic principles to enhance function in daily life and participation in social roles?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

15. Have I been informed about a healthy lifestyle?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

16. Have I been informed about alternative therapies and the limited evidence available?

No, not at all										**Yes, fully**	**Not applicable**	**I do not understand**
0	1	2	3	4	5	6	7	8	9	10	☐	☐

To me, this type of care is…..

Not important										**Very important**	**No opinion**
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

If you miss an important aspect of care that has not been covered in the 16 recommendations, please comment in the box below

We now introduced the *16 recommendations of the European Standards of Care* to you. You may have identified areas where you do not yet receive the recommended type of RA care. In the following set of questions we would like to learn more about reasons that may help to explain why you do not yet receive RA care as recommended

What could be reasons (barriers) why patients do not yet receive RA care as recommended?

We developed several statements which target potentially relevant barriers. Please indicate on a 0 (does not apply at all) to 10 (fully applies) scale the extent to which these statements apply to the RA care as you experience it.

Attitude/agreement:

1. **I have the impression that doctors do not see the *need to implement the recommendations* in clinical practice**

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

2. **I have the impression that doctors think patients do not need to be educated about all aspects of care they receive**

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

3. **My active involvement in the management of my rheumatoid arthritis is very important to improve my symptoms**

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

Limited time/resources:

4. In clinical practice, the time healthcare professionals have for patients seems increasingly limited.

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

Health insurances coverage

5. Several recommendations of the Standards of Care are not (or not fully) covered by the national health service or my health insurance.

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

Access

6. The access to specialists and other healthcare providers is extremely limited in my area making implementation of some recommendations difficult

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

Applicability:

7. All recommended Standards of Care are applicable or useful to my particular situation

I do **not agree** at all										**I fully agree**	I do not know
0	1	2	3	4	5	6	7	8	9	10	☐

Please add any additional comments in the box below

Background information

We now have a very good understanding of what you think about the Standards of Care. At the end of the survey you could help us with information about **you, your personal situation and your needs**. This information will help us to better understand your previous responses.

All your responses will be anonymous, treated strictly confidential and used for the purpose of this study only.

1. **What is your gender?**
   - ☐ Male
   - ☐ Female

2. **What is your age?** (in years)

3. **Please indicate what best describes your highest level of education**
   - ☐ Completed primary school
   - ☐ Completed secondary education (e.g. high school and/or trade/technical/vocational training)
   - ☐ Completed university education (e.g. Bachelor or Master degree or equivalent)

4. **Are you currently working (several responses possibel)?**

1. Working (full or part time)
2. Retired (because of age)
3. Officially work disabled (full or partial)
4. Currently not working (for other reasons e.g. student, homemaker, unemployed)

5.

A. How often do you have someone help you read materials you receive from your doctor?

○	○	○	○	○
Never	Occasionally	Sometimes	Often	Always

B. How confident are you filling out medical forms by yourself?

○	○	○	○	○
Not at all	A little bit	Quite a bit	Somewhat	Extremely

C. How often do you have problems learning about your medical condition because of difficulty understanding written information?

○	○	○	○	○
Never	Occasionally	Sometimes	Often	Always

6. **How many years ago was you diagnosis “rheumatoid arthritis” made?**

7. **Considering all the ways in which the illness (and health conditions) may affect you at this time, please mark below to show how you are doing**

Very poor **Very well**

0	1	2	3	4	5	6	7	8	9	10

8. **Which types of medication do you/did you use to treat your RA?** Please tick below (multiple responses possible)

   ☐ **(Anti-inflammatory) painkillers** (e.g. diclofenac, naproxen, ibuprofen, etoricoxib, paracetamol, codeine, morphine).
   ☐ **Synthetic disease modifying anti-rheumatic drugs (DMARDs) (e.g.** Methotrexate, MTX (Metotrexate); Salazopirine (Sulfasalazine); Plaquenil (Hydroxychloroquine); Arava (Leflunomide)
   ☐ **Biologic DMARDs** (e.g. Enbrel (Etanercept); Humira (Adalimumab); Remicade (Infliximab); Simponi (Golimumab); Cimzia (Certolizumab); Mabthera (Rituximab); Abatacept (Orencia); Kineret (Anakinra); Ro-Actemra (Tocilizumab); Remsima (Infliximab); Inflectra Mabthera)
   ☐ **Steroids** (e.g. prednisone)
   ☐ **None**
   ☐ **I do not know**

