EULAR Points to Consider (PtC) for designing, analysing and reporting of studies with work participation as an outcome domain in patients with inflammatory arthritis

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INTRODUCTION

Earlier diagnosis and more effective treatment strategies have improved work outcomes in patients with inflammatory arthritis (IA), including presenteeism, sick leave and, to a lesser extent, employment rates. However, work participation (WP) remains lower compared to the general population.1,2 For patients with IA, retaining work or (re)gaining a job is relevant to their life3 and an important treatment goal.4 From a societal perspective, participation in paid work contributes to each country’s gross domestic product, and many (costly) innovations in IA can only approach cost-effectiveness when improvements in health are matched by improvements in long-term workforce participation.5,6

To bridge the WP gap with the general population, EULAR’s current strategy states that by 2023, EULAR’s activities and related advocacy will have...
increased participation in work by people with rheumatic and musculoskeletal diseases (RMDs). This requires actions within the healthcare system, but also at the level of workplaces and policies. To ensure efficient actions, high quality evidence from interventional and observational studies is needed.

WP studies face challenges that have been repeatedly highlighted in reviews of studies with WP as an outcome domain. Identified issues relate to heterogeneity of definitions and measures to assess WP across studies. The role of contextual factors that modify or confound the outcome is often ignored. Sample size calculation specifically for the work outcomes and other methodological aspects are neglected and reporting of outcomes is often heterogeneous. To overcome such limitations that hamper correct interpretation, guidance for conducting and reporting studies with WP as an outcome are a first step. However, no such guidelines exist for studies on WP in RMDs.

To fill this need, a EULAR taskforce was convened. The aim of the taskforce was to formulate Points to Consider (PtC) for the design, analysis and reporting of studies in patients with IA with work as a primary or secondary outcome domain. The target users of these PtC are researchers and any other persons that plan, conduct, analyse and critically appraise studies with WP as an outcome domain in patients with IA.

METHODS

Following approval by the EULAR Executive Committee, the convenor (AB) and methodologists (SR and PP) led a taskforce guided by the 2014 EULAR Standardised Operating Procedures, while being also aware of the Developers of Health Research Reporting Guidelines.

At the first meeting, the taskforce decided the focus within IA would be on rheumatoid arthritis (RA), peripheral and axial spondyloarthritis (axSpA), psoriatic arthritis and adult patients with juvenile idiopathic arthritis. The definitions of participation and employment, central concepts to the current initiative, were specified following the WHO: participation: an active engagement in a life situation; employment: being employed or self-employed for a specific period in time (even as short as 1 day) to deliver products or services for compensation as wage, salary or in kind. While outcomes such as employability, work (in) stability, and satisfaction with work can be relevant, they do not reflect active engagement in a production process (but the subjective experience) and thus are beyond the scope of these PtC. The taskforce also proposed to include unpaid work, as this is a relevant aspect of work participation for an even larger group of patients, and further emphasised that the PtC explicitly serve as an extension of existing reporting guidelines (eg, Consolidated Standards of Reporting Trials (CONSORT)) and assume adherence to them. The group agreed on 24 topics of concern across several methodological areas: study design; outcome domains; outcome measurement instruments; contextual factors; data analysis, reporting of results and work productivity costs (online supplemental table S2), and decided to perform two systematic literature reviews (SLRs) and two surveys. The first SLR included prospective studies with WP as an outcome domain in patients with IA and aimed at critically appraising methodological choices and heterogeneity across studies. The second SLR was an overview of reviews addressing SLRs of studies with WP as an outcome domain in chronic diseases other than IA, and focused on finding new aspects not yet identified by the taskforce or in IA studies. SLR findings have been published in an accompanying paper. The first survey was conducted among professional organisations to identify other similar (unpublished) recommendations/guidelines beyond rheumatology. The second survey was conducted among experts on WP to identify other relevant methodological areas/topics (online supplemental tables S1 and S2). The SLRs and surveys resulted in 16 topics within four areas: study design, work outcome domains and measurement instruments, data analysis and reporting of results.

