Gaining consensus on an operational definition of contextual factors within rheumatology trials: A protocol for a Delphi survey

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ABSTRACT

Background: The Outcome Measures in Rheumatology (OMERACT) initiative established the Contextual Factors Working Group (CFWG) to guide the understanding, identification, and handling of contextual factors for clinical trials. The CFWG has explored researcher and patient perspectives in a qualitative study, providing the basis for designing a consensus study.

Objectives: The objective of the study is to achieve consensus among relevant stakeholders on an operational definition of contextual factors relevant for clinical trials within rheumatology research.

Methods and analysis: Based on the previously conducted qualitative study, we have refined the descriptions (i.e. suggested operational definitions) of contextual factors and formulated statements on which we seek consensus. We will conduct an online Delphi survey (anticipating three rounds) among relevant stakeholders, i.e. patients, clinicians, and 'others' (e.g. researchers, trialists, statisticians, etc.), from the OMERACT community. Consensus will be defined as ≥70% scored 7 to 9 (i.e. 'agree') or ≥70% scored 1 to 3 (i.e. 'disagree'), within each stakeholder groups.

Dissemination: The results will be disseminated through presentations at rheumatology meetings, in particular at the OMERACT meeting, and through publications in international peer-reviewed journals.

INTRODUCTION

In 2012, the concept of contextual factors was introduced for the first time in the OMERACT process, but understanding, approaching, and identifying contextual factors proved difficult. The Contextual Factors Working Group (CFWG) was formed to provide guidance on how to address the challenges of contextual factors in clinical trials [1 2].

The CFWG has recently conducted a qualitative study to explore researcher's and patient's perspectives on the definition of a contextual factor, its related terminology, how to identify such factors, and how to account for them in clinical trials across rheumatology. Individual semi-structured interviews were conducted with researchers (incl. clinicians), who are recognized in the field of contextual factors in clinical trials or other potentially relevant areas, and group interviews with patients. The interviews were recorded, transcribed, and analysed through qualitative content analysis. Researcher and patient descriptions of contextual factors were categorised into two broad themes, each describing two types of contextual factors.

The first theme, 'treatment effect', focused on factors that influence treatment effects, i.e. what explains the variability in treatment effects a) between patients ('*effect modifying'* contextual factors), and b) - between studies ('*meta-confounding'* contextual factors).

The second theme, 'outcome measurement', focused on factors that influence the outcome measurement within/between patients, i.e. what explains the variability in the measurement result itself (apart from actual changes/differences in the outcome; '*measurement affecting'* contextual factors), and what explains the variability in the outcome itself (apart from the treatment tested in the trial; '*outcome explaining'* contextual factors). There were clear differences between themes (and factor types) with regard to the related terminology and methods for identifying and handling contextual factors that were suggested by the participants. Three of the contextual factor types were considered relevant within individual clinical trials (i.e. '*effect modifying' -,* '*measurement affecting' -, and* '*outcome explaining'* contextual factors). Based on the research agenda of the CFWG, the next step is to facilitate consensus on an operational definition for these contextual factors, to make the concept of 'contextual factors' understandable, distinguishable (what contextual factors are and are not), measurable, as well as providing clear descriptions of the different types of factors, and how they can be handled (i.e. taken into account) in clinical trials.

Objectives

The objective is to achieve consensus among relevant stakeholders on an operational definition of contextual factor, i.e. a definition that can be directly used to guide the understanding, identification and

handling of contextual factors in clinical trials, and which is relevant for clinical trials within rheumatology research.

METHODS

Protocol and reporting standards

We will publish this protocol online on the Parker Institute's web page (www.parkerinst.dk) prior to inviting participants for the Delphi Survey. This study is briefly mentioned in an overall protocol (available at http://www.parkerinst.dk/ongoing-projects/defining-and-identifying-contextual-factors-within-rheumatology-protocol-semi). The present protocol describes the consensus process in detail.

We will conduct and report the Delphi study according to current OMERACT guidelines [3 4], and 'Guidance on Conducting and Reporting DElphi Studies in palliative care' (CREDES) [5], slightly modified for our setting and purpose. This study will be carried out in accordance with the Helsinki Declaration. The Danish Data Protection Agency has approved the study and data will be handled according to agreements (ID 06081, BFH-2017-127).