9. **Did you ever receive joint surgery because of RA?**
   ☐ Yes
   ☐ No

10. **Are you a member of a patient organization engaged in the field of rheumatic diseases?**

    ☐ Yes
    ☐ No

11. **In the last year, did you see your rheumatologist for the RA?**
    ☐ Yes
    - I have seen my rheumatologist approx. __ times last year

    ☐ No

12. **In the last year, did you see other healthcare professionals because of your RA**
    ☐ Yes
      ☐ Orthopedic surgeon: ___times
      ☐ Physiotherapist: ___times
      ☐ Rheumatology nurse: ___times
      ☐ Other___________________: ___times

    ☐ No

OPTIONAL: Questionnaire Part II – Education and active involvement of RA patients in the management of their disease

The previous part of the questionnaire helped us to gain insights into the level of RA care you receive at present and into possible barriers.

This part aims to assess to what extent the Patient Version of the Standards of Care for RA could help patients
a) to understand what is considered optimal care for RA patients and
b) to get actively involved in the management of their disease.

We highly appreciate your time and effort taken for the previous sections of the questionnaire and fully understand if your time does not allow for any additional questions. However your contribution to this part of the survey would help enormously to develop the right materials and tools for patients. It takes about 5min to fill in the questionnaire.

The role of patients in the management of the disease - What do you think about it?

1. It is the responsibility of my doctor to define and monitor the treatment strategy for me

I do **not** agree at all									I **fully** agree			I do not know
0	1	2	3	4	5	6	7	8	9	10		☐

Please add any additional comments in the box below

2. It is also my responsibility as patient to get actively involved in the management of my disease and state my preferences

I do **not** agree at all									I **fully** agree			I do not know
0	1	2	3	4	5	6	7	8	9	10		☐

Please add any additional comments in the box below

3. Active participation of the patient in the treatment course can influence the treatment outcomes/ symptoms

I do **not** agree at all									I **fully** agree			I do not know
0	1	2	3	4	5	6	7	8	9	10		☐

Please add any additional comments in the box below

The Standards of Care as checklist for patients to actively monitor their disease

We prepared several statements. Please indicate on the scale ranging from 0 (agree not at all) to 10 (fully agree) what you think about each of the statements.

4. All rheumatoid arthritis patients should know the Standards of Care (i.e. optimal care for their disease)

I do **not** agree at all — I **fully** agree — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

5. The Standards of Care could be used by patients to get an overview of the most relevant aspects of RA care they should receive

I do **not** agree at all — I **fully** agree — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

6. The Standards of Care help patients to evaluate the quality of care they receive

I do **not** agree at all — I **fully** agree — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

7. Knowing the Standards of Care helps patients to request from their doctor additional information, service or care they want/should receive

I do **not** agree at all — I **fully** agree — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

How can the Standards of Care be easy accessible to patients?

We believe that access to current Standards of Care could be further improved. We would appreciate to receive your feedback on a few statements we prepared below.

8. I could imagine that a brochure/leaflet or e-health program with explanatory information could support me to fully understand the content and purpose of the Standards of Care

Not important **at all** — **Extremely** important — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

9. The Standards of Care should be available as a print copy (e.g. flyer, leaflet) that I can receive from my doctor

Not important **at all** — **Extremely** important — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

10. The standards of care should be easy to find in the internet

Not important **at all** — **Extremely** important — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

11. The Standards of Care should be available as "App" for smartphones and tablets. I want to have fast and simple access to it and receive updates automatically

Not important **at all** — **Extremely** important — I do not know

0	1	2	3	4	5	6	7	8	9	10	☐

The questionnaire is completed,
thank you very much for your participation!