At the second meeting, the taskforce members formulated the PtC based on evidence from the two SLRs, findings of the surveys and expert opinion of taskforce members following a process of discussion and voting. Consensus was accepted if >75% of the members voted in favour of the PtC in the first (or >67% and >50% in a second and third) round. After the meeting, the levels of evidence derived from the SLRs following the standards of the Oxford Center for Evidence Based Medicine were added to each of the recommendations. Finally, each taskforce member anonymously indicated the level of agreement (LoA) via email (numeric rating scale ranging from 0=’do not agree at all’ to 10=’fully agree’). The mean and SD of the LoA as well as the percentage of taskforce members with an agreement ≥8 are presented.

Based on the gaps in evidence and the issues of controversy, a research agenda was formulated. The final manuscript was approved by the EULAR Executive Committee.

RESULTS

The taskforce agreed on two overarching principles and nine PtC (table 1).

Overarching principles

1. WP is important for people with inflammatory arthritis, their families and society as a whole.

2. There are unique methodological aspects around designing, analysing and reporting studies with WP as a primary or secondary outcome that require specific attention.

Points to consider

1. In studies with WP as primary or secondary outcome the study design, the study duration and the choice of WP outcome domains and measurement instruments should be considered in relation to the work-related study objective.

WP studies can serve a variety of objectives, such as developing risk-identification tools to predict adverse work outcomes, proving effectiveness of pharmacological or non-pharmacological interventions, assessing the impact of costs of work productivity loss in economic evaluations and so on. While each study objective requires a specific design, non-pharmacological interventions pose additional challenges related to contamination of the intervention, problems with double blinding, difficulty controlling for confounders, and long lag times for some outcomes. For these studies, strengths and weaknesses of various semieperimental study designs should be weighted. Next, careful consideration should be given to the target population as different WP outcomes may apply to distinct (sub)populations. For example, when the aim is to assess the impact of a certain treatment on employment, all persons below the age of retirement are the target, whereas for a study on the impact of treatment on sick leave, employed persons are the target. Additionally, some studies might wish to target specific patients, for example, those with short disease duration; with low educational level; doing manual work; or with low self-management skills, requiring specification of eligibility criteria. Further, interpretation of the work outcome(s) depends on the participation rate in...
Table 1  EULAR Points to Consider when designing, analysing and reporting studies with work participation as a primary or secondary outcome domain: LoE, SoR and LoA

| Overarching principles                                                                 | LoE (0–5) | SoR | LoA (0–10) | Mean (SD) | % with score ≥8 |
|----------------------------------------------------------------------------------------|-----------|-----|------------|-----------|-----------------|
| 1. Work participation is important for people with inflammatory arthritis, their families and society as a whole. | n.a       | n.a | 9.6 (0.7)  | 100       |                 |
| 2. There are unique methodological aspects around designing, analysing and reporting studies with work participation as an outcome that require specific attention. | n.a       | n.a | 9.5 (0.7)  | 100       |                 |

Points to consider

|                                                                 | LoE (0–5) | SoR | LoA (0–10) | Mean (SD) | % with score ≥8 |
|----------------------------------------------------------------|-----------|-----|------------|-----------|-----------------|
| 1. In studies with work participation as primary or secondary outcome the study design, the study duration and the choice of work participation outcome domains and measurement instruments should be considered in relation to the work-related study objective. | 5         | D   | 9.7 (0.6)  | 100       |                 |
| 2. In studies with work participation as primary or secondary outcome, the power to detect meaningful effects deserves particular attention as work participation outcomes may not apply to the entire study population. | 5         | D   | 9.6 (0.8)  | 96        |                 |
| 3. The work participation outcome domains (eg, work status, absenteeism, presenteeism) should be clearly defined and assessed with validated measurement instruments. | 5         | D   | 8.6 (0.8)  | 91        |                 |
| 4. Key contextual factors (eg, job type, social security system), that is, contextual factors that are highly likely to confound or modify work participation outcomes, have to be identified upfront, considered in the study design and appropriately accounted for in the analysis. | 5         | D   | 9.1 (1.3)  | 87        |                 |
| 5. Interdependence among different work participation outcome domains (eg, between absenteeism and presenteeism) should be taken into account in the analyses. | 5         | D   | 9.4 (0.8)  | 100       |                 |
| 6. Populations included in the analysis of each work participation outcome domain should be specified and relevant characteristics described. | 5         | D   | 9.1 (1.3)  | 83        |                 |
| 7. In longitudinal studies work status should be regularly assessed and changes reported. | 5         | D   | 9.3 (1.0)  | 91        |                 |
| 8. Reporting both aggregated results (eg, mean/median) and proportions of individuals based on predefined meaningful categories (eg, no sick leave) should be considered. | 5         | D   | 9.3 (1.6)  | 91        |                 |
| 9. In studies assessing costs of changes in work participation, volumes of work productivity (eg, days, hours) should also be reported. | 5         | D   | 9.3 (1.3)  | 91        |                 |