Study design

The study is a consensus study using an online Delphi survey with (anticipating) three rounds conducted among stakeholders, based on results from a recently conducted qualitative study. The Delphi technique is a widely used approach to promote consensus among stakeholders. While a Delphi process can be labour-intensive and does not involve formal discussion among participants of areas with no consensus, key strengths of the Delphi process include anonymity of participants, i.e. allowing opinions to be expressed free from group pressure, participants are able to change opinion between each 'round', and the process can be conducted without face-to-face meetings, which enables large groups of individuals to participate [6 7]. A Delphi consists of at least two rounds and involves presenting the group's previous results to the participants [6 7], potentially together with a (automatically generated) reminder of the participant's own previous rating.

Establishing the panel

Inclusion criteria

The participants will consist of relevant stakeholders, defined as individuals or groups who have an interest in the development and implementation of an operational definition of contextual factors within OMERACT. As contextual factors need to be considered for all core outcome sets within OMERACT [8], and

since all OMERACT working groups are either directly or indirectly working on the development of core outcome sets, we will consider all OMERACT members stakeholders.

We will divide the participants into three stakeholder groups:

- Patients
- Clinicians, who are currently involved in rheumatology patient care (such as physicians, nurses, physiotherapists, occupational therapists etc.)
- Others (such as biostatisticians, methodologists, researchers or trialists etc., currently NOT involved in patient care)

Prior knowledge on OMERACT methods will be needed.

Recruitment

We will invite all members of the OMERACT organisation to participate in the online Delphi survey. Invitations will be emailed from the OMERACT secretary to all who are part of one or more OMERACT working groups and/or have participated in any of the OMERACT meetings, and/or are part of one or more of the five committees (i.e. the Executive Committee, the Technical Advisory Group, the Scientific Advisory Committee, the Business Advisory Committee, and the Patient Research Partner Network). OMERACT members cover a broad range of disciplines and conditions within rheumatology and musculoskeletal conditions, and we seek each stakeholder group to have representatives from at least three geographical continents and represent a wide range of working groups.

OMERACT recommends inviting 100 participants from each stakeholder group, with at least 50 (i.e. 50%) responding at the final Delphi round [3], however, in our case, the sample size will be determined by the number of current OMERACT members available (and responding) within each stakeholder group. We anticipate sending email invitations to around 974 (currently listed as OMERACT members), of which 85 are patients. However, we do anticipate that the mail list will include some that no longer are active OMERACT members, have retired, or for other reasons are no longer possible to reach through email contact. We hope to reach a minimum 30 from each stakeholder group (i.e. Patients, Clinicians and 'Others') responding at the final Delphi round.

Retention

We will apply methods associated with good retention in online Delphi surveys [9 10]. This will include personalized reminder emails (with details of current response rates) from the co-chairs (LM, PT, RC), the fellow (SMN), and patient research partners (MdW, MV) to encourage participation, aiming for clearly

formulated survey questions understandable to all stakeholder groups by co-creating and pilot testing these with representatives of each stakeholder group, ensuring short wait between rounds of the survey where possible (i.e. between round 2 and 3), and to acknowledge participants completing all Delphi rounds in the publication (with individual permission).

Collecting demographics

Consenting participants will be asked to complete a short demographic questionnaire, including:

- Stakeholder group affiliation (Patient, Clinician, 'other'; where 'other' needs to be further specified)
- Age
- Sex (Female, Male, Other/Do not want to declare)
- Country of residence
- Involvement in OMERACT (name of working group[s], years involved)
- Primary rheumatic condition (*for patients only*)

Furthermore, while participants' identity by default will not be tied to their individual responses, we will ask whether we are allowed to contact them regarding any comments, they may provide in the survey, that we find unclear.

Developing the Delphi survey

The initial survey questions

The Delphi survey is structured in three sections, one for each type of contextual factor (i.e. 'effect modifying' -, 'measurement affecting' -, and 'outcome explaining' contextual factors). Each section is introduced with a refined description of the contextual factor type including an explanation, a case scenario, and further specifications (e.g. what this contextual factor type is *not*), followed by statements on which we will try to gain consensus (**Appendix 1**). We have formulated the statements based on the results of the previously conducted qualitative study (*results not yet published*). The statements are supported by relevant explanations, examples and references, where possible, appearing as 'pop-up' help texts (i.e. text boxes popping up when holding the cursor over a statement) (**Appendix 2**). The participants will be asked to what degree they agree with the individual statements on a numerical rating scale from 1 to 9. Along with the survey, we will provide a glossary (**Appendix 3**).

Pilot testing

We conducted a pilot test of the Delphi survey including individuals from each stakeholder group (3 patients, 5 clinicians, 2 'others'), to make sure all relevant terms are sufficiently explained, and the

introduction texts and statements are clear and understandable. Most pilot testers had not been involved in the work of the Contextual Factor Working Group before. The pilot testers were invited to participate in the Delphi survey in the same manner as intended for the Delphi survey participants. In addition, they were asked to assess the time needed for answering the survey. After completing the survey, they were invited to provide their feedback in an internet call.

We asked for feedback on:

- The email invitation (**Appendix 4**)
- The registration page (incl. the demographic questionnaire [**Appendix 5**])
- The survey (incl. introduction texts, survey statement formulation [**Appendix 1**], 'pop-up' help texts [**Appendix 2**], and the overall survey structure and experience)
- The glossary (**Appendix 3**)

The time needed for participating in the Delphi survey (from clicking on the DelphiManager link provided in the invitation until completion of the survey) based on our pilot testing was a median of 25 minutes (range: 20 to 32 minutes). The survey and related material has been modified according to the pilot test feedback.

The consensus process

For each statement, the participants will be asked to what degree they agree with the statement on a numeric rating scale from 1 to 9 (1-3, Disagree; 4-6, Undecided; 7-9, Agree), as well as the option 'Unable to score' (**Figure 1**). For each rating, they will be able to provide feedback. We anticipate to conduct three rounds.

Round 1

The participants will be asked to rate each statement, to give feedback where necessary, and will have the option to suggest further statements (**Appendix 1**). Subsequently, Contextual Factors Working Group will arrange a 'special interest group' (SIG) session inviting OMERACT members to discuss the results and feedback of round 1, e.g. whether additional questions need to be posed to the Delphi participants. Modifications of the survey for next round will be decided by the CFWG steering group (based on discussions of the feedback from round 1 as well as inputs from the SIG).

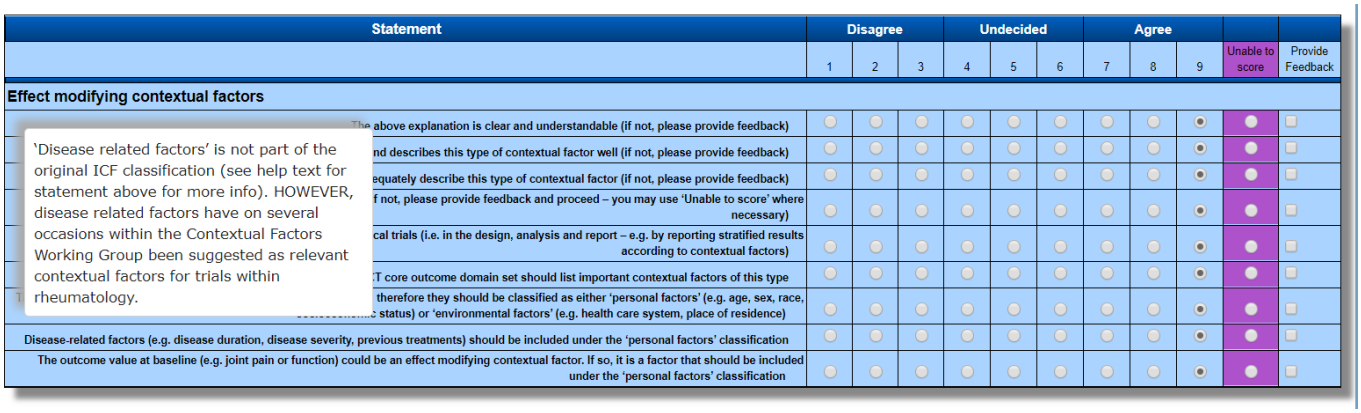
Round 2

The participants will be informed about any modifications of the Delphi survey (e.g. addition/removal/reformulation of statements, and changes in the descriptions of the contextual factor types). Again, the participants will be asked to rate each statement, and to give feedback where necessary.

This time, stakeholder group-wise distribution of scores from the previous round will be visible to the participants, as well as a (automatically generated) reminder of their own score for statements that remain unmodified since previous round. Modifications of the survey for next round will be decided by the CFWG steering group (based on discussions of the feedback from round 2).

Round 3

This will be similar to round 2.



Statement	Disagree			Undecided			Agree				
	1	2	3	4	5	6	7	8	9	Unable to score	Provide Feedback
Effect modifying contextual factors											
The above explanation is clear and understandable (if not, please provide feedback)											
nd describes this type of contextual factor well (if not, please provide feedback)											
equately describe this type of contextual factor (if not, please provide feedback)											
f not, please provide feedback and proceed – you may use 'Unable to score' where necessary)											
cal trials (i.e. in the design, analysis and report – e.g. by reporting stratified results according to contextual factors)											
T core outcome domain set should list important contextual factors of this type											
therefore they should be classified as either 'personal factors' (e.g. age, sex, race, status) or 'environmental factors' (e.g. health care system, place of residence)											
Disease-related factors (e.g. disease duration, disease severity, previous treatments) should be included under the 'personal factors' classification											
The outcome value at baseline (e.g. joint pain or function) could be an effect modifying contextual factor. If so, it is a factor that should be included under the 'personal factors' classification											

Figure 1: Delphi Manager screen sample view

Software

The Delphi survey will be conducted using the software DelphiManager (www.comet-initiative.org/delphimanager/) customized for our purpose (**Figure 1**, **Table 1**).

Table 1: Delphi Manager setup checklist

Checklist item	Answer
Finalised list of outcomes [statements], domains [contextual factor type] and help text	Available in Appendix 1 and Appendix 2
Finalised survey structure - number of rounds, page per domain [contextual factor type], feedback type in round 2/3	Three rounds, 1 page per domain (i.e. contextual factor type), and feedback will be score distribution according to stakeholder group
Appropriate person/group to determine inclusion of additional outcomes [statements] after round 1	CFWG steering group decide on inclusion of additional statements.
DelphiManager team made aware if you DO NOT want randomisation	No randomization
Finalised list of stakeholder groups (if presenting feedback by stakeholder group)	Yes (Patients, Clinicians, and 'Others'), and feedback by stakeholder group will be presented
Appropriate person identified to analyse the data to produce the chosen feedback format (if using graph display in round 2/3)	No graph display as feedback

Content for main DelphiManager pages – home page, question page	Available in Appendix 1
Finalised registration form questions	Available in Appendix 5
Content for reminder/missing data emails	Templates from the DelphiManager program will be used and modified where needed
Terminology for Likert table – Outcome/Item/Question	'Statement' will be used (see Figure 1)
Contact email address for DelphiManager emails to be sent from	Mail address of the fellow (SMN)

This setup checklist is from the 'COMET DelphiManager brochure' authored by Richard Crew and Professor Paula Williamson, available online at: http://www.comet-initiative.org/delphimanager/docs/DelphiManagerBrochureV4.0.pdf

Anonymity

Anonymity will be ensured in DelphiManager as the individual responses per default are separated from the demographic data of the individual participants. When exporting data, DelphiManager will automatically assign each participant with an ID number. When the participant is presented with his/her own scores from the previous round, this is automatically generated within DelphiManager and only visible for the participant. Anonymity will only be compromised if the participants allow us to contact them (regarding any comments, they may provide in the survey, that we find unclear) in the demographic questionnaire. In that case, only the email will be linked with the survey responses, and not any demographic data.

Expected timelines and reminders

For each Delphi round, the survey will be open for four weeks (approx. one month). Reminders will be sent if participants do not answer the survey; one reminder per week and two reminders during the last week (**Figure 2**) inspired by Hall and colleagues [9]. Reminder emails will personalised, i.e. include the name of the participant, and will include details on current response rates and will be sent from the co-chairs, fellow and patient research partners, as well as providing contact information in case of technical problems, to encourage non-responders to complete the survey. Only responders of round 1 will be invited for subsequent rounds. Non-responders of round 2 will still be invited for round 3 [3]. We will consider a response rate of 50% in each stakeholder group (compared to the first Delphi round) for any of the subsequent rounds to be acceptable [3], but preferably a minimum of 30 participants from each stakeholder group. As round 3 response rate may be influenced by the summer holiday period, this round may be further extended if ≥50% response rate is not achieved. Participants responding to all three rounds will be

asked whether they would want their name in the acknowledgement section, and how they prefer it written.

Figure 2: Anticipated schematic timeline of the three Delphi surveys

Solid fill rectangles illustrate when the survey will be open (approx. 1 month). White fill rectangles illustrate analysis of data and (potential) modification of the survey for the next round. Asterisks indicate email reminders to participants who have not yet completed the survey. On April 22nd, the Contextual Factors Working Group will arrange a 'special interest group' meeting (marked with 'X') inviting OMERACT members to discuss the results of round 1, and round 2 will be modified accordingly.

Analysis

Analysis of ratings

After conducting each Delphi round, we will analyse the ratings for each stakeholder group and evaluate any proposed statements. Feedback to the participants in the subsequent rounds will include score distribution according to stakeholder group and a reminder of their own score (where possible). For the analyses, the R software (version 3.5.1 or newer) will be used.

Definition of consensus

We will consider participants within each stakeholder group 'agree' with a statement if ≥70% scored 7 to 9, and that they disagree with a statement if ≥70% scored 1 to 3 [3]. Consensus for a statement is reached if all stakeholder groups 'agree' (or 'disagree') with the statement.

Summarising the results

We will report the response rate for each round and the demographics of participants according to stakeholder group. The ratings from each round will be summarised and reported in appendices, including figures showing group response, as well as any modifications of the survey [5]. Furthermore, demographics of responders and non-responders of round 2 and 3 will be compared.

Based on the consensus-process, the operationalisation of the definition of contextual factors will be finalised. For statements where no consensus was reached in the last Delphi round, the CFWG steering group will decide whether and how these should be implemented in the operationalisation. After summarising the results from the last Delphi round, the fellow will invite the steering group members for a structured online call to discuss each of the statements for which no consensus was reached.

DISCUSSION AND PERSPECTIVES

In this study, the three types of contextual factors (i.e. '*effect modifying' -,* '*measurement affecting' -, and* '*outcome explaining'* contextual factors) will be introduced for the first time within the OMERACT community, testing the comprehensibility of these, while seeking consensus on different aspects. Based on experiences from the recently conducted qualitative study, it is interesting whether comprehension of the three contextual factor types will be dependent on stakeholder group, and whether modifications of the Delphi (incl. the descriptions of the contextual factor types) according to feedback will improve a mutual understanding of contextual factor types between the stakeholder groups.

The study results will be disseminated through presentations at rheumatology meetings, in particular at meetings within OMERACT, and through a publication in an international peer-reviewed journal. Following this study, guidance should be developed for individual contextual factor types where necessary. We anticipate that this effort will improve understanding, identification and handling of contextual factors when developing core outcome sets within OMERACT, as well as facilitate research in contextual factors within rheumatology in general.

ETHICS

The Danish Data Protection Agency has approved the study and data will be handled according to agreements (ID 06107, BFH-2018-003).

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Initial questions for the Delphi survey

This is an overview of what will be used in the online DelphiManager program:

Introduction to survey

Background

The OMERACT Contextual Factors Working Group (CFWG) aims to update the current OMERACT definition* of contextual factors to make it useful for OMERACT working groups and rheumatology clinical trials. At the moment, the definition is felt to be unclear and unspecific by many. We interviewed patients, clinicians and researchers about contextual factors, and their descriptions tended to group into separate types of contextual factors:

1) Effect Modifying Contextual Factors
2) Measurement Affecting Contextual Factors
3) Outcome Explaining Contextual Factors

We need your input on a suggested update of the current OMERACT definition to make it operational (i.e. understandable, useful and applicable) by describing each of the three types of contextual factors in detail and how they should be handled within OMERACT and in rheumatology research.

Instructions

On the following pages, each contextual factor type will be explained. You will be asked to what extent you agree with a statement on a scale from 1 to 9: 'Disagree' (1-3), 'Undecided' (4-6), and 'Agree' (7-9). It will be possible to provide feedback where necessary or choose 'Unable to score'.

What's next?

After this first Delphi round, your ratings will be anonymously** summarized with the ones of your stakeholder group. Consensus will be present if ≥70% rate 'agree' (or 'disagree') for a statement. You will be invited for the next Delphi round (likely in a modified version), where you will be presented with the results from the previous round, and you will rate the survey again. A total of three Delphi rounds are anticipated for this study.

What can we offer?

To express our gratitude, we will write your name (with your permission) in the acknowledgment section, if you complete all Delphi rounds. Furthermore, you will have the chance to win a traditional Danish souvenir. But more importantly, you will have a chance to explore our proposed definitions and have a say in how contextual factors should be understood and considered within OMERACT in the future.

CLICK 'REGISTER' TO CONTINUE

***The current OMERACT definition:** OMERACT currently defines a contextual factor as a "*variable that is not an outcome of the study, but needs to be recognized (and measured) to understand the study results. This includes potential confounders and effect modifiers*" (OMRACT filter 2.0, Boers et al, 2014; similar description in filter 2.1)

****Ethics and data protection:** This study will be carried out in accordance with the Helsinki Declaration. The Danish Data Protection Agency has approved the study and data will be handled according to agreements (ID 06081, BFH-2017-127). Your contact data will only be used to sent emails regarding this study. As a default, your answers in the survey will be anonymous. A participant ID code will be auto-generated for each participant to be able to analyse your data across rounds, but it will not be linked to your personal details. Your email will only be linked to your survey answers, if you while signing up allowed this so we can contact you if any of your comments provided in the survey seem unclear to us.

Part 1 - EFFECT MODIFYING contextual factor

Explanation

Effect Modifying Contextual Factors (EM-CFs) are factors that explain part of the ***variability in treatment effects*** between patients.

If patients experience different treatment effects depending on certain factors (i.e. characteristics such as age, sex etc.) measured when they start a treatment, then the treatment effect is 'modified' by these factors. Such factors (i.e. EM-CFs) therefore explain part of the variability in treatment effect between patients participating in a trial, and they are needed to assess whether the results of a trial can be generalized to other populations ('generalizability'). E.g. if a trial tests a treatment in young men only, the effect may not be the same as in old women. Accounting for such factors in trials helps to identify patients likely to benefit most (or experience least harm) from treatments, and therefore facilitates research in personalized care and assessment of generalizability, i.e. whether the trial results are applicable to routine care in the clinics.

Case scenario

A trial investigated the effect of a drug ('Baricitinib') compared to a placebo (i.e. a fake drug) among patients with rheumatoid arthritis who had a history of not responding (i.e. improving sufficiently) to other drugs. As expected, more patients responded to the drug compared to placebo (28% vs 11%; difference of 17%-points). However, when the results were evaluated according to the duration of their disease, patients with longer disease duration (10 years or more) had better effects of the drug compared to the placebo (36% vs 9%; difference of 27%-points) than patients with shorter disease duration compared to placebo (19% vs 13%; difference of 6%-points). [Genovese et al., Rheumatology, 2018]

In this example, the effect of the drug depends on the patients' disease duration. Disease duration is therefore an Effect Modifying Contextual Factor.

Other examples of contextual factors that may modify treatment effects in trials are age, sex, race, disease severity, treatment history, socioeconomic status, healthcare system, place of residence.

Criteria for deciding whether a factor is an effect modifying contextual factor

● The factor fulfils statistical criteria of an 'effect modifier' (i.e. a so-called 'statistical interaction' between treatment group and the contextual factor is found in the analysis of a trial; Wang N Eng J Med 2007).

● The factor is measurable and is measured at the beginning of a trial (baseline).

To what extent do you agree with the following statements?

*Need help? A glossary list is available **HERE**, and help-text will appear as a pop-up box when holding the cursor over a statement. If you want bigger text size, increase the text size in your web browser (guide **HERE**).*

[1st link: Glossary list, i.e. appendix 3, stored in Dropbox; 2nd link: https://www.health.ny.gov/help/text_size.htm]

	Statement
1.a)	The above explanation is clear and understandable (if not, please provide feedback)
1.b)	The above case scenario is clear and understandable, and describes this type of factor well (if not, please provide feedback)

1.c)	The above criteria are clear and understandable, and adequately describe this type of factor (if not, please provide feedback)
1.d)	The factor described above is a type of contextual factor (if not, please provide feedback and proceed – you may use 'Unable to score' where necessary)
1.e)	Such factors should be measured and taken into account in clinical trials (i.e. in the design, analysis and report – e.g. by reporting stratified results according to contextual factors)
1.f)	An OMERACT core outcome domain set should list important contextual factors of this type
1.g)	Effect modifying contextual factors should be classified as either 'personal factors' (e.g. age, sex, race, socioeconomic status) or 'environmental factors' (e.g. health care system, place of residence)
1.h)	Disease-related factors (e.g. disease duration, disease severity, previous treatments) should be included under the 'personal factors' classification
1.i)	The outcome value at baseline (e.g. joint pain or function) could be an effect modifying contextual factor. If so, it is a factor that should be included under the 'personal factors' classification

Part 2 - MEASUREMENT AFFECTING contextual factor

Explanation

Measurement Affecting Contextual Factors (MA-CFs) are factors that explain ***variability in the measurement result itself*** (apart from actual changes/differences in the outcome) within/between patients.

When an outcome is measured, the measurement instrument may be influenced by certain factors (e.g. literacy of the patient, temperature in the room) that alter the measurement, i.e. the measurement is either distorted by these factors (systematic error, bias; reducing the internal validity) or the factors cause an increase in random variability (random error, 'noise'; reducing reliability). Such factors (i.e. MD-CFs) therefore explain (unwanted) variability in the measurement within and/or between patients in a trial and lead to less valid or less reliable results, that could lead to false conclusions. Accounting for these factors, i.e. selecting instruments that are suitable for the patient populations studied in the trial (and use them in a standardized way) will improve the internal validity and/or reliability of the measurements.

Case scenario

Researchers studied to what extent measurement instruments for chronic pain would produce the same results when repeated, in a situation where the patients' pain was not expected to change ('test-retest reliability'). They tested different instruments in rheumatoid arthritis patients, including the visual analogue scale (VAS) and numerical rating scale (NRS). They grouped (stratified) the results according to whether the patients were literate or illiterate. The researchers found the VAS to be less reliable in illiterate patients compared to literate patients. The NRS had high reliability for both patient groups. [Ferraz et al., J Rheumatol., 1990]

In this example, literacy affects the reliability (precision) of the measurement of pain with VAS (but not with NRS). Literacy is therefore a Measurement Affecting Contextual Factor for the VAS instrument.

Other examples of contextual factors that potentially affect the measurement of patient reported outcomes (PROs) are patient education, presence of dementia, time of the day, or how the questionnaire is administered (e.g. completed by the patients themselves or through interview by a health care professional). As an example of measurement outside of PROs, when joint inflammation is measured with ultrasound, skin temperature is a measurement affecting contextual factor.

Criteria for deciding whether a factor is a measurement affecting contextual factor

- The factor leads to random error (noise) or systematic error (bias) of the measurement that is NOT attributed to true changes or differences (within/between patients) in the outcome from treatment or natural variation.
- The factor may impact properties of the measurement instrument (such as 'reliability', 'validity', 'responsiveness', etc.).
- The factor is specific to the measurement instrument (or type of measurement instrument).
- The factor is measurable and is measured at the same time as the outcome.

To what extent do you agree with the following statements?

*Need help? A glossary list is available **HERE**, and help-text will appear as a pop-up box when holding the cursor over a statement. If you want bigger text size, increase the text size in your web browser (guide **HERE**).*

[1st link: Glossary list, i.e. appendix 3, stored in Dropbox; 2nd link: https://www.health.ny.gov/help/text_size.htm]

	Statement
2.a)	The above explanation is clear and understandable (if not, please provide feedback)
2.b)	The above case scenario is clear and understandable, and describes this type of contextual factor well (if not, please provide feedback)
2.c)	The above criteria are clear and understandable, and adequately describe this type of contextual factor (if not, please provide feedback)
2.d)	The factor described above is a type of contextual factor (if not, please provide feedback and proceed – you may use 'Unable to score' where necessary)
2.e)	These factors should be considered when choosing measurement instruments for clinical trials
2.f)	Measurement instruments for an OMERACT core outcome set should be selected with relevant contextual factors of this type in mind
2.g)	Measurement affecting contextual factors should be classified as either 'personal factors' (e.g. literacy when measuring patient reported outcomes [PROs]) or 'environmental factors' (e.g. temperature when measuring joint inflammation with ultrasound)
2.h)	Measuring method related factors (e.g. whether a questionnaire is self-administered or the patient is interviewed by healthcare professionals) should be included under the 'environmental factor' classification

Part 3 - OUTCOME EXPLAINING contextual factor

Explanation

Outcome Explaining Contextual Factors (OE-CFs) explains the ***variability in the outcome itself*** (apart from the treatment tested in the trial) within/between patients.

If a patient experiences that their outcome (e.g. pain) varies due to certain factors, other than the treatment they are receiving, then their current level of the outcome is (partly) 'explained' by such factors. Such factors (i.e. OE-CFs) relate to 'what is behind the numbers' of an outcome measurement. Accounting for changes in such factors during a trial may prevent inappropriate (potentially 'confounded') conclusions about the effectiveness of a treatment when in fact OE-CFs have played a role. Some outcome measures may need the OE-CFs be measured in order to be fully understood (e.g. job type is needed to fully understand a measurement of worker productivity).

Case scenario

A study investigated the association between weather conditions and pain in patients with knee osteoarthritis. They found that patients reported more severe pain when ambient temperature was low and barometric pressure changes were big. [McAlindon et al., Am J Med., 2007]

In this example, temperature and barometric pressure are associated with variations in pain level - and thus, are Outcome Explaining Contextual Factors.

Other examples may be use of assistive devices when measuring mobility or activities of daily living (ADL); and type of leisure activities when measuring participation in leisure activities.

Criteria for deciding whether a factor is an outcome explaining contextual factor

- When the factor varies, this leads to variations in the outcome.
- The factor is measurable and is measured at the same time as the outcome.
- The factor is specific to the outcome.

To what extent do you agree with the following statements?

*Need help? A glossary list is available **HERE**, and help-text will appear as a pop-up box when holding the cursor over a statement. If you want bigger text size, increase the text size in your web browser (guide **HERE**).*

[1st link: Glossary list, i.e. appendix 3, stored in Dropbox; 2nd link: https://www.health.ny.gov/help/text_size.htm]

	Statement
3.a)	The above explanation is clear and understandable (if not, please provide feedback)
3.b)	The above case scenario is clear and understandable, and adequately describes this type of contextual factor (if not, please provide feedback)
3.c)	The above criteria are clear and understandable, and describe this type of contextual factor well (if not, please provide feedback)
3.d)	The factor described above is a type of contextual factor (if not, please provide feedback and proceed – you may use 'Unable to score' where necessary)

3.e)	These factors should be taken into account when interpreting levels of outcome, changes in an outcome within groups and differences in changes between groups in clinical trials
3.f)	An OMERACT core outcome domain set should list important contextual factors of this type
3.g)	Outcome explaining contextual factors should be classified as either 'personal factors' (e.g. age, sex, race, job type) or 'environmental factors' (e.g. weather, place of residence)

Part 4 – All Contextual Factor Types

Now that all three contextual factor types (Effect Modifying -, Measurement Affecting -, and Outcome Explaining Contextual Factors) have been introduced, please let us know to what extent you agree with the following statements:

Need help? Help-text will appear as a pop-up box when holding the cursor over a statement.

	Statement
4.a)	I consider the three types of contextual factors to adequately cover the concept "contextual factors" (if not, please provide feedback)
4.b)	I think EFFECT MODIFYING contextual factors should be part of OMERACT work (if not, please provide feedback)
4.c)	I think MEASUREMENT AFFECTING contextual factors should be part of OMERACT work (if not, please provide feedback)
4.d)	I think OUTCOME EXPLAINING contextual factors should be part of OMERACT work (if not, please provide feedback)

Review Scores

Please review your scores and ensure that the scores you have allocated are correct. If not, you can amend them and then click Next Page.

Additional Statements

If you think this survey is missing important aspects that should be clarified regarding contextual factors, please propose additional statements to be rated in next round.

Write clearly which section your statement would fit within:

- Part 1 - Effect Modifying Contextual Factors
- Part 2 - Measurement Affecting Contextual Factors
- Part 3 - Outcome Explaining Contextual Factors
- Part 4 - All Contextual Factor Types

*Need help? An overview of all explanations and statements presented in this survey is available **HERE**.*

[Link: Short version of this document, i.e. appendix 1, stored in Dropbox]

Comments

If you have any comments for the survey or contextual factors in general, please write them here.

Thank You

Thank you for your participation. Your answers are very valuable for us.

You have received an email from 'DelphiManager' with your login information (it may be in your spam folder).

With kind regards,
Peter Tugwell (co-chair), **Lyn March** (co-chair), **Robin Christensen** (co-chair), **Maarten de Wit** (PRP), **Marieke Scholte Voshaar** (PRP), and **Sabrina Mai Nielsen** (fellow)
On behalf of the Contextual Factors Working Group

Help text (pop-up text) for the Delphi survey

	Pop-up text (only visible when having cursor over statement)
	Questions part 1
1.a)	Please evaluate the section, 'Explanation', above.
1.b)	Please evaluate the section, 'Case scenario', above.
1.c)	Please evaluate the section, 'Criteria for deciding (…)', above.
1.d)	Please consider whether you accept the type of factor described above to be 'contextual factor'.
1.e)	If a clinical trial takes into account contextual factors, such as sex, this could reveal important differences in treatment effects between men and women. (As a note, most trials are unlikely to include enough patients to detect differences between subgroups, however, by reporting stratified analyses anyway, e.g. in an appendix, this can be investigated later in meta-analyses based on results from several trials.)
1.f)	Lots of potential contextual factors can be investigated in a clinical trial, and if trials investigate different factors, it is likely impossible to make any conclusions that can improve patient care. Therefore, it is reasonable that it is decided WHICH factors should be measured and taken into account in clinical trials. This could be a job for OMERACT.
1.g)	Effect modifying contextual factors may cover many categories of factors that are not relevant for clinical trials. This can be narrowed down by specifying categories that the factors need to fit into: 'personal factors' and 'environmental factors'. These categories are part of a recognized classification system of 'contextual factors' developed by the ICF ('International Classification of Functioning, Disability and Health'). ICF states: PERSONAL FACTORS comprise features of the individual that are not part of a health condition or health states, e.g. gender, race, age, other health conditions, fitness, lifestyle, etc., all or any of which may play a role in disability at any level. ENVIRONMENTAL FACTORS make up the physical, social and attitudