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Expectations of new treatment in rheumatoid arthritis: developing a patient-generated questionnaire

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Abstract

Background Service-user partnerships in research exist in mental health, but there have been few advances in other disciplines, apart from cancer.

Objectives To develop a patient-generated expectancy measure for new treatments in rheumatoid arthritis (RA), using a participatory method.

Method Stage 1: three repeated focus groups and two expert panels with patients with RA conducted by a patient researcher to generate items for the draft questionnaire. Stage 2: feasibility study of draft scale with consecutive outpatient attendees.

Results Patients identified 21 dimensions of new treatment expectations, grouped into (i) physical, (ii) psycho-social and (iii) expectations relating to the impact of treatment. This resulted in a draft instrument assessed in a feasibility study.

Discussion and Conclusion The participatory research method was useful in involving patients actively in research and to produce collaboratively a feasible, valid and acceptable measure in RA. The scale will be included in a longitudinal observational study, with newly diagnosed patients, to assess (i) whether the new scale demonstrates sensitivity to change for expectations when receiving new treatment and (ii) participants' completion rate of the new scale compared with five instruments included in the future study.

Introduction

Partnerships with service users are now understood as essential for the development of evidence-based care in government guidance across the globe (e.g. Department of Health 2007, National Health and Medical Research Council Strategic Plan 2010–2012, Canadian Arthritis Network Consumer Advisory Council 2003).[1–3] They may offer one solution to the slow translation of clinical science into meaningful treatment. There is much evidence of

their development in mental health, but little indication of their widespread adoption in other diseases. Close collaborations are likely to be most rewarding in long-term conditions where significant partnerships are commonly established between service users and health professionals over time.

Rheumatoid arthritis (RA) is one such condition. It is a systemic autoimmune chronic disease with symmetrical inflammatory polyarthritis.[4,5] It typically develops in middle or late life and is three times more common in women than in men.[5] The condition fluctuates, is unpredictable in treatment response and can show sudden exacerbations, which may be severely disabling. RA results in high direct and indirect medical and social costs, as well as reductions in quality of life.[1,6,7] Comorbidities (e.g. coronary artery disease, infections) and extra-articular diseases (e.g. anaemia, ophthalmological manifestations) can reduce life expectancy by 5–10 years.[8] It is because of these long-term disabilities linked to the reductions in life expectancy and quality of life that there always has been a search for new treatments.

During the past decades, the therapeutic options of RA have expanded significantly with the key aim to achieve remission or sustained low disease activity. This can now be achieved by disease-modifying anti-rheumatic drugs (DMARD) monotherapy, combinations of DMARDs (with or without glucocorticoids) and DMARD–biologics combination. In addition, 'treatment to target' is now commonly recommended for individual patients, and its use is supported by a number of studies and recommendations.[9–11]

Expectations of health outcomes and health care are complex, important and poorly understood. Ross *et al.*[12] defined expectations as 'beliefs stated temporally, reflecting cognitive elements related to health care'. The New Oxford Dictionary of English (1998)[13] defined the construct as a (i) strong belief that something will happen or be the case in the future and (ii) a belief that someone will or should achieve something. Expressing expectations is a cognitive process that requires some degree of knowledge, possibly due to previous experiences, and therefore allows balance of the probability of "success" or "failure".[14] Identifying patients' expectations may aid a tailored approach, so that specific individual clinical outcomes from new treatments can provide guidance on patients' values in relation to medication. However, in a recent systematic review of treatment and patient-related expectations in musculoskeletal conditions,[15] none focused on new treatments in RA.

A number of *patient-generated or patient-led outcome measures* have been developed, for example, (i) continuity of care user-generated measure in mental health[16]; the Brief Index of Lupus Damage[17]; and the Rheumatoid Arthritis Self-Efficacy Scale (RASE).[18] The RASE instrument has been developed to measure task-specific self-efficacy in relation to behaviour change, based on the social learning theory.[19] What makes our new draft scale unique and relevant from the ones above is that none focused on treatment expectations. However, availability of RA medication is in a stage of constant flux due to the new emerging evidence about treatment modalities, and the measure is therefore timely.

