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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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ABSTRACT

Background Clinical studies with work participation (WP) as an outcome domain pose particular methodological challenges that hamper interpretation, comparison between studies and meta-analyses.

Objectives To develop Points to Consider (PtC) for design, analysis and reporting of studies of patients with inflammatory arthritis that include WP as a primary or secondary outcome domain.

Methods The EULAR Standardised Operating Procedures were followed. A multidisciplinary taskforce with 22 experts including patients with rheumatic diseases, from 10 EULAR countries and Canada, identified methodologic areas of concern. Two systematic literature reviews (SLR) appraised the methodology across these areas. In parallel, two surveys among professional societies and experts outside the taskforce sought for additional methodological areas or existing conducting/reporting recommendations. The taskforce formulated the PtC after presentation of the SLRs and survey results, and discussion. Consensus was obtained through informal voting, with levels of agreement obtained anonymously.

Results Two overarching principles and nine PtC were formulated. The taskforce recommends to align the work-related study objective to the design, duration, and outcome domains/measurement instruments of the study (PtC: 1–3); to identify contextual factors upfront and account for them in analyses (PtC: 4); to account for interdependence of different work outcome domains and for changes in work status over time (PtC: 5–7); to present results as means as well as proportions of patients reaching predefined meaningful categories (PtC: 8) and to explicitly report volumes of productivity loss when costs are an outcome (PtC:9).

Conclusion Adherence to these EULAR PtC will improve the methodological quality of studies evaluating WP.

Key messages

What is already known about this subject?

- Several systematic reviews of studies with work participation (WP) as a primary or secondary outcome domain have documented methodological deficiencies in the study design, analysis and reporting of results, hampering interpretation and pooling of data.

What does this study add?

- These Points to Consider (PtC) complement existing reporting guidelines, focusing on specificities of studies of patients with inflammatory arthritis that include WP as an outcome domain.
- The nine PtC address: study design, WP domains and instruments, data analysis and reporting of results.

How might this impact on clinical practice or future developments?

- Adherence to the PtC will improve the quality of studies on WP in patients with inflammatory arthritis, enabling comparisons across studies and meta-analyses.

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 with the general population.[1 2] For patients with IA, retaining work or (re)gaining a job is relevant to their life[3] 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)'.[7] 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.[8 9] 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.[10]

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 updated EULAR Standardised Operating Procedures, while being also aware of the Developers of Health Research Reporting Guidelines.[11]

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.[12 13] 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))[11 14 15] 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.[16] 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[1]: study design,[2] work outcome domains and measurement instruments,[3] data analysis and[4] 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.[17] 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 cointerventions, and long lag times for some outcomes. For these studies, strengths and weaknesses of various semiexperimental study designs should be weighted.[18] 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

	LoE (0–5)	SoR	LoA (0–10) Mean (SD)	LoA (0–10) % with score ≥8
Overarching principles				
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				
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)[17]; SoR: A to D (D indicating troublingly inconsistent or inconclusive studies of any level).[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 Work Productivity and Activity Impairment Index (WPAI)[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 (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.[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.[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.

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	When the hours of work are less than the 'normal' hours of work of a comparable full-time employment.
Sick leave	WIKI	Time off from work that workers can use to stay home to address their health and safety needs without losing pay.
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. In many constituencies definitions of disability are identical with an administrative act of recognising a 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.

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 suggests 4 weeks is more representative.[22 23] Attribution to overall health (opposed to IA-related) is preferred, as patients struggle to attribute restrictions to arthritis vs overall health, and it allows benchmarking with the general population. Of note, in several countries regulations are in place to link healthcare data to social security databases that include information on sick leave and work disability. While avoiding non-response and recall bias, such linkage of data is not without challenges. A pertinent example is that registration only starts when sick leave exceeds a number of prespecified days.

4. Key contextual factors (eg, job type, social security system), that is, contextual factors that are highly likely to confound or modify WP outcomes, have to be identified upfront, considered in the study design, and appropriately accounted for in the analysis.