Appendix B - Questionnaire for Rheumatologist (English)

Survey among European rheumatologists to understand level of implementation and relevance of the Standards of Care for management of Rheumatoid Arthritis

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Introduction

Dear colleagues,

Recently, a set of patient-centred Standards of Care (SOC) for the management of Rheumatoid Arthritis (RA) has been developed by the eumusc.net project (a project supported by EULAR and the EU). The 16 SOCs summarize the most relevant aspects of care patients with RA should receive. They aim at improvement and harmonization of RA care across Europe. All recommended SOC are also available as lay version, written in a simple language that ensures that patients can understand the content.

In the present survey, we would like to learn from you as rheumatologist

1. To what extent your RA patients already receive care as described in the Standards of Care
2. How important you think it is to apply each recommendations to your RA patients

The study is an independent research project coordinated by the University of Maastricht, the Netherlands. The project aims to understand the current clinical practices in RA care across Europe, and raise awareness on potentially existing gaps and barriers. With the study, we aim to contribute to discussions on improvement of RA care on national but also European level.

It will take 10 minutes to complete the questionnaire. Participation in the survey is entirely voluntary. All responses will be anonymized, treated strictly confidential and used for the purpose of this study only. There are no right or wrong answers as we are solely interested in your personal opinion and clinical experience.

In case of questions please do not hesitate and contact the research team at Maastricht University (contact person: Monika Hifinger, m.hifinger@maastrichtuniversity.nl).

Again thank you very much for the time you dedicate to the questionnaire.

Yours sincerely,

The research team
Annelies Boonen, Professor of Rheumatology
Monika Hifinger, Investigator and PhD student
Polina Putrik, Researcher
Sofia Ramiro, Senior Researcher
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Tanja Stamm, Associate Professor Rheumatology
Michaela Stoffer, Researcher
Till Uhlig, Professor of Rheumatology
Rikke Moe, Senior researcher
Maarten de Wit, Patient Researcher

The Questionnaire

Thank you very much for your participation. In the following survey, we will present you each of the 16 recommendations of the Standards of Care and will ask you two questions per recommendation.

- **To what extent** do your patients **receive care** as recommended in the standard?
- How **important** (in your opinion) is this particular aspect of RA care for your patients?

We are aware of the fact that not all Standards of Care are equally applicable to all patients. **When answering the survey questions, please think of an average patient and a frequent standard situation in your clinic.**

Please read the recommendations carefully. Each recommendation is introduced above the set of two questions and marked in **bold.** To answer the two question, please simply mark your personal opinion on a 0 (SOC not applied/not important to patients) to 10 (SOC fully applied/very important to patients) scale.

In case the standard of care does not apply to your clinical practice, or in case you have no opinion on the importance, you can cross the filed “not applicable” or “no opinion’”.

Note, for the present survey the 16 SOC recommendations have been formulated as questions to you personally.

1. Have your RA patients been diagnosed by a specialized health professional within 6 weeks of onset of symptoms?

No, does not apply to ↓my patients at all										**Yes, fully applies to my patients↓**		**Not applicable ↓**
0	1	2	3	4	5	6	7	8	9	10		☐

This type of care is:

Not ↓important										**Very important ↓**		**No opinion**
0	1	2	3	4	5	6	7	8	9	10		☐

2. Do your RA patients understand their disease, their role in its management and the role of health professionals?

2. 1. Do your patients receive information in different formats and/ or education about their disease?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

2. 2. Do your patients receive information and / or education about treatments, their benefits and risks?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

2.3. Do your patients receive information and education relevant to their needs i.e. pain/flare management, drug reactions?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

2.4. Do your patients receive information and contact details of relevant patient charities and organisations which are considered to be trusted sources of evidence based information?

No,
does not apply to
↓**my patients at all**

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10		☐

This type of care is:

Not
↓**important**

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10		☐

3. Do your patients receive a treatment plan which includes explanation of their management, expected goals and outcomes and important contact details?

No,
does not apply to
↓**my patients at all**

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10		☐

This type of care is:

Not
↓**important**

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10		☐

4. Are your patients informed about expected benefits and potential risks of treatments?

4. 1. Are your patients assessed for clinical status and safety before the treatment is started?