In a recent literature review, Staley[20] highlighted four key areas in relation to the impact of patient involvement in health-care and social care research: (i) an increase in the recruitment to all types of research; (ii) particular value in qualitative research for participants when invited to share their views and experiences; (iii) useful in clinical trials where it helps to improve trial design and ensured the use of relevant outcome measures; and (iv) benefit for the people involved as well as the research participants. Kjeken *et al.*[21] suggested that patient researchers can contribute in a range of different ways to research projects, for example, help to identify relevant outcomes, develop the interview guides, come up with suggestions that facilitate (e.g. relevance of questionnaire selected for study) or hamper participation (e.g. awareness of fatigue, restricted mobility in RA), monitor the research, analyse and interpret the results. Moreover, another advantage

might be a reduction in the power relationship between the patient researcher and participants due to shared experiences of the illness trajectory (e.g. side-effects of medication, management of disease progress of long-term conditions), or a fast rapport might be established with patients during the focus groups. These personal experiences of affinity through a common ground and mutual respect were highlighted by past publications, for example Gillard *et al.*[22] However, Mason and Boutelier[23] were critical about the set-up of an equal power balance between both parties, due to the organizational power complexities that can affect the research process.

Against this background of valuing greater patient involvement in clinical research in the United Kingdom, we describe here the first two phases (questionnaire items development and feasibility study) of putting together a novel treatment expectancy measure with the direct involvement of patients who live with RA and a patient researcher diagnosed with an autoimmune condition. The aim of this study was to develop a patient-generated expectancy measure for new treatments in RA, using a participatory research method.

Patients and methods

We have chosen to adopt the *participatory* method that was originally developed and employed in mental health.[16,24] Our service users all had a diagnosis of RA and were recruited from a tertiary outpatient clinic in South East England. We chose a quota sample, stratified by gender, ethnicity, age and disease duration, based on the rheumatology outpatient clinic population. The inclusion criteria were as follows: adult patients, aged 18–85 years, diagnosed with RA for more than 6 months and ability to understand and communicate in English. Exclusion criteria were as follows: individuals below the age of 18, with a diagnosis < 6 months ago, who were seriously physically or mentally unwell and who were unable to understand or communicate in English.

The draft semi-structured topic guide for the focus groups was initially developed by the patient researcher from (i) the literature[25–27] and (ii) consultations with two departmental patient experts and outpatient clinic staff (see description of research team staff roles and research activities in Table 1A in Appendix 1). The pilot and subsequent two main focus groups were held in the medical school from December 2010–April 2011, lasting on average 2 h, led by the patient researcher in conjunction with the focus group patient facilitator. We chose a focus group methodology to allow interaction between patients and to help with brainstorming and the generation of new ideas and personal reflections[25] based on the common experience of living with RA. Each participant provided written informed consent and received financial remuneration for the first phase of the study. Local Ethics Committee and Research & Development approval was received prior to commencement of the study (10/HO718/82).

Phase 1: Generation of draft measure

The generation of the draft measure is outlined in Appendix 2 (Sequence and tasks of each focus group). All focus groups were digitally recorded and transcribed verbatim by the patient researcher with the agreement of the patients.

Data analysis

All transcribed focus group data were imported into the qualitative data analysis computer program NVivo8[28,29] by the patient researcher, and thematic content analysis was applied.[30]

Coding

The patient researcher undertook two types of coding on the transcripts of the first focus group meetings: level 1 to identify relevant data (identify themes, sentences or paragraphs) and level 2 (axial coding) to group similar codes into broader categories, based on shared content. At the same time, emerging themes

were inductively checked and compared against transcripts to further refine them.[31]

For better comprehension, the expert panel and patient researcher suggested and then agreed to split the 21 items into three key categories (level 3 coding).[32] This resulted in an analytical framework under which the expectations domains were presented for the draft questionnaire: (i) expectations of physical impact (e.g. pain, morning stiffness, fatigue); (ii) expectations of psycho-social impact (e.g. emotional well-being, maintenance of social roles, maintenance of independence); and (iii) expectations of impact of new treatment (e.g. prevent additional physical complications, regular physical assessments, involvement in shared decision with medical staff) (See Appendix 3 Questionnaire).

A defining issue for participants in all focus groups was that the selection of domains in the draft instrument matched well and was relevant to their personal treatment expectations. At this stage, patients selected to name the draft instrument MAPLe-RA (measuring actual patient-led expectations).

Validity of the data

A number of steps were followed to strengthen the validity, robustness and credibility of the qualitative data: (i) the patient researcher double-checked that her interpretations were in line with the verbal accounts of the pilot and two main focus group participants during the repeat group sessions; (ii) following the reading of the focus group transcripts and the 1–2 level coding, a discussion was held and an agreement was reached between the patient researcher and an experienced external qualitative researcher for the emerging codes; (iii) the cross-referencing of the draft measure and the content of the group discussions (focus groups and the expert panels) allowed triangulation, thus giving a comprehensive picture of the views expressed in the groups; (iv) single counting for the domain descriptions[33]; and (v) the inclusion of negative instances (deviant cases that contradict emergent accounts)[34] were applied.