LoE: 1–5 (5 indicating evidence from expert committee reports or opinions and/or clinical experience of respected authorities, and/or evidence extrapolated for quasi experimental or descriptive studies)\(^\text{15}\); SoR: A to D (D indicating troublingly inconsistent or inconclusive studies of any level).\(^\text{18}\)
LoA, level of agreement; LoE, level of evidence; n.a, not applicable; SoR, strength of recommendation.

the general population. It is useful to reflect in the design phase whether population benchmarks for sick leave, work disability and employment status are important and feasible. Crucial in any design is the choice of the outcome domain(s) of interest and their match with the objective and study duration. While changes in presenteeism and sick leave can occur over short periods in time, longer term sick leave and, in particular, work disability require longer observation periods. Additionally, the taskforce urges researchers to ensure alignment of the frequency of assessment of WP outcomes to the recall of the measurement instruments and the study objective. For example, in a 24-week randomised controlled trial with a rapidly acting intervention, assessment of sick leave in the past 7 days (eg, using the Work Productivity and Activity Impairment Index (WPAI))\(^\text{16, 19, 20}\) at baseline and endpoint is useful, as the interest is to assess change in sick leave on a group level. Alternatively, when cumulative days of sick leave over time are of interest in an observational study with long follow-up, the recall (eg, past 3 months) should fit the duration of the inter-assessment period (ie, in casu 3 months). Importantly, the taskforce emphasised that for studies with WP as a primary outcome, the choices on the issues above should be ‘justified’, not just ‘considered’. 2. In studies with WP as primary or secondary outcome, the power to detect meaningful effects deserves particular attention as WP outcomes may not apply to the entire study population.

The majority of WP studies include work as a secondary objective.\(^\text{16}\) As work outcomes often relate to a sub-sample of the population for which the initial sample size was calculated (eg, 18–64 years when work status is the outcome of interest; those employed when sick leave or presenteeism are studied), the number of patients eligible for the work outcome analyses drops, likely reducing the power to detect differences between groups. Researchers should consider this when designing the study or selecting a dataset.

3. The WP outcome domains (eg, work status, absenteeism, presenteeism) should be clearly defined and assessed with validated measurement instruments.

Heterogeneity or lack of definitions of the WP outcome domains are an important cause of incomparability and a risk for misinterpretation of findings across studies. While for some commonly used (sub)-domains (eg, employment) formal definitions have been proposed, operationalisation varies greatly across administrative entities (countries, regions, states, etc). As a consequence, researchers may have good reasons to use a specific or adjusted definition (eg, self-reported vs formal work disability). Nevertheless, a clear description of each WP outcome domain under study is warranted, and definitions should fit the research objective but also strike a balance between local usefulness and generalisability of the study findings (table 2).

To support measurement of WP outcome domains, Outcome Measures in Rheumatology (OMERACT) continuously updates the validity of self-reported instruments to assess presenteeism.\(^\text{21}\) The taskforce specified that for presenteeism the study objective should guide the choice between single-item and multi-item/multidimensional instruments. Of note, specific aspects of measurement instruments including the recall period, disease attribution or the anchors for presenteeism or absenteeism (compared with your own best or to an average worker) are not specifically addressed in the above assessments of validity.
Regarding recalling information, there is evidence that recall beyond 3 months for sick leave becomes inaccurate and that patients prefer a recall period of 1–4 weeks for presenteeism; patients suggest 4 weeks is more representative. Attribution patients prefer a recall period of 1–4 weeks for presenteeism; sick leave and recall struggle to attribute restrictions to arthritis vs overall health, and as effect modifiers, or other types of covariates. Contextual factors are variables that are not the outcome of the study, but need to be recognised to understand the study results. They also include confounders and effect modifiers. They can be measurement affecting, outcome influencing or effect modifying. Such linkage of data is not without challenges. A framework of outcome assessment, contextual factors are variables that are part of the environment of the individual (eg, social attitudes, architectural characteristics, legal and social structures, as well as climate, etc) or characterise the individual him/herself (eg, gender, age, coping, lifestyle, social background, education, profession, past and current experiences). They influence occurrence and course of disease and determine how illness and disability is experienced by the individual.

### Table 2 Glossary of terms relevant for the current Points to Consider

| Term                     | Source       | Definition                                                                                                                                 |
|--------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Work participation       | ICF          | Active engagement in paid or unpaid work.                                                                                                                                                             |
| Contextual factor        | ICF          | In the bio-psycho-social framework of health contextual factors refer to variables that are part of the environment of the individual (eg, social attitudes, architectural characteristics, legal and social structures, as well as climate, etc) or characterise the individual him/herself (eg, gender, age, coping, lifestyle, social background, education, profession, past and current experiences). They influence occurrence and course of disease and determine how illness and disability is experienced by the individual. |
| OMERACT                  |              | In the framework of outcome assessment, contextual factors are variables that are not the outcome of the study, but need to be recognised to understand the study results. They also include confounders and effect modifiers. They can be measurement affecting, outcome influencing or effect modifying. |
| Employment               | ILO/WHO      | An agreement to produce goods or services for a specific period in time for compensation by a salary, a wage or in kind. Different types of employment exist, among which is self-employment. |
| Part-time employment     | ILO/WHO      | Time off from work that workers can use to stay home to address their health and safety needs without losing pay.                                                                                     |
| Sick leave               | WIKI         | When the hours of work are less than the ‘normal’ hours of work of a comparable full-time employment.                                                                                                 |
| Paid sick leave          | ILO/WHO      | A statutory requirement in many nations or organisations that comprise (universal) income substitutions for persons that have temporary time off from the employment contract due to illness or disability. Against this background sick leave consists of two components: leave from work due to sickness and cash benefits that replace the wage during the time of sick leave. |
| Presenteeism             | Various      | Refers to: 1. The behaviour of attending (paid) work while being ill. 2. The level of influence on the work process (productivity, efficiency, performance) experienced by the worker (ability, difficulty). |
| Work productivity        |              | The amount of goods and services produced in a specific time frame/period in time.                                                                                                                   |
| Unemployment             | ILO/WHO      | Not being employed but looking for an employment.                                                                                                                                                     |
| Work disability          | ILO          | When an individual is unable to perform work-related tasks due to physical or mental impairments or disability. This recognition as disabled becomes a prerequisite for the claiming of support on the basis of a physical or mental limitation or for litigation under an antidiscrimination law. Such support can comprise provisions for rehabilitation, special education, retraining, privileges in the securing and preserving of a place of employment, guarantee of subsistence through income, compensation payments and assistance with mobility, etc. Virtually every existing definition of disability thus mirrors a legal system and draws its meaning from this system. It is also a highly heterogeneous concept, making the search for a homogeneous definition a virtually impossible task. |
| Decent work              | ILO          | Decent work involves opportunities for work that are productive and deliver a fair income, security in the workplace and social protection for families, better prospects for personal development and social integration, freedom for workers to express concerns, organise and participate in the decisions that affect their lives and equality of opportunity for all women and men. |
| Unpaid work              | WHO          | Unpaid work activities include own-use production of services and volunteer work in households or organisations producing services for others.                                                        |