There is ample evidence associating work-related environmental and personal contextual factors to WP outcomes, either as effect modifiers, or other types of covariates.[24] Contextual factors can be facilitators or barriers for WP.[25] For example, manual workers experience more impact from axSpA on presenteeism, but also experience more beneficial effect of bDMARDs on presenteeism.[26] Country of residence (likely reflecting social security regulations, including income substitution) is another contextual determinant of variation in employment and sick leave rates across countries,[27 28] and may cause effect modification of interventions.[29] OMERACT proposed a classification of 12 contextual factor domains potentially relevant for WP outcomes[30 31] (table 3). The choice of contextual factors, as well as the methodological approach to account for them (eg, stratification, post hoc analyses) should be prespecified in the study protocols. Whereas contextual factors refer—according to some definitions—to factors outside the disease (eg, job type),[32] also disease-related factors (eg, early vs established disease; type of joints involved) or factors within the work outcome continuum (eg, being partly work disabled) can be equally relevant as effect modifiers or covariates. On this line, jobs requiring hand dexterity might affect work outcomes more importantly in patients with small joint involvement compared with those with only back manifestations.

5. Interdependence among different WP outcome domains (eg, between absenteeism and presenteeism) should be taken into account in the analyses.

WP presents a continuum of subdomains which are *dependent* on each other, and may *compete over time*. For example, formal work disability cannot occur anymore after early retirement from paid work; and presenteeism cannot occur when a person is on sick leave (ie, absent form work). Dependency of outcome

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	
Demographics	Workplace support/barriers
Age and gender	Assistance by coworkers
Education	Attitude of employer
Economic need	Workplace organisation
Income needs	Team dynamics at work
Quality of benefits	Compensation of absence (eg, replacement practices)
Personal appraisal of work	Workplace accommodation
Job satisfaction	Adaptive devices
Career perspectives	Modified hours/duties
Skills and abilities	Economic climate/labour regulations
Work-efficacy	Income compensation
Coping	Employment opportunities
Work-life balance	Workplace accommodation
Competing social roles	Adaptive devices
Quality of leisure	Modified hours/duties
	Non-workplace support/barriers
	Support from family
	Task assistance at home

*In the setting of clinical studies, health factors are relevant to interpret the study 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).

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 33] For example, the WPAI deals formally with this issue by combining presenteeism and absenteeism into an overall work impairment scale.[34]

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 have often 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 what is used by the social security system (eg, proportion with specific number of sick leave days). For presenteeism, work has been done on the minimally important difference, but data do not seem robust and more work is needed before a generalisable threshold is proposed.[35]

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 highlight 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]

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).

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 CONSORT[15 36] and Strengthening the Reporting of Observational Studies in Epidemiology[14] statements, they accumulate in work outcome studies and are frequently ignored in existing studies.[16]

Table 4 Research agenda

Topic	Questions
Unpaid work participation	How can unpaid work participation as an outcome domain be defined? Which measurement instruments are valid to assess the domain unpaid work (in IA)?
Contextual factors	How to *measure* contextual factor domains relevant for work participation? What is the *operational definition* of a 'key' contextual factor (eg, if it has proven to behave consistently as: (a) Relevant effect modifier of interventions in work outcome studies, or (b) Consistently relevant covariate of work outcomes in observational studies.)? To what extent are contextual factors specific to certain setting (eg, specific for a certain outcome are a certain intervention)?
Interdependence and integration of the work outcome domains	How to deal with interdependence or competition between work participation outcomes (work status, absenteeism and presenteeism)? Can we redesign work outcome measurement that integrates work disability, absenteeism and presenteeism?
Analyses of skewed data	What is the comparative accuracy of methods to deal with different types of skewed or zero-inflated data?
Decent work and healthy workplaces	What is a healthy work and what is a healthy workplace? How can we measure it? What are the health effects of *not* taking sick leave and *not* adjusting productivity while at work (presenteeism)?

IA, inflammatory arthritis.

The taskforce identified and discussed some areas or topics where no consensus could be reached due to lack of evidence and placed these in the research agenda. In the first taskforce meeting, it was proposed to broaden the scope of PtC to studies with unpaid work as an outcome domain clearly impacted by IA. However, the absence of appropriate definitions and absence of evidence from both SLRs, led the taskforce to urgently recommend more research focus on unpaid work. The lack of evidence on specific methodological issues (eg, contextual factors, skewness or interdependence of outcomes) prevented 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.[7] 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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REFERENCES

1 Eriksson JK, Neovius M, Bratt J, *et al*. Biological vs. conventional combination treatment and work loss in early rheumatoid arthritis: a randomized trial. *JAMA Intern Med* 2013;173:1407–14.
2 Webers C, Vanhoof L, van Genderen S, *et al*. Employment and the role of personal factors among patients with ankylosing spondylitis: a Dutch cross-sectional case-control study. *RMD Open* 2018;4:e000680.
3 Boonen A, Boone C, Albert A, *et al*. Understanding limitations in at-work productivity in patients with active ankylosing spondylitis: the role of work-related contextual factors. *J Rheumatol* 2015;42:93–100.
4 Strand V, Wright GC, Bergman MJ, *et al*. Patient expectations and perceptions of Goal-setting strategies for disease management in rheumatoid arthritis. *J Rheumatol* 2015;42:2046–54.
5 van der Velde G, Pham Ba', Machado M, *et al*. Cost-Effectiveness of biologic response modifiers compared to disease-modifying antirheumatic drugs for rheumatoid arthritis: a systematic review. *Arthritis Care Res* 2011;63:65–78.
6 Boonen A, Webers C. Economic Evaluations in Axial Spondy loarthritis. In: Mease P, Khan M, eds. *Axial spondyloarthritis. Paperback ISBN: 9780323568005, eBook ISBN: 9780323568012*. Elsevier, 2019.
7 EULAR. EULAR strategy 2023, 2020. Available: https://www.eular.org/eular_strategy_2018.cfm
8 van der Burg LRA, Ter Wee MM, Boonen A. Effect of biological therapy on work participation in patients with ankylosing spondylitis: a systematic review. *Ann Rheum Dis* 2012;71:1924–33.
9 ter Wee MM, Lems WF, Usan H, *et al*. The effect of biological agents on work participation in rheumatoid arthritis patients: a systematic review. *Ann Rheum Dis* 2012;71:161–71.
10 Equator network. Enhancing the quality and transparency of health research, 2020. Available: https://www.equator-network.org/
11 Moher D, Schulz KF, Simera I, *et al*. Guidance for developers of health research reporting guidelines. *PLoS Med* 2010;7:e1000217.
12 ILO. Employment by status in employment, 2020. Available: https://www.ilo.org/ilostat-files/Documents/description_STE_EN.pdf
13 Institut national de la statistique et des etudes economiques. Employement (ILO), 2020. Available: https://www.insee.fr/en/metadonnees/definition/c1159
14 von Elm E, Altman DG, Egger M, *et al*. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008;61:344–9.
15 Schulz KF, Altman DG, Moher D, *et al*. Consort 2010 statement: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010;63:834–40.
16 Marques ML, Alunno A, Boonen A, *et al*. Methodological aspects of design, analysis and reporting of studies with work participation as an outcome domain in patients with inflammatory arthritis: results of two systematic literature reviews informing EULAR points to consider. *RMD Open* 2021;7:e001522.
17 Oxford centre for evidence-based medicine. levels of evidence (updated in 2012), 2009. Available: https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009
18 Schelvis RMC, Oude Hengel KM, Burdorf A, *et al*. Evaluation of occupational health interventions using a randomized controlled trial: challenges and alternative research designs. *Scand J Work Environ Health* 2015;41:491–503.
19 Reilly MC, Gooch KL, Wong RL, *et al*. Validity, reliability and responsiveness of the work productivity and activity impairment questionnaire in ankylosing spondylitis. *Rheumatology* 2010;49:812–9.
20 Zhang W, Bansback N, Boonen A, *et al*. Validity of the work productivity and activity impairment questionnaire--general health version in patients with rheumatoid arthritis. *Arthritis Res Ther* 2010;12:R177.

21 Beaton DE, Dyer S, Boonen A, *et al*. OMERACT filter evidence supporting the measurement of At-work productivity loss as an outcome measure in rheumatology research. *J Rheumatol* 2016;43:214–22.
22 Severens JL, Mulder J, Laheij RJ, *et al*. Precision and accuracy in measuring absence from work as a basis for calculating productivity costs in the Netherlands. *Soc Sci Med* 2000;51:243–9.
23 Leggett S, van der Zee-Neuen A, Boonen A, *et al*. Content validity of global measures for at-work productivity in patients with rheumatic diseases: an international qualitative study. *Rheumatology* 2016;55:1364–73.
24 WHO. *International classification of functioning, disability, and health*. Geneva: ICF, 2001.
25 Hedley D, Uljarević M, Cameron L, *et al*. Employment programmes and interventions targeting adults with autism spectrum disorder: a systematic review of the literature. *Autism* 2017;21:929–41.
26 Boonen A, Boone C, Albert A, *et al*. Contextual factors influence work outcomes in employed patients with ankylosing spondylitis starting etanercept: 2-year results from AS@Work. *Rheumatology* 2018;57:791–7.
27 Rodrigues Manica S, Sepriano A, Ramiro S, *et al*. Work participation in spondyloarthritis across countries: analysis from the ASAS-COMOSPA study. *Ann Rheum Dis* 2018;77:1303–10.
28 van der Zee-Neuen A, Putrik P, Ramiro S, *et al*. Large country differences in work outcomes in patients with RA - an analysis in the multinational study COMORA. *Arthritis Res Ther* 2017;19:216.
29 Stolwijk C, Castillo-Ortiz J-D, Gignac M, *et al*. Importance of contextual factors when measuring work outcome in ankylosing spondylitis: a systematic review by the OMERACT worker productivity group. *Arthritis Care Res* 2015;67:1316–27.
30 Tang K, Escorpizo R, Beaton DE. *Measuring the impact of arthritis on worker productivity: perspectives, methodologic issues, and contextual factors*, 2011: 1776–90.
31 Nielsen SM, Tugwell P, de Wit MPT, *et al*. Identifying provisional generic contextual factor domains for clinical trials in rheumatology: results from an OMERACT initiative. *J Rheumatol* 2019;46:1159–63.
32 OMERACT. Chapter 4. developing core domain sets. OMERACT Handbook. Available: https://omeracthandbook.org/handbook2019
33 Donoghoe MW, Gebski V. The importance of censoring in competing risks analysis of the subdistribution hazard. *BMC Med Res Methodol* 2017;17:52.
34 Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993;4:353–65.
35 Verstappen SMM, Lacaille D, Boonen A, *et al*. Considerations for evaluating and recommending worker productivity outcome measures: an update from the OMERACT worker productivity group. *J Rheumatol* 2019;46:1401–5.
36 Moher D, Hopewell S, Schulz KF, *et al*. Consort 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010;63:e1–37.

Online Supplementary Text with Tables S1-S3 and figure S1

Survey among external researchers and experts

The questionnaires addressed level of importance to emphasize in '*points to consider on condcting and reporting studies with work participation as an outcome domain'* each of the 24 methodological topics accross 6 main areas:(I) Study design; (II) Work participation; (III) outcome domains; (IV) Work participation outcome instruments; (V) Contextual factors; (VI) Data analyses; (VII) Reporting.

Forty-three respondents were included, from 13 different countries (Netherlands (n=11); Hungary (n=8); United Kingdom (n=6); Sweden (n=4); Canada (n=3); United States of America (n=3); Denmark (n=2); Belgium (n=1); Finland (n=1); France (n=1); Mexico (n=1); Portugal (n=1) and Romania (n=1) . Their background and experience in work outcome studies varied.

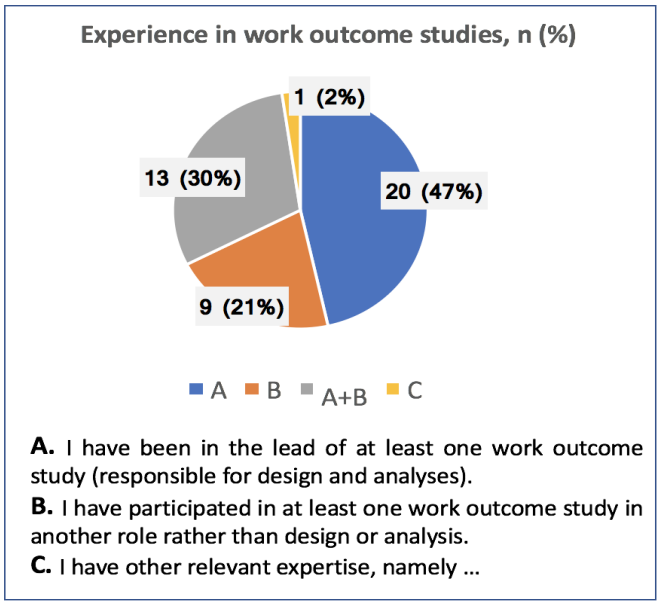
Supplementary Table S1: Background of the 43 respondents

Background[#]	*n**
Rheumatologist	**17**
Other medical specialist	3
Health professional	6
Epidemiologist or statistician	**12**
(Health)-economist	5
Researcher	4
Patient research partner/patient advocate	2

[#] 72% with experience in inflammatory arthritis or other musculoskeletal diseases

* Several answer options were possible

Supplementary Figure S1: Experience with work outcome studied of the respondents



Supplementary Table S2: Level of importance (0= *do not agree at all* to 5= *fully agree*) for each topic.

Area	***Statements***	***n/43****	***Level of importance#*** *Mean (SD)*
I. Study design	**Statement 1. The target population and eligibility criteria should be clearly defined and chosen in relation to the work-related objective(s).**	42	4.8 (0.4)
	Statement 2. The sample size calculation of a study with work as one of the outcomes deserves specific consideration as work outcomes often apply to subpopulations only.	42	4.0 (0.9)
	Statement 3. The time horizon should align with the study objective, outcome domain(s) of interest.	41	4.3 (0.6)
	Statement 4. Comparison with (matched groups of) the general population should be considered to provide a better understanding of the impact of the disease (or the interventions) on work participation, as it reveals the 'normal' participation level.	42	4.2 (0.8)
	Statement 5. The frequency of assessment of the endpoints and contextual factors (confounders) should be related to the study objective and the recall period of the measures.	39	4.4 (0.7)
II. Work outcome domains	**Statement 6. When selecting the work outcomes domains, the interdependence of work status, sick leave and presenteeism needs specific consideration.**	38	4.6 (0.6)
	Statement 7. The assessment of both paid- and unpaid work outcomes should be considered, to provide a complete picture of worker participation.	38	4.0 (0.9)
	Statement 8. Definitions of work outcome domains need to be explicit, in particular when no validated instruments are used.	38	4.8 (0.4)
III. Work outcome measurement instruments	**Statement 9. Validated self-report instruments** or **objective data sources to assess work outcome domains** should be preferred above self-composed questionnaires.	39	4.6 (0.8)
	Statement 10. The *attribution* of work participation should be assessed in relation to overall health and not merely in relation to the inflammatory arthritis.	37	4.1 (1.0)
	Statement 11. The choice between ***single*** and ***multi-dimensional* instruments** should be justified and aligned with the study objective.	39	4.1 (0.8)
	Statement 12. The ***construct* measured to assess presenteeism and restrictions in unpaid work** should be justified and aligned with the study objective.	37	4.1 (0.7)
	Statement 13. The ***recall period*** of the instruments should be aligned with the study objective, the frequency of assessment and the study duration.	39	4.3 (0.8)
	Statement 14. When **measuring days absent from paid work,** the measurement should reflect **actual *workdays absent***, i.e. excluding weekend days or other days one would not work.	38	4.3 (1.0)

Area	***Statements***	***n****	***Level of importance#*** *Mean (SD)*
IV. Contextual factors	**Statement 15. Specific contextual factors** (e.g. physical demand of the work, support from colleagues, characteristics of the social security system) should be chosen in view of the study objectives.	39	4.4 (0.8)
	Statement 16. The **OMERACT framework** on classification of contextual factors for work outcomes (Tang et al. 2011) should guide the selection of contextual factors.	36	4.2 (0.9)
V. Data analysis	**Statement 17. Appropriate methods should be applied to understand (the type) of skewness of work outcomes** with a continuous scale and the choice of method for further analyses should be justified.	37	4.6 (0.6)
	Statement 18. Longitudinal data analyses on work status should account for potential interdependence or competition between outcomes (e.g. when a person is absent due to sick leave, presenteeism is no longer possible).	37	4.7 (0.5)
	Statement 19. Analyses of work outcomes should be **corrected for contextual factors**.	38	4.4 (0.9)
VI. Reporting	**Statement 20.** In longitudinal studies, **work-related reasons for drop-out should be described** (i.e. changes in work status) in addition to traditional **reasons for loss to follow-up.**	39	4.4 (0.8)
	Statement 21. The size and characteristics of the (sub)groups in which the analyses are performed should be described.	39	4.7 (0.6)
	Statement 22. The descriptive data (status or changes) should be presented as means (with SD) in addition to medians (with range or IQR), even in case of skewness.	36	3.8 (1.1)
	Statement 23. In addition to aggregated group results at the group level (mean/median), **reporting results on the individual patient level should be considered** (e.g. the proportion of patients with 'no presenteeism' and/or 'no sick leave').	39	4.1 (0.7)
	Statement 24. In case **productivity costs** is included as an outcome, **volumes** (e.g. days, hours) of work loss should be reported.	39	4.6 (0.6)

*excluding no opinion