Phase 2: Feasibility study

The feasibility study had the aim of assessing whether consecutive clinic attendees with RA understood the content and structure of the 21-item draft scale, including ecological validity of brevity, simplicity, relevance, acceptability and availability.[35,36] The patient researcher approached 22 patients in the RA outpatient clinic over one week and asked them to complete the draft questionnaire and provide feedback on the following aspects: '*How relevant are these questions to you?', ' Are they easy to understand?', ' Do you agree with the array of verbal responses presented?'* The patient researcher sat with the participants and recorded their verbal comments, for example, 'sounds as if the questionnaire is making patients think', 'I do not think that patients are being overburdened completing the questionnaire', or 'I like the three sections – all sections sound useful'.

Results

Phase 1

Forty-one patients with RA were initially approached by outpatient clinic staff and then formally invited by the patient researcher to take part in the focus groups. Seventeen participants agreed to take part in the study. The median disease duration was 11 years (range: 3–44 years), median age was 57 years (range: 34–71 years), and median Disease Activity Score (DAS) 28 – erythrocyte sedimentation rate (DAS28–ESR score) was 3.92 (range 0.88–6.39). Twenty-four patients (20F/4M) did not wish or were unable to participate due to feeling unwell, family commitments and inconvenience of date and time. They had similar socio-demographic background to the focus group cohort.

In Table 1, the final interview schedule endorsed by the pilot focus group participants consisted of three main questions: (i) to describe three aspects that affected them most while living with RA; (ii) what expectations they anticipated from new treatments; and (iii) how their experiences could be best captured in

Table 1 Socio-demographic characteristics of focus group cohorts (n = 17)

Gender (female/male)	13/4
Median disease duration (range)	11 yrs (3–44 years)
Median age in years (range)	57 yrs (34–71 years)
Median DAS28-ESR score* (range)	3.92 (0.88–6.39)
Ethnicity (self-described)	
British/English/White	9
White + Other	2
African	2
Black	2
Caribbean	2
Employment	
Full-time work	3
Part-time work	1
Unemployed	4
Retired	7
Other	2
Registered disabled (yes/no)	9/8
Current treatment	
DMARDS	18
Biologics	8
Analgesics	1
Non-steroidal anti-inflammatory drugs	1
Steroids	2

*Disease Activity Score (DAS) 28 – erythrocyte sedimentation rate.

questions that would support outpatient clinic staff to assess the effects of new treatment.

Emergent themes generated in the pilot and two focus groups

A table was formed by the patient researcher outlining the domain names, all domain descriptions from patients that corresponded with the identified domain item and the patient researcher's understanding and meaning of the accounts. See three random examples:

Domain Name	Random examples of Domain descriptions from three individual patients	Examples of patient researcher's understanding based on participants' accounts
Mobility	'a point in time came, when it [RA] was so bad that my ankles could not support me, it difficult to get out of bed' JK	Patients expect that new treatment will help to improve mobility, to gain freedom to walk for example to the park/shop.
Independence	'I cannot do things in my house at the moment, but before [diagnosis of RA] I did not need any help.' CG	Patients expect that new treatment allows patients to maintain the ability to carry out activities of daily living independently.
Patient–doctor relationship	'I was dismissed by two doctors who thought my symptoms were just in my imagination'. DW	Patients expect that when receiving new treatment they will be listen to and work in partnership with doctors.

Twenty-nine main themes emerged during the pilot and two focus groups (17 and 12 themes respectively), of which the first 14 with the highest frequencies are summarized in the frequency table (cut-off point of 20).

In Table 2, by consensus across the six held groups, the data analysis resulted in items' reduction from the original 29 to 21 of the draft scale. For example, items with similar content were condensed into one (e.g. sleep expectation was incorporated into the item asking about fatigue, and expectations about minimizing depression and mental pain were encompassed into the item emotional well-being in agreement with the focus group

Table 2 Frequency Table of first 14 items with highest frequency (cut-off point 20)

Item	Frequency
Pain	57
Treatment	55
Mobility	55
Independence	42
Patient–doctor relationship	30
Support from families and friends	28
Illness trajectory	27
Activities of daily living	26
Frustration	24
Lack of understanding in relation to RA and treatment	24
Convenience of medication	24
Measuring pain	21
Additional medical problems	22
Aids to assist with daily living	20

participants.). This process was achieved through detailed discussions with members in the repeated focus groups.

In addition, further themes with a frequency between 19 and 9 were identified, for example, personal relationships (19); embarrassment (19); side-effects of medication (18); employment (18); impact of alternative remedies (16); information about medication (15); will power (15); emotional well-being (14); physical improvement (13); comprehensive physical assessment (11); unpredictability of illness (11); change in life perspective (10); reduction in medication (9); acceptance of RA (9); unpredictability of efficacy of medication (9). The following accounts are five illustrative examples linked to the above lower-ranking themes.

> 'It [RA] shuts you off and you do not get to go out so much and that sort of ends up in a downward spiral'. MA (relates to the above theme of 'emotional well-being').

> 'It is difficult to hold something and you feel like embarrassed, you are fumbling and I am very self-conscious'. CR (relates to the above theme of 'embarrassment').

> 'I tried different homeopathic remedies, it was worth a try, it maybe helped me to control the pain… not control it but cope with it'. PR (relates to the above theme 'impact of alternative medicine').

> 'You are always ok for a limited period of time and then you need to go on something else [new treatment]'. SY (relates to the above theme of 'unpredictability of efficacy of medication').

> I have not had an examination of my joints and swelling for one year, you know'. PR (relates to 'comprehensive physical assessment').

Generation of draft measure: expert and independent expert panel

Following the above item reduction from 29 to 21 and the agreement to present the domains into three key sections, further detailed discussion and feedback were obtained from the expert panel and the independent expert panel in relation to the comprehensibility, spelling, applicability and format of the questionnaire. The aim was for the draft instrument to be self-completed by patients.

In each section of the MAPLe-RA, four random accounts are reported, with the patient identifier, single counting (in brackets) and refinement/confirmation by the expert panels for the draft questionnaire (indented text) given (see Appendix 3).

Expectations of physical impact

Pain – 'What I would like is just help with the pain and I would get a better sleep… and I would not feel so tired'. DW (12/14)

> It's good to have this in the questionnaire, you do expect to be better after treatment, especially if you weren't feeling very well you would expect an improvement on what you have been going through. (7/7)

Morning stiffness – 'Return to normal is getting rid of the stiffness in my hands and the pain goes as well'. PR (6/14)

> I think "morning" is important to put before the stiffness, you need to put morning in. (6/7)

Mobility – 'I cannot do much walking and standing anymore'. MA (8/14)

> Yeah I think this is good to put mobility in, as it is separate from your fatigue and exhaustion, although they are obviously all linked. (5/7)

Visible signs of RA (e.g. deformities in my hands) – 'The really visible signs might take a long time to develop.' BW (5/14)

> Yeah the question is good and there is an example as well that is good. (7/7)

Expectations of psycho-social impact

Maintain independence – 'My hands and wrists were so sore, I could not lift a cup of tea. I had to drink it with a spoon'. PR (14/14)

> Yes it makes people think what contributes to their independence; this item is an important point. (5/7)

Ability to work and/or stay in salaried employment – 'My boss retired and the

company decided to cut numbers and they made me redundant'. DR (11/14)

> I guess you would be hoping to go back to doing things more normally and have a proper routine, if you were working, even to get back on a part time basis. (5/7)

To feel in control of my RA self-manage (e.g. diet) / cope (e.g. frustration), alongside medical treatment – 'RA likes to say, I don't feel well today, so you have to push yourself a little bit [so you can cope].' DW (12/14)

> Taking care of your RA along medical treatment I think a lot of that is mental. Putting in examples is a good idea, so people understand the question better. (6/7)

Emotional well-being – 'I think the mental and psychological aspects have an effect on yourself, how you deal with the treatment. It is very important regarding your treatment'. RS (11/14)

> I think you should take away the word "psychological" wellbeing and replace it with "emotional," the word psychological is scary, and people may not complete the question. (7/7)

Expectations on impact of new treatment

Make me feel better overall despite side-effects – 'If treatment is well managed and I feel well most of the time that is important'. JK (11/14)

> I would say to write "feel better overall" instead of "quality of life," because some people might not understand that [phrase], particular the ones that just got diagnosed. (4/7)

To prevent other physical complications – 'Then I was having other problems…a collapsed lung, I had other problems with my chest, my stomach, my thighs, everything. It was just one thing after the other'. DW (9/14)

> Having this question [domain] after "reduce the likelihood of surgery" [domain] is good; there are obviously other physical complications, so I think that makes sense. (7/7)

Regular emotional well-being assessment – 'If you are down and depressed, your lifestyle will be affected by the condition and the treatment.' CG (12/14)

> Yeah emotional wellbeing is better than "psychosocial," nobody would understand that word, emotional covers the meaning better. (4/7)

Not to have to change medication so often – 'I've been on Sulfasalazine since the beginning of my illness. I found out about 6 months ago that it is attacking my immune system, so they wanted to change it [medication]'. BG (11/14)

> I can imagine that there are many patients who get a bit fed up with having to change medication frequently [so this point is valid]'. (5/7)

Development of scoring system

Finally, a scoring system was developed by the patient researcher in collaboration with a psycho-metrician and with the patient cofacilitator. Each dimension had five response options with a 0–5 scoring system, with the total score ranging from 0 to 105, the highest score representing high expectations of new treatment and vice versa (see Appendix 3). We chose the five-point scale as it works well for interview-based items where participants can be encouraged to think whether another option might be more appropriate rather than having a yes/no response. The focus group members emphasized that they preferred questionnaires with worded answer choices as compared to numerical responses, because these resonated better with their understanding and meaning of the question. In contrast, they perceived that numerical responses did not accurately match their degree of expectation posed in each statement. For example, when queried on preference of how to structure the answers (i.e. verbal or numerical), two-fourth of the independent expert panellists stated:

> I personally think the words, from my point of view are better, it is quite accessible for me. LB

> I think sometimes when you got the numerical scales, I know when I have done it, I have put down not necessarily how I really feel, just how I want to feel…. verbal responses are probably better. CG

Phase 2 – Feasibility study

The criteria outlined by Slade *et al.*[31] and the guidelines on feasibility studies by the NIHR Health Technology Assessment programme (National Institute for Health Research)[32] provided a useful framework to assess practicability and user-friendliness of MAPLe-RA. The draft score was brief (i.e. all patients commented on the fact that it was short in length), easy to use (i.e. all patients were able to complete the questionnaire without assistance), straightforward (i.e. the meaning of the rating was clear) and easy to comprehend by patients (i.e. few questions required clarification). On average, the completion time ranged between 5 and 10 min. Furthermore, the majority of patients commented that the content of the scale was relevant (i.e. the items of the questionnaire were salient and familiar to them), acceptable (i.e. questionnaire being perceived as probing yet unobtrusive) and available (i.e. capable of being photocopied easily by the patient researcher). Finally, the suggestions expressed by the 22 outpatient clinic attendees were incorporated by the patient researcher into the final draft scale together with continuous cross-checking with the focus group patient facilitator and departmental patient experts, for example, rephrasing the instructions and replacing: '*before I have the new treatment I expect'* to *'with the new treatment I expect'*. No further item reduction was necessary at this stage.

Discussion

In this study, we have described the two initial phases of the development of a patient-generated treatment expectancy draft measure, using a participatory methodology. Both stages were led, conducted and co-ordinated by a patient researcher in close collaboration with a focus group patient facilitator and 39 patients with a diagnosis of RA (17 focus group members/22 feasibility study participants) from a tertiary outpatient clinic. To our knowledge, this is the first one in rheumatology.

Phase 1

The findings in Phase 1 included origination of the items for the questionnaire and the generation and development of the draft scale. The 21 dimensions came about through detailed discussion and final agreement with the patient expert and the independent expert panel. The process resulted in a draft MAPLe-RA instrument with three distinctive domains: (i) physical expectations, (ii) psychosocial expectations and (iii) expectations relating to impact of treatment. The participants in the focus groups were keen to include psychosocial expectations of new treatments in the new draft measure. In their experience, these were aspects commonly not captured by routine clinical outcome measures, for example, disability, pain or fatigue scales. In Phases 3 and 4 of the MAPLe-RA development, more patients will be included. Additional statistical tests, such as exploratory and confirmatory factor analysis respectively, may further reduce some of the current questionnaire dimensions. Moreover, the majority of patients preferred worded answer choices compared with numerical responses. Such specifically expressed viewpoints may be of importance when developing instruments for patients with RA in the future.

Following each focus group debriefing, the patient researcher and focus group patient facilitator remarked how quickly the participants jelled as a group, characterized by an open and supportive atmosphere, specifically when many members disclosed painful aspects while living with RA, for example, loss of independence, loss of salaried work, living with continuous pain and fatigue. Similar observations were remarked upon in recent publications.[21,22]

Phase 2

The second phase of our study demonstrated that the five criteria identified by Slade *et al.*[35] and the NIHR Health Technology Assessment programme guidelines (National Institute for

Health Research)[36] were useful and easy to apply for our feasibility study.

Expectations as a predictor of treatment outcome

In our view, expectations for new treatment, specifically in RA, are rarely measured, despite the on-going drive for new combination therapies and new biologics therapy. Van Hartingsfeld *et al.*[15] in line with Crow *et al.*[37] identified three outcome expectations that are either treatment or patient-related, based within Bandura's social learning theory[19]: (i) beliefs that certain actions will achieve particular outcomes (e.g. taking the medication will reduce the pain); (ii) process expectations: beliefs about the content and process of interventions (e.g. side-effects of medication/detailed information from doctors); and (iii) self-efficacy expectations: beliefs in ones capabilities to organize and execute a certain course of action to achieve the required goal (e.g. exercising in order to keep mobile and reduce stiffness). The first two relate to treatment and the latter one to patients outcome expectations. The MAPLe-RA falls within the first two notions.

Impact of patient researcher's role

This study was patient-led and generated a set of expectations for new treatment that resulted in MAPLe-RA. In the context of patient involvement in research as stipulated by the Department of Health in the UK,[1] we have been able to fulfil their recommendation. The patient researcher has contributed positively from her personal experiences of living with a long-term autoimmune condition (with similarly prescribed treatment). To our knowledge, we have successfully extended patient-led research within the field of rheumatology (inflammatory arthritis).

Future work and conclusion

Full direct patient involvement in research allows the development of new research methodologies that when applied in clinical research may further contribute to patient-centred and relevant measures. Ross *et al.*[12] suggested a number of future studies that would provide further important information to clinicians, for example, what types of expectations are most likely to be influenced by the experience of the disease, exploration of the dynamics of the expectation satisfaction relationship and the extent to which expectation changes with the illness duration, that is, patients with established or newly diagnosed RA.

We are now in the process of completing Phases 3 and 4 of the study. Phase 3 will assess the reliability of MAPLe-RA, including an exploratory factor analysis. We plan for Phase 4 to incorporate the new draft instrument into a large multicentre observational study for newly diagnosed patients with RA with the aim to further assess the validity of the scale, including (i) sensitivity to change of new treatment expectations over time (18 months) and (ii) the participants' completion rate of the MAPLe-RA scale compared with five included standardized instruments.

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Conflict of interest

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Contributions of authors

Daria Hofmann conducted phases 1 and 2 of the study and wrote the first draft of the manuscript. Fowzia Ibrahim contributed to the writing and edited the manuscript. Diana Rose provided feedback to DH during the two phases of the study and contributed to the editing of the manuscript. David L. Scott provided feedback to DH during the two phases of the study and contributed to the editing of the manuscript. Andrew Cope provided feedback to DH during the two phases of the study. Til Wykes contributed to early drafts of the manuscript. Heidi Lempp co-ordinated writing and submission of the manuscript, supervised DH, advised on conduct of focus groups, on the analysis of the focus groups' data and contributed to the writing and editing of the manuscript. All authors have seen final draft of the manuscript and agreed with its content.

References

1 Department of Health. *Best Research for Best Health. A New National Health Research Strategy*. London: Department of Health, 2007.
2 National Health and Medical Research Council. Strategic Plan 2000–2003. Commonwealth of Australia. http://www.nhmrc.gov.au/guidelines/publications/nh132, accessed 6 March 2013.
3 Canadian Arthritis Network Advisory Council. Partnership. 2012. http://www.arthritisnetwork.ca/partnerships/partnerships_en.php, accessed 6 March 2013.
4 Scott DL, Lempp H. Outcomes associated with early rheumatoid arthritis. *Expert Review of Pharmacoeconomics & Outcomes Research*, 2006; **6**: 495–508.
5 Simpson C, Franks C, Morrison C, Lempp H. The patient's journey: rheumatoid arthritis. *British Medical Journal*, 2005; **331**: 887–889.
6 Scott DL, Smith C, Kingsley G. What are the consequences of early rheumatoid arthritis for the individual? *Best Practice and Research Clinical Rheumatology*, 2005; **19**: 117–136.
7 Pugner K, Scott D, Holmes J, Hieke K. The costs of rheumatoid arthritis: an international long-term review. *Seminars in Arthritis and Rheumatism*, 2000; **29**: 305–320.
8 Symmons D, Jones M, Scott D, Prior P. Long-term mortality outcome in patients with rheumatoid arthritis: early presenters continue to do well. *Journal of Rheumatology*, 1998; **25**: 1072–1077.
9 Grigor C, Capell H, Stirling A *et al*. Effect of treatment strategy of tight control for rheumatoid arthritis (the TICORA study): a single-blind randomised controlled trial. *The Lancet*, 2004; **364**: 263–269.
10 Smolen JS, Aletaha D, Bijlsma JW *et al*. Treating Rheumatoid Arthritis to target: recommendations of an international task force. *Annals of the Rheumatic Diseases*, 2010; **69**: 631–637.
11 Singh JA, Furst DE, Bharat A *et al*. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease modifying drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care and Research*, 2012; **64**: 635–639.
12 Ross CK, Sinacore JM, Stiers W, Budiman-Mak E. The role of expectations and preferences in health care satisfaction of patients with arthritis. *Arthritis Care & Research*, 1990; **3**: 92–98.

13 Oxford Corpus. *New Oxford Dictionary of English*. Oxford: Oxford University Press, 1998.
14 Barron CJ, Moffett JAK, Potter M. Patient expectation of physiotherapy: definitions, concepts and theories. *Physiotherapy Theory and Practice*, 2012; **23**: 37–46.
15 van Hartingsveld F, Ostelo RW, Cuijpers P, de Vos R, Riphagen II, de Vet HCW. Treatment-related and patient-related expectations of patients with musculoskeletal disorders. A systematic review of published measurement tools. *Clinical Journal of Pain*, 2010; **26**: 470–488.
16 Rose D, Sweeney A, Leese M *et al*. Developing a user-generated measure of continuity of care: brief report. *Acta Psychiatrica Scandinavica*, 2009; **119**: 320–324.
17 Yazdany J, Trupin L, Gansky SA *et al*. Brief Index of lupus damage: a patient-reported measure of damage in systemic lupus erythematosus. *Arthritis Care & Research*, 2011; **63**: 1170–1177.
18 Hewlett S, Cockshott Z, Kirwan J, Barrett J, Stamp J, Haslock I. Development and validation of a self-efficacy scale for use in British patients with rheumatoid arthritis (RASE). *Rheumatology (Oxford)*, 2001; **40**: 1221–1230.
19 Bandura A. *Social Learning Theory*. New York: General Learning Press, 1977.
20 Staley K. *Exploring Impact: Public Involvement in NHS, Public Health and Social Care Research*. Eastleigh: INVOLVE/National Institute for Health Research, 2009.
21 Kjeken I, Ziegler C, Skrolsvik J, Bagge J, Smedslund G, Tovik A. How to develop patient-centred research: some perspectives based on surveys among people with rheumatic disease in Scandinavia. *Physical Therapy*, 2010; **90**: 450–460.
22 Gillard S, Borschmann R, Turner K, Goodrich-Purnell N, Lovell K, Chambers M. 'What difference does it make?' Finding evidence of impact of mental health service user researchers on research into the experiences of detained psychiatric patients. *Health Expectations*, 2010; **13**: 185–194.
23 Mason R, Boutilier M. The challenge of genuine power sharing in participatory research: the gap between theory and practice. *Canadian Journal of Community Mental Health*, 1996; **15**: 145–152.
24 Rose D, Evans J, Sweeney A, Wykes T. A model for developing outcome measures from the perspectives of mental health service users. *International Review of Psychiatry*, 2011; **23**: 41–46.
25 Marshall NJ, Wilson G, Lapworth K, Kay LJ. Patients' perceptions of treatment with anti-TNF therapy for rheumatoid arthritis: a qualitative study. *Rheumatology (Oxford)*, 2004; **43**: 1034–1038.
26 Ahlmen M, Nordenskioeld B, Archenholtz I *et al*. Rheumatology outcomes: the patient's perspective. A multicentre focus group interview study of Swedish rheumatoid arthritis patients. *Rheumatology (Oxford)*, 2005; **44**: 105–110.
27 Edwards J. An exploration of patients' experiences of anti-TNF therapy. *Musculoskeletal Care*, 2004; **2**: 40–50.
28 Seale C. Using computers to analyse qualitative data. In: Silverman D (ed) *Doing Qualitative Research: A Practical Handbook*. London: Sage Publications, 1999: 154–172.
29 Fisher M. Selecting computers for qualitative analysis. In: Millsom H (ed) *IT in Social Sciences: A Students' Guide to the Information and Communication Technologies (ICS)*. Oxford: Blackwell Publishers, 1999.
30 Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qualitative Health Research*, 2005; **15**: 1277–1288.
31 Glaser B, Strauss A. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Chicago: Aldine Publishing Company, 1967.
32 Sanderson T, Morris M, Calnan M, Richards P, Hewlett S. What outcomes from pharmacologic treatments are important to people with Rheumatoid Arthritis? Creating the basis of a patient care set. *Arthritis Care and Research*, 2010; **62**: 640–646.
33 Seale C. *Using numbers. The Quality of Qualitative Research*. London: Sage Publications, 1999: 119–139.
34 Seale C. *Accounting for contradictions. The Quality of Qualitative Research*. London: Sage Publications, 1999: 73–86.
35 Slade M, Thornicroft G, Glover G. The feasibility of routine outcome measures in mental health. *Social Psychiatry and Psychiatric Epidemiology*, 1999; **34**: 243–249.
36 National Institute for Health Research, www.nihr.ac.uk/files briefing document, 2012 Version 6, accessed 6 March 2013.
37 Crow R, Cage H, Hampson S, Hart J, Kimber A, Thomas H. The role of expectations in the placebo effect and their use in the delivery of health care: a systematic review. *Health Technology Assessment*, 1999; **3**: 1–96.

Appendix 1

Table 1A Descriptions of role and research activities for Phase 1

Role	Research activity
Patient researcher	Patient with long-term autoimmune disease and research skills. Leading the focus groups and developing the draft treatment expectation measure.
Focus group patient facilitator	Patient with RA for >25 years, cofacilitated focus groups following formal written and verbal instructions by patient researcher, and collaborated in Phases 1 and 2 of the study with the patient researcher.
Departmental patient experts	Patients with RA (> 5 years) who have an honorary contract with the academic Rheumatology Department who contribute to departmental research projects.
Pilot focus group	Patients with RA who helped to refine the interview schedule and develop first draft dimensions of the draft treatment expectation measure.
Main focus group	Patients with RA who helped generate the additional dimensions of the draft treatment expectation measure and contributed to the item reduction.
Expert panel	Group of patients with RA selected from the two main focus groups to comment on the comprehensibility, feasibility, acceptability, language and format of the draft treatment expectation measure (MAPLe-RA).
Independent expert panel	Patients with RA who have not participated in the previous focus groups and have professional research experience. They provided final objective views about the new treatment expectation measure.

Appendix 2

Sequence and tasks of each focus group

Phase 1

Pilot study
Aim: Patient researcher to present the draft interview guide and to receive feedback about the relevance, understanding and comprehension of the draft interview schedule. The pilot study group generated an initial list of 17 treatment expectation domains.

Main focus groups
Aim: To generate and refine additional treatment expectation items for the draft measure. The two focus groups created extra 12 treatment expectation domains.

The pilot and two main focus groups met on two separate occasions during which the patient researcher and focus group patient facilitator cross-checked with the participants emerging themes from their accounts, that is, whether the content and the information they provided accurately captured the descriptions for the draft instrument items and its meanings. The items were reduced from 29-21 and divided into three key sections.

Independent and expert panels
Aim: To provide further suggested improvements and comments on the comprehensibility, acceptability, language and format of the draft questionnaire. Both groups met once.

Feasibility study – Phase 2

The patient researcher distributed the draft instrument to 22 outpatient attendees with RA (20 females and 2 males) over a period of one week at the Rheumatology Outpatient Clinic in a local NHS Foundation Trust.

Appendix 3

MAPLe-RA

Patient Initials

Study Number:

Date of Assessment

Even if you are not starting on new medication at the moment, please record your expectations based on your experience so far.

Please answer ALL the questions on the following pages by circling the answer which you think most applies to you.

Expectations of Physical Impact

This part looks at whether you expect new treatments to help you with the physical impact of RA such as pain, fatigue, swelling among others.

With the new treatment, I expect:

The swelling of the joints to be	Much better	Better	Same	Worse	Much worse
The pain to be	Much better	Better	Same	Worse	Much worse
My morning stiffness to be	Much better	Better	Same	Worse	Much worse
My mobility to be	Much better	Better	Same	Worse	Much worse
My fatigue to be	Much better	Better	Same	Worse	Much worse
The visible signs of RA (e.g. deformities on my hands) to be	Much better	Better	Same	Worse	Much worse
The joint damage to be caused by RA	Much better	Better	Same	Worse	Much worse

Expectations of Impact of Treatment on Emotional Well-being and Social aspects of RA

This part looks at whether you expect new treatments to help you with your emotional well-being and social aspects of RA such as your independence, employment and social roles.

With the new treatment, I expect:

To be able to maintain my independence (e.g. not needing to ask for help making tea)	Much more than usual	More than usual	Same	Worse than usual	Much worse than usual
Improvements in my general health in order for me to be able to go back to work and/ or stay in salaried employment: (Please tick here if not applicable: □)	Much more than usual	More than usual	Same	Worse than usual	Much worse than usual
My everyday activities (e.g. shopping) to be facilitated	Much more than usual	More than usual	Same	Worse than usual	Much worse than usual

To feel in control of my RA self-manage (e.g. diet)/ cope (e.g. frustration) alongside medical treatment	Much more than usual	More than usual	Same	Worse than usual	Much worse than usual
To be able to maintain my social roles (e.g. supporting family/going out with friends)	Much more than usual	More than usual	Same	Worse than usual	Much worse than usual
My emotional well-being (e.g. mood) to be	Much more than usual	More than usual	Same	Worse than usual	Much worse than usual

Overall Expectations on Impact of Treatment (care delivery)

This final part looks at your general expectations on the impact of new treatments such as number of other complications, physical assessments and treatment decision

With the new treatment I expect it:

To make me feel better overall despite side-effects	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To reduce the likelihood of surgery	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To prevent other physical complications	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To come with detailed information from the medical staff	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To allow me to be involved in the treatment decision making with the clinical staff	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To include regular physical (e.g. hands and feet) assessments	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To include regular emotional well-being assessments	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
To allow me to not have to change medication so often	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree

Researcher Initials: ☐ ☐