ICF, International Classification of Functioning, Disability and Health; ILO, International Labour Organisation; OMERACT, Outcome Measures in Rheumatology.
domains can explain why an intervention that markedly reduces sick leave days, can lead to an increase in presenteeism. To account for dependencies, it is advised to always collect information on the (sub-)domains that are hierarchically higher (presenteeism depends on sick leave, sick leave depends on work status) on the work ability/productivity continuum, or conceptually related to the outcome (sub-)domain of interest (eg, absenteeism and presenteeism; retiring early or becoming work disabled). Authors need to report whether and how they dealt with this dependency.16 17 For example, the WPAI deals formally with this problem as it requires the distinction between workers who are temporarily absent from work (eg, due to an acute disease) and workers who are working while they are still ill (eg, due to a chronic disease). Absenteeism and presenteeism can be treated as two different concepts that are conceptually related but not identical.16 17

6. Populations included in the analysis of each WP outcome domain should be specified and relevant characteristics described.

WP outcomes are often performed in subsamples of the original study.16 For example, a model exploring risk factors for work disability is to be analysed in the at-risk population below retirement age (usually 18–64 years old), while a model on risk factors for long-term sick leave or presenteeism addresses the employed population. Especially when measurement instruments report impact on paid as well as unpaid work (eg, WPAI), numbers and details of the employed and unemployed patients should be provided.16 To facilitate the correct interpretation of the output of the analyses, the baseline demographic and disease characteristics of each (sub-)group should be described.

7. In longitudinal studies work status should be regularly assessed and changes reported.

Given the chronic, progressive character of IA, longitudinal studies are encouraged to assess changes in WP. Those changing their work status (especially, becoming work disabled) are likely prognostically different from the rest of the population. For example, if an improvement in sick leave of employed persons with early RA was observed over time, this may partly be due to patients with the highest disease impact—and thus sick leave—becoming work disabled over time. Therefore, in longitudinal studies transitions should be described, and either accounted for in analyses or discussed when interpreting the results.

8. Reporting both aggregated results (eg, mean/median) and proportions of individuals based on predefined meaningful categories (eg, no sick leave) should be considered.

In addition to mean and median values of continuous measures (such as sick leave days, level of presenteeism), also the proportion of patients attaining a specific meaningful (change in) outcome adds to insight of the WP outcome. For example, as presenteeism and absenteeism often have a skewed (or zero-inflated) distribution, it is informative to present also the proportion of patients that had no sick leave or presenteeism. Meaningful categorisation can also be based on the WPAI, the most common WP assessment instrument, which is used in most studies and thus provides a useful reference point.

9. In studies assessing costs of decreased WP, volumes of work productivity loss (eg, days, hours) should also be reported.

Productivity costs are a relevant aspect of WP but valuing loss of productivity in monetary terms (ie, costing) is complex and beyond the expertise of this taskforce. Nevertheless, the taskforce wanted to identify a basic principle that should be fulfilled when researchers aim to proceed towards calculating costs of productivity loss. In any cost study, authors should first collect/report the natural volumes of production loss (usually time; days/hours) before providing the cost-estimates. In view of poor agreement between self-reported productivity loss while at work (presenteeism) and actual productivity loss, presenteeism costs should be considered in sensitivity analyses only.16

### DISCUSSION

Assessment of WP as an outcome domain in clinical studies has specific methodological challenges. The nine PtC aim to improve the quality of interventional and non-interventional studies and should eventually contribute to improving WP for patients with IA. Specifically, adherence to these methodological considerations should lead to unbiased results and facilitate meta-analyses.

A clear study objective constitutes a first and critical step of any WP outcome study, as it determines the target population, the outcome domains, the study duration, the frequency with which outcomes should be assessed in relation to the recall of the measurement instrument, and, finally, the contextual factors that should be accounted for. In addition, in the analysis and report the interdependence (and competition) between WP outcomes should receive specific attention. While these individual topics seem basic epidemiological knowledge, and some of them are (implicitly) part of the CONSORT13 36 and Strengthening the Reporting of Observational Studies in Epidemiology13 statements, they accumulate in work outcome studies and are frequently ignored in existing studies.36

### Research agenda

Areas or topics that were considered important by the taskforce experts but for which the level of uncertainty was too high to formulate a PtC were included in a research agenda (table 4).

### Table 3 Proposal for classification of contextual factors relevant for studies with work participation as an outcome domain. Contextual factors can be facilitators or barriers

| Personal contextual factors | Environmental contextual factors |
|-----------------------------|----------------------------------|
| Health*                     | Nature of work                   |
| Pain                        | Physical/mental demands          |
| Fatigue                     | Job autonomy                      |
| Physical function           | Workplace support/barriers        |
| Demographics                | Workplace organisation            |
| Age and gender              | Team dynamics at work            |
| Education                   | Compensation of absence (eg,    |
|                             | replacement practices)           |
| Economic need               | Workplace accommodation           |
| Income needs                | Modified hours/duties            |
| Quality of benefits         | Economic climate/labour regulations |
| Personal appraisal of work  | Income compensation              |
| Job satisfaction            | Employment opportunities          |
| Career perspectives         | Workplace accommodation           |
| Skills and abilities         | Workplace support/barriers        |
| Work-efficacy               | Competing social roles           |
| Coping                      | Adaptive devices                  |
| Work-life balance           | Modified hours/duties            |
| Competing social roles      | Non-workplace support/barriers    |
| Quality of leisure          | Support from family               |
| Personal appraisal of work  | Task assistance at home           |

*In the setting of clinical studies, health factors are relevant to interpret the results and (contrary to the International Classification of Functioning, Disability and Health (ICF) definition) considered to represent personal contextual factors. In the ICF classification, contextual factors are by definition external to health factors. In the Outcome Measures in Rheumatology methodological definition, health factors can be covariates (effect modifiers, confounders).
We expect the PtC will facilitate improved conduct of WP outcome ensuring these aspects were included in statements or research agenda. Forcing the discussions on unpaid work, healthy work and context, of complex methodological issues, but were instrumental in rein representatives found it challenging to take an active role in the discourse. To improve work circumstances of people with RMDs.7 Patient representatives found it challenging to take an active role in the discourse. Reaching these goals will not only depend on efforts within the healthcare system to support patients to stay at work but will also require supportive employers, behavioural adjustments in work productivity can be tools to reach this goal. Defining and measuring ‘healthy and sustainable work’ is added as a challenge to our research agenda. Reaching these goals will not only depend on efforts within the healthcare system to support patients to stay at work but will also require supportive employers, behavioural changes towards workers with a chronic disease and policies for healthy workplaces and support systems for persons with chronic diseases. This underpins the urgency of EULAR’s strategic goal to prevent more specific statements on these issues, which were also added to the research agenda.

The taskforce would like to emphasise that while important, improvement of WP, employment, reduced sick leave or presenteeism should never be reached at the expense of long-term health or even life satisfaction. Rather, the final goal should be to support patients in healthy and sustainable work, and days off work or adjustments in work productivity can be tools to reach this goal. Defining and measuring ‘healthy and sustainable work’ is added as a challenge to our research agenda. Reaching these goals will not only depend on efforts within the healthcare system to support patients to stay at work but will also require supportive employers, behavioural changes towards workers with a chronic disease and policies for healthy workplaces and support systems for persons with chronic diseases. This underpins the urgency of EULAR’s strategic goal to improve work circumstances of people with RMDs.2 Patient representatives found it challenging to take an active role in the discourse of complex methodological issues, but were instrumental in reinforcing the discussions on unpaid work, healthy work and context, ensuring these aspect were included in statements or research agenda.

In conclusion, guidance is now available to improve interpretation and comparison of studies in IA with WP as an outcome domain. We expect the PtC will facilitate improved conduct of WP outcome studies.

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