No,
does not apply to
↓**my patients at all**

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10		☐

This type of care is:

Not
↓**important**

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10		☐

4.2. Are your patients informed about vaccination?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

5. Do your patients receive a schedule of regular assessments of their disease – The symptoms, disease activity and what they can do?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

6. Do your patients receive information about when, how, and whom they can contact in case their disease is worsening?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

7. **Do your patients receive a disease modifying anti-rheumatic drug, and if not, do they understand why not?**

No,
does not apply to
↓**my patients at all**

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓**important**

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

8. **If the patient´s target of low disease activity or remission is not achieved, is their treatment reappraised at least every 3 months?**

No,
does not apply to
↓**my patients at all**

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓**important**

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

9. **Do patients know how to control pain associated with their RA?**

No,
does not apply to
↓**my patients at all**

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓**important**

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

10. Are your patients informed about the options of surgery and have the benefits and risks been explained?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

11. Do your patients have access to pharmacological and non-pharmacological treatments according to their clinical need?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

12. Do RA patients have the opportunity to receive support if needed from health professionals such as rheumatologist, dietician, general practitioner, nurse, occupational therapist, physiotherapist, psychologist and social worker?

12.1 Are your patients offered information about how, why and when to contact different members of the multi-disciplinary team as soon as possible after their diagnosis was made?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

13. Are your patients informed about physical activity and exercises specific for them?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

14. Do your patients receive information and if necessary advice and training on aids, devices and ergonomic principles to enhance function in daily life and participation in social roles?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

15. Are your patients informed about a healthy lifestyle?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

16. Are patients informed about alternative therapies and the limited evidence available?

No,
does not apply to
↓my patients at all

Yes,
fully applies to my
patients↓

Not
applicable

0	1	2	3	4	5	6	7	8	9	10	☐

This type of care is:

Not
↓important

Very
important ↓

No
opinion↓

0	1	2	3	4	5	6	7	8	9	10	☐

Do you miss an important aspect of care that has not been covered in the 16 recommendations? E.g. other services or treatments a patient should have regular access to?

Do you want to add a general comment on the Standards of Care (e.g. general barriers you experience in clinical practice, applicability of the recommendations, your level of agreement with the content)?

Background information

We now have a very good understanding of what you think about the Standards of Care. At the end of the survey you could help us with information about **you and your work environment.** This information will help us to understand your previous answers.

All your responses will be anonymous, treated strictly confidential and used for the purpose of this study only.

1. What is your gender?

- ☐ Female
- ☐ Male

2. What is your age?

☐

3. What best describes your current work environment? (In case several responses apply, please select your main work environment only)

- ☐ University hospital (academic setting)
- ☐ Non-university (private or public) hospital
- ☐ Private practice
- ☐ Other: ________________________________

4. How many years of work experience as certified rheumatologist do you have?

☐

5. Could you please share the number of hours you spend on patient care per week (average)?

☐

The questionnaire is completed, thank you very much for your participation!

Appendix C

INFORMED CONSENT FORM

Level of implementation of the new Standards of Care for management of Rheumatoid Arthritis across Europe – the patient perspective

Name of Chief Investigator: Prof. Annelies Boonen, MD, PhD

Name Principal Investigator: *individualized per country* ______________________________

1. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
2. I confirm that I have read and understand the information for the above study provided in the "introduction". I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. I was given enough time to decide on my participation ☐
3. I agree that a copy of the questionnaire will be send to the co-ordinating centre (Maastricht University, Maastricht, the Netherlands) to be analyzed by researchers involved in this study. ☐
4. I understand that the data collected during the study may be looked at by individuals from the University of Maastricht, from regulatory authorities or participating centres. I give permission for these individuals to have access to my records ☐
5. I agree to take part in the above study. ☐

------------------------	----------------	------------------------
Name of patient	Date	Signature
------------------------	----------------	------------------------
Name of researcher	Date	Signature

1 copy to patient; ORIGINAL copy to be kept in site file