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ORIGINAL RESEARCH

Unmet need for patient involvement in rheumatology registries and observational studies: a mixed methods study

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ABSTRACT

Objective The contribution of patient research partners (PRPs) is well established in EULAR recommendation development. However, in observational and registry studies, PRP involvement is not well-defined and remains limited.

Methods Based on a round table discussion during the EULAR Registries and Observational Drug Studies (RODS) meeting in 2019, a mixed methods study was undertaken, including a survey to RODS participants and EULAR PRPs and focus groups with volunteers from the survey. An inductive thematic analysis approach was applied to qualitative data and descriptive statistics to survey data.

Results We retrieved 45 survey responses and ran 3 focus groups with a total of 17 participants. The notion of PRP involvement in research was positively perceived by PRPs and the wider academic rheumatology community. There is universal agreement that PRP involvement in registry research is low and inclusion in different parts of the research cycle is limited. Potential benefits of PRP involvement include: input on the research objectives based on patients' needs, advice and support regarding recruitment and retention strategies, obtaining patient views on analysis and interpretation, and assistance in disseminating results. Researchers and PRPs highlighted that education, inclusion of PRPs with diverse backgrounds and a welcoming environment as important facilitators for PRP involvement. On the other hand, preconceptions of researchers and insufficient budget allocation have been identified as barriers.

Conclusion There is an unmet need to involve PRPs in registries and observational studies and to better define their required input during all research stages. This study provides suggestions for successful PRP integration.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patient involvement has been successfully implemented in core outcome set development and the development of management recommendations.

⇒ There is a need to better integrate patients within the research team of registries and observational studies and to better define their role.

WHAT THIS STUDY ADDS

⇒ Patients can provide meaningful input in the management of registries, all the way from setting up a register and outcome selection to data analysis and dissemination.

⇒ The barrier of patient research partner (PRP) inclusion from diverse backgrounds can be overcome by appropriate remuneration.

⇒ Barriers to PRP inclusion in different stages of registries and projects nested in these can be mitigated by education and training in collaboration with patient organisations.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The learnings from our research may help dismantle institutional barriers to integrating PRPs in observational research.

⇒ Engaging PRPs in registries and at different levels will increase the relevance of outcomes, the understanding of research among patients and patient recruitment, while reducing data missingness.

INTRODUCTION

In rheumatology, there is a growing recognition of the importance of including the views of people with rheumatic and musculoskeletal diseases (RMDs) in research projects.[1] For developing core outcome sets[2] and for recommendations,[3] the involvement of patient research partners (PRPs) has become common practice. Even more, the EULAR does not grant support to task forces without PRPs. This is not the case for other research fields or methodologies, such as clinical trials[4] or observational studies and registries, the latter being of particular importance to EULAR.

PRPs operate as active team members on an equal basis with professional researchers, adding their experiential expertise to the benefit of their experiential knowledge on the

target disease. Experiential knowledge can be described as the knowledge that relates to a person's condition, as well as the impact of the condition on all areas of life, including social relations and experiences with healthcare. Experiential expertise is the skills and attitudes that are needed to collaborate effectively in the context of scientific research.

The integration of PRPs evolved during the last 20 years and may seem to be the obvious approach in a set of conditions, which are traditionally chronic and require long-term treatment. After the recognition of the value of patient-reported outcomes,[5] followed the realisation that these outcomes might even be more useful when incorporating patients in the design process.[6–8]

The rheumatology community finds appreciation for the milestones achieved in collaborative research but, in many areas, effective strategies for engaging with patients need to be developed and implemented.[9] At the third EULAR Registry and Observational Drug Studies (RODS) meeting in 2019, the issue of lack of adequate PRP engagement in registries was raised, prompting the undertaking of this project.[10] Participants noted that there is little guidance for researchers on how to deploy strategies for patient involvement. Active discussions during RODS, and important input from patients, identified uncertainty and unmet needs and inspired the undertaking of this study.

Of note, the RODS meetings aim to provide insights into practical and methodological aspects of RODS, data handling and analysis, promoting and facilitating collaborative work through a series of interactive lectures, workshops, and round table discussions. Registries are critical to providing data on pharmacovigilance and have become the norm after a pharmaceutical product is authorised.[11 12] In rheumatology, there is proven competency in setting up efficient registries.[13–17]

Our objective was to understand the patient role in registry and observational study design, development and management, and to identify barriers and facilitators to their involvement.

METHODS

A mixed methods approach was followed, including an online survey based on the findings of the round table discussion during the RODS meeting and three online focus groups. We choose an explanatory sequential design, meaning that the quantitative data collection took place before the start of the qualitative data collection and analysis. We chose this design to have the qualitative data helping to explain the quantitative data and put it in a better context. Triangulation was carried out by synthesising survey data and results from the focus groups analysis.

Table 1 Survey participants (n=45)

Primary background	
Persons living with a rheumatic and musculoskeletal disease	19
Academic researchers	17
Rheumatologists	17
Health professionals	3
Regulator	1
Research nurse/clinical research manager	1
Head Research National Patient Organisation	1

Research team

The research team was comprised of two faculty members of the EULAR RODS course (LC, EN), one tutor and patient expert (MdW) and one independent researcher (PS), all with extensive expertise in both quantitative and qualitative research. An experienced researcher in qualitative research (MS) completed the data analysis of the transcripts of the focus groups. A series of research team meetings were undertaken to discuss the results.

Survey

An online survey was developed based on important questions raised during the discussion at the RODS meeting. These questions included six on the extent of implementation of patient involvement in registries, its perceived value and potential benefits and barriers. The last question asked respondents whether they were willing to provide additional input. Two questions related to personal characteristics (primary background and country of residence) (online supplemental 1). Participants from the second (2015)[18] and third (2019) EULAR RODS course, a selection of principal investigators involved in registries, and the members from the EULAR network of PRPs, were invited to complete the survey.

Focus groups

Survey respondents who provided their names were invited to take part in a 1-hour virtual focus group meeting. The invitees were allocated in a group with only PRPs, a group with only rheumatology researchers or a mixed group (convenience sampling). Participants were not aware of the different composition of the focus groups. We developed one semistructured interview guide for all three focus group sessions informed by the survey results. This guide centred around successful stories, good practices and potential pitfalls (online supplemental 2). Each focus group took place virtually and was moderated by two team members (as pairs: PS, EN, MdW, LC). The recording was transcribed verbatim and subjected to thematic analysis.

Analysis of the focus group data

Prior to data analysis, the transcripts were circulated to the focus group facilitators to read and check for accuracy. An inductive thematic analysis approach was chosen to identify and describe patterns in data.[19] Data analysis was completed in NVivo V.12, using a multistage coding process consisting of six key phases: (1) familiarisation with the data; (2) generating preliminary codes—these

were identified from verbatim quotes from the transcripts; (3) developing potential themes, based on the preliminary codes; (4) reviewing the themes, for which the primary coder seek discussions with the research team to ensure that all the significant responses were extracted and allocated to appropriate groupings with the greatest possible interpretive depth; (5) labelling the themes; and (6) conducting the write-up of the analysis.

RESULTS

The outcomes of the survey followed by a summary of the analysis of the focus group discussions are presented below.

Survey insights

Out of 45 surveys returned, complete responses were received by 35 participants. Almost half of the surveys received were from PRPs (n=20); one was from a regulatory officer (table 1). Participants came from 21 European countries and 1 from Australia.

The involvement of PRPs was perceived to be important in registry research (mean importance on a 100 mm Visual Analogue Scale (VAS)±SD: 75±24 mm, among 41 respondents). Five respondents set their importance mark below 50 mm. The level of patient involvement in registries and cohorts was perceived as low (32±20 on a 0–100 VAS), with 12 out of 40 not having experienced at all PRP involvement in these studies.

The most common current practice (each around 30% of 41 respondents) was to involve PRPs in the design of studies or even the management board, and cooperation with patient organisations for recruitment (table 2).

An indication on which phase of the research cycle PRPs could be involved in was obtained from 36 respondents in open text boxes, summarised in figure 1. Eleven respondents provided suggestions that could not be attributed to the research cycle, for example, consulting, survey studies or offering research seminars. Another 11 participants stated that PRPs need to be involved in all stages. The majority of free text responses pointed out the need to involve PRPs during study preparation and data collection. Help in the interpretation of findings was also mentioned.

Table 2 Current practices of involving patients and patient research partners in registry studies (n=41)

Practices	n (%)
None	12 (29)
I have undertaken patient interviews	7 (17)
I have conducted patient focus groups	11 (27)
I have worked with patients in designing these studies	13 (32)
I have involved patient organisations in the recruitment of study participants	13 (32)
I have involved patients in our research or management team	13 (32)
Others	12 (29)

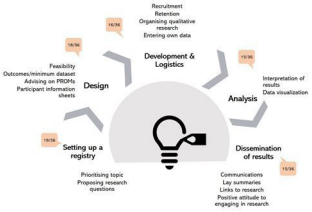

Figure 1 Suggestions from 36 survey participants on specific tasks in which patient research partners could be involved in the research cycle of registries and observational drug studies. The suggestions were simplified and conceptualised to fit in the figure. The numbers in the speech bubbles represent the number of respondents that mentioned potential involvement in the corresponding phase. PROMs; patient-reported outcome measures.

Several respondents highlighted the importance of patients being part of the steering or scientific committees of registries or to act as independent advisors if the registries wanted to capture their perspective. Moreover, some mentioned that the only way to achieve this would be to make a prerequisite that patients are included in the boards. This way they will also have access to research updates and any challenges.

Responses were received on potential benefits and barriers by 41 survey participants (figure 2). A lack of awareness of the benefits was regarded as the most important barrier, whereas poor previous experience with PRPs was regarded as the least important one. Regarding benefits, over 50% of respondents indicated that relevant outcomes and research questions, better understandable patient information material and improved recruitment, were all important.

Differences between the perceived potential benefits and the actual involvement of patients demonstrated that there is an unmet need to engage with patients when designing, developing and maintaining registries and observational studies.

Focus groups insights

In the three focus groups, 17 rheumatology researchers and PRPs from 14 different countries across Europe (the Netherlands, Greece, Italy, Austria, Denmark, Portugal, Sweden, the UK, Spain, France, Romania, Switzerland, Germany and Cyprus) participated. Table 3 provides an overview of the focus groups participant composition. We refrain from presenting further personal details, since deidentification of participants would be likely. In the researcher as well as the mixed group, one participant did not attend due to time constraints.

Table 4 presents an overview of the main themes, subthemes and the corresponding focus group in which each of the themes and subthemes were identified. Data were analysed and grouped into 5 main themes and 17 subthemes. These are discussed in more detail below, with supporting quotes.

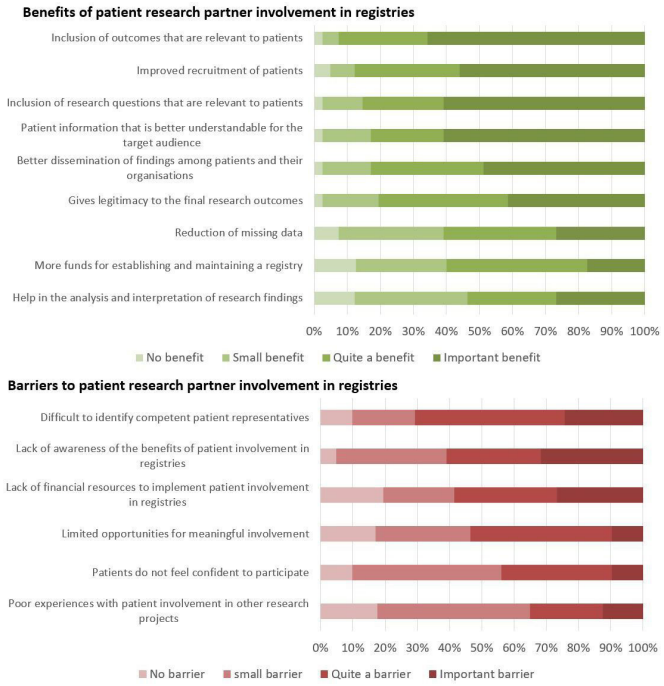

Figure 2 Survey results on benefits and barriers of patient research partner involvement, in order of importance.

Current experiences of PRP involvement in research

Researchers' experiences of involving PRPs

Researchers discussed at length their experiences of involving PRPs in research. Experiences described included: involving patients in priority setting, identifying important outcomes and involving them in the planning and dissemination phases of studies. Example quote:

> I've had a few occasions running meetings about the research with only the patients and myself, for priority setting and research setting. That's been a hugely fruitful experience because they were given free range to say whatever they wanted. (R08)

Patients' experiences of being involved as PRPs

Patients described their individual experiences, for example, being part of various committees providing feedback on importance and relevance of outcome measures, how data should be collected, as well as helping with recruitment and dissemination of results. Example quote:

> What I do in the steering committee is provide feedback on the outcome measures that are registered in the registry. I give my opinion on what's relevant and important from a patient perspective, and how often things should be measured, and how the data should be collected. (P13)

Table 3 Focus groups participants

Participant ID	Focus group	Role
R01	Researchers	Academic researcher
R02	Researchers	Rheumatologist
R03	Researchers	Academic researcher
R04	Researchers	Rheumatologist
R05	Researchers	Rheumatologist
R06	Researchers	Rheumatologist
P07	Mixed	Health professional (working in patient organisation) representing PRPs
R08	Mixed	Academic researcher
R09	Mixed	Rheumatologist
R10	Mixed	Rheumatologist
R11	Mixed	Academic researcher
R12	Mixed	Rheumatologist
P13	PRPs	PRP trained by EULAR
P14	PRPs	PRP trained by EULAR
P15	PRPs	PRP trained by EULAR
P16	PRPs	PRP
P17	PRPs	PRP

PRP, patient research partner.

The role of PRPs in registries and research

Complementary perspectives between researchers and PRPs

Across all three focus groups, participants emphasised the importance to understand the purpose of patient involvement in registries and research more generally. Participants felt that often there is added value in complementing the view and knowledge of researchers by asking patients for their input. Example quote:

> I think that the patient's perspective and the doctor's perspective are complementary views of the same problem. So, if we want to have a global view of the disease, we need to incorporate both perspectives and not neglect one part of the perspective. (R06)

> We have the same objectives, we all want benefit for the patients, the best kind of treatment, that involves the patient, from a social point of view, from a health point of view, and from a psychological point of view. Once we realized that we are not against the doctors, we are with them, but we just have a different perspective then it worked very nicely. (P17)

The aim of patient involvement in research

Within the researcher only focus group, participants acknowledged the importance of involving patients in the setup of research projects and registries as this can enhance patient involvement further along the research process. Example quote:

> I see it as an important set-up process in involving patients when establishing a research project. If you discuss the proposal with the patients, you get more reliable outcomes, and then you will have, of course, more rapid involvement from patients. (R04)

Table 4 Overview of themes, subthemes and focus groups in which these were identified

Themes	Sub themes	Focus groups		
		Researchers	Mixed	PRP
Current experiences of PRPs involvement in research	Researcher experiences of involving PRPs	X		X
	Patient experiences of being involved as PRPs		X	X
The role of PRP in registries and research	Complementary perspectives between researchers and PRPs	X	X	X
	The aim of patient involvement in research	X		
Points to consider for involving PRPs in research	Consider professional and social backgrounds of PRPs		X	
	Provide PRPs education and training		X	X
	A welcoming environment for PRPs to contribute		X	X
PRP involvement in different phases of the research process	PRPs as members in research committees	X		X
	Identify questions that are most relevant to patients	X	X	
	Select the most relevant outcomes to patients	X		X
	Improve recruitment strategies		X	
	Analysis, interpretation, and dissemination of results	X	X	
Barriers and challenges to involving PRPs in research	Recruiting PRPs from ethnic minorities		X	
	Researchers' preconceptions of patients' ability to be involved in research	X		
	Help analyse or interpret quantitative data	X		
	Limited financial resources	X		

PRP, patient research partner.

Points to consider for involving PRPs in research

Consider professional and social backgrounds

In the mixed researcher and professionals focus group, participants felt it was important to include PRPs from a range of professional and social backgrounds. Patients would not only be beneficial in describing their lived experiences of their clinical condition, but in some instances, they may also provide additional insights to research based on their educational and professional expertise. Example quote:

> It might be an advantage to have patients with different degrees of education and understanding of the problems, I think that it's very important to find the right person to be involved in projects. (R11)

> Often people bring something to the table. Sometimes a patient is a lawyer, and he may know about legal aspects, or he knows more about communication than doctors typically do. So, it is best that the patient has certain expertise that they can bring something to the group that wouldn't be there if he or she wasn't there. (R12)

Provide PRPs education and training

Participants across all countries within the researchers and professionals focus group, and PRPs only focus group emphasised the importance of providing training and educational resources to support and enhance patient involvement in research. An example quote by an academic researcher is shown here:

> So, thinking how patients might be involved, I think the answer should be education. We have to educate our patients and I think that the easiest way to do that is through patient organisations. They are able to get patients together to educate them, of course, with our help, and I think that should be one way to do it. (R11)

Similarly, a PRP highlighted the importance of receiving training to aid their own involvement in future research:

> Can I have a workshop or a course, on registries for patient research partners? Because I think this will be very useful, to involve myself in the future in research. (P14)

A welcoming environment for PRPs

Within the mixed and PRPs only focus groups, participants highlighted the importance of researchers creating a safe environment for PRPs and patients, to ensure they feel accepted in various settings and that they feel comfortable to share their views and ideas. It is a responsibility of the researcher to enable PRPs to provide the input necessary for the project. An example quote by a PRP who describes the experience of a researcher making an effort to prepare the PRP for participating in this project, is shown here:

> I had a long telephone call with the leader of the project, and he gave me an explanation of this

project and of other things I wanted to know. It was very good when we had this meeting. That's a thing that helped to feel accepted, to get the explanation because I am not a specialist in this field and to also be asked questions. Another thing that helps is if there is another patient, and I am not the only lay person on advisory boards. (P13)

An academic researcher also echoed the importance of creating a comfortable environment:

I would imagine that it could be very intimidating for patients to suddenly come and sit around a table with a bunch of doctors and professors. To suddenly think "these people want to hear my opinion" might be a very different experience for them. We would love for them to come and be part of our discussions but it's how we set the environment that makes it a welcoming place for them to want to come. (R08)

PRP involvement in different phases of the research process

Across all three focus groups participants identified a range of opportunities for involving PRPs and patients more widely in the different phases of the research process.

PRPs as members of research committees

Participants felt patients should have the opportunity to participate in committee meetings, to identify ethical issues as well as to enhance their understanding of why certain data is being collected. An example quote by a PRP (trained by EULAR) is shown here:

The point of the registries is to have access to patient data. It is very important to who you give permission to change data, because it is our data at the end of the day. So, we should have an opportunity to be part of ethics committees and decide how our data is disseminated, to whom you give permission to use the data and for what reason they use the data. (P15)

A similar viewpoint was shared by another patient:

I think a patient should be there from the very beginning and have a seat in the board. To also work on the consent form also and help make all the questions as lay as possible. We should also explain the reason why we are collecting the data and that the only owner of the data is the patient himself or herself. (P16)

Identify questions that are most relevant to patients

Within the researchers only and mixed focus groups, participants felt patients should be included from the design phase of a project, so that they can be involved throughout the research cycle, specifically in helping identify research objectives. Example quotes:

I think that the input of patients is very important when we phrase questions and having input when discussing the selection of variables that we collect or outcomes that we want to study. (R01)

I think it's important for future projects to involve patients as research partners to get reliable research questions, and to get questions which are of importance for the whole community, not only for physicians, but also for patients and their relatives. (R04)

Select the most relevant outcomes to patients

Both researchers and PRPs considered that involving patients in the decision of selecting patient reported outcome measures and other data would be an advantage in helping to identify potential problems with measures selected, as well as helping to enhance the quality of data collected. Example quote:

Patients can be involved in the selection of PROs or outcomes. They can have their opinion of how best to phrase questions, or how to improve the clarity of some of these questionnaires. They can provide guidance on which circumstances it is best to complete the questionnaires, is it best during a phone conversation or while waiting for their visit and monitoring by the physician. (R02)

Improve recruitment strategies

Within the mixed focus group, participants identified that patients and patient organisations can help enhance recruitment to research studies. For example, a patient organisation representative stated:

We are contacted by researchers more or less all the time to get patients involved in their research. So, we help them to recruit through our social media or through the magazine that we give out via websites, or special interest groups. (P07)

Similarly, an academic researcher described their experience of working with a national patient association to help with recruitment:

So, for the rheumatoid arthritis registry we use the national patient society and they put adverts in their magazine 'If you're starting a biological ask your rheumatologist about the register'. You need ethics to do everything but if the patient group does it, we can get around it. (R08)

Analysis, interpretation and dissemination of results

Researchers and PRPs considered that patients can provide important input (face validity; reality check) within the analysis stage of a study, as well as discussing initial findings, prior to dissemination through patient organisations. Example quotes:

I think that the inclusion of patients in analysing data can help add extra value and help legitimize results of the research. Patients are important in helping to interpret the results, because they can provide their

own views, or how this can have an impact on their lives or their disease from their own perspective. (R02)

Patients have also been very good at helping us with the dissemination of our results, so we frequently write articles for their magazine, which they send out. (R08)

Barriers and challenges to involving PRPs in research

Four main barriers to involving PRPs in research were identified within the researcher and mixed focus groups.

Recruiting PRPs from minorities

Challenges in identifying patients from a range of ethnic backgrounds and educational background results in a limited representation. Example quote:

We have a paucity of black ethnic minority patient representatives, people who may not be educated, they're just not represented at all. (R08)

Researchers' preconceptions of patients' ability to be involved in research

Researchers also acknowledged that their own preconception of involving patients in research may inhibit future involvement of patients in studies. Example quote:

Do we have some preconceptions about the patients' literacy, or is it that patients are not used to participating in partnerships regarding research? So, because we feel they are not used to being involved we do not ask them or is it that we do ask them to get involved? Probably both things occur. (R06)

Reluctance to ask patients to help analyse quantitative data

Researchers also thought that it is unfair or not always feasible to include patients in the analysis of quantitative data because of the skills required. Example quote:

If you think statistical analysis, it's very technical. I think it's very difficult to use patients because I think it takes statistical knowledge. It would require enormous knowledge of patients and I'm not sure if that is possible or feasible. (R01)

Limited financial resources

Limitations in offering financial resources for involvement in research were also identified as a barrier. Researchers acknowledged the difficulty in finding patients of working age, they would need to take time of work to participate in meetings. Example quote:

If patients are working full-time, it's hard to come to meetings during the day. For me, this is my job, but for patients this is an extra thing they do. So, I think that has often been an issue. We now offer financial remuneration. It might pay for a day's leave from work, but this isn't the case across the board for patients involved in research. (R08)

DISCUSSION

This study highlights the value of patient engagement in the design and management of registries and observational studies and encourages researchers to develop local strategies for active PRP participation. Potential barriers and facilitators for PRP involvement in all stages of the research cycle are identified and discussed. Other studies have highlighted the importance for any patient registry to serve its aims by ensuring the right objectives, the right data collection for the right patient and in the right way.[20]

What is striking is that there is a discordance between the enthusiasm of participants in the study for PRP engagement in observational and registry studies and the current reality of patient involvement in registries and observational studies. Yet, it is reassuring that the notion of PRP involvement was received with enthusiasm within the rheumatology academic community. Our findings call for realistic efforts to address the unmet need of patient and PRP engagement in the design and management of rheumatology registries. Our study supports that patients have an important role to play in every stage of the research cycle (figure 1), from inception (research relevant to patients), to study design (feasibility, setting outcomes, PROMs, participant information sheets), logistics (to optimise recruitment and retention), analysis and interpretation to dissemination (communications, checking or developing lay summaries).

This is in line with examples of best practices of patient-focused designs and strategies in rare diseases to address the challenges of long-term follow-up of patients.[21 22] Strategies to ensure data completeness and patient retention in these rare disease registries help fulfil pharmacovigilance requirements, and answer questions relevant to patients and their families. Various modes of data collection are possible; the implementation of remote tracking applications for data input into registries is one example. For instance, an electronic, remote tracking system can enable monitoring of patients on anticoagulation therapy.[23] This remote monitoring puts the patients in charge of their monitoring, making them their own assessors and giving them, at least in part, ownership and responsibility for their condition. Additionally, it entails benefits from the researchers' perspectives since it also reaches patients for whom only incomplete data would otherwise be available due to poor clinic attendance.

The undertaking of this study was inspired by the desire among rheumatology researchers and PRPs to evaluate PRP involvement in the design and running of registries, with the ultimate aim of maximising PRP engagement and experience. During the RODS meeting, and as also confirmed by the survey and the focus groups as part of this study, we identified a discrepancy between reported relevance of patient involvement and current practice: it is evident that we could be doing better. There is a clear need to increase awareness into the benefits of participation of patients in registries among the rheumatology community, in line with the findings

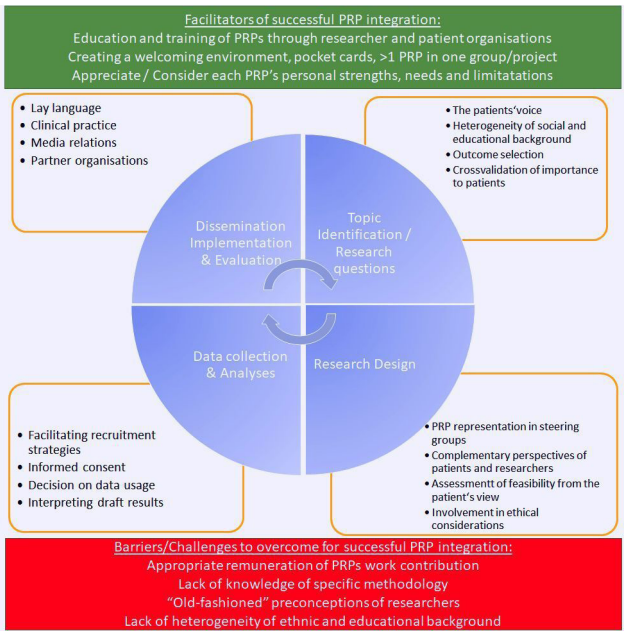

Figure 3 Overview of patient research partner (PRP) involvement in the domains of the research cycle as well as facilitators and barriers of successful PRP integration based on the qualitative analyses of focus groups.

of other studies.[24] There is also a need to prevent tokenistic approaches of engagement by exploring potential barriers and challenges of PRP involvement and ways to overcome them. Based on the empirical research cycle, we have mapped potential contributions that patients and PRPs can provide when adequately involved and supported. This integrated view on roles within the steps of research is highly beneficial, as it may guide the development of meaningful and feasible relationships between researchers and PRPs (figure 3). Acknowledging the value of patient registries in improving patient outcomes, inherently makes patients the key allies to ensure that the overarching aims and objectives align to unmet need.

However, implementing patient and public involvement (PPI) strategies is challenging because there is no 'one-size-fits-all' of PPI for all types of research. This is also true for registry studies. More research is needed to provide greater insights in the feasibility and limitations of PPI in different research stages. During the focus groups, PRPs emphasised the need to include their voice in strategic decisions and outcome selection. Our researcher focus group touched on involvement of PRPs throughout the research process, although the challenge of coanalysing data with PRPs was also pointed out. We believe that PPI is possible during all stages of research although the inclusion of PRPs into all phases of a registry project may be hindered by cultural and institutional barriers. For instance, researchers' preconceptions about the patients' ability to understand and be involved in more complex research settings, in particular in the phase of analysing quantitative data, may be associated with the under-representation of PRPs in registries. To change these beliefs is difficult in organisations that have not considered facilitating patient involvement and in which it is simply not part of organisational culture involving patients as partners in a project. It requires a change of mindset from the researchers and the patients that collaboration in research is feasible and valuable. Institutional barriers can be various such as lack of guidance, lack of commitment from the leadership, lack of training and support for researchers to develop effective strategies for patient involvement, lack of guidelines for developing budgets for PPI, the absence of incentives for engaging patients in research projects and finally no procedures to provide renumeration for PRPs.[25] But we may also consider barriers arising from patient organisations. The structure and internally set goals of the latter may also hamper effective communication between patient representatives and researchers. It is hoped that full integration of PRPs in scientific projects will become more common once sustainable relationships are built and maintained, alongside capacity building.

An important requirement for successful PPI is the establishment of a welcoming environment for PRPs to contribute. This can be accomplished by exchanging mutual expectations between PRPs and researchers, small preparatory meetings and the involvement of at least two PRPs. By adhering to basic rules of hospitality, and using plain language or terminology cards, PRPs can provide invaluable input in multiple areas and research stages. In addition, support, education and appropriate acknowledgement of contributions increases the motivation and empowerment of both researchers and PRPs (figure 3).[26] Our findings might be applicable to any research that involves patients, beyond observational and registry studies. Specifically, the approaches outlined in figure 3 could potentially empower and enhance PRP integration in any other research setting, including clinical trials.

Our study is limited by the small sample sizes, especially of the survey. Furthermore, our choice of focus group set-up, deciding on the conduction of three focus groups upfront, excluding the option to continue with focus groups until data saturation would be reached, by already analysing transcripts in parallel. Even though our results were based on responses of investigators from across Europe, who participated during the EULAR RODS meeting, they might still not be fully representative of views of all observational researchers or settings of PRP engagement. However, the main analyses of transcripts have been carried out by a scientist not involved in the design of the focus groups or the conduction, enabling a more unbiased analytic approach. Participants of focus groups have been recruited via the survey on a voluntary basis. This might have introduced a selection bias, to retrieve more positive voices on PRP involvement, because of the general interest of the participating researchers. At the same time, targeting the survey also to most of Europe's main principal investigators (21 countries) of registry and observational studies, potentially ensures a real-life representation of current status.

In conclusion, the notion of more active PRP engagement across all stages of the research cycle has received positive responses from within the rheumatology community and opens doors to many opportunities for researchers and patients to work and learn together through innovative ways of real-world data collection and evidence building. With this publication, we call on researchers to prioritise patient involvement in registries as a starting point. Not only experienced PRPs but also young people and representatives from minority or deprived groups who are often excluded from RMD studies should be approached.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants but as we invited only investigators and patient research partners of whom we did not collect any medical information and whose roles are nowadays accepted as research experts, we deemed permission from a medical ethics review committee not necessary. Informed consent was obtained from all focus groups participants. Exempted this study, participants gave informed consent to participate in the study before taking part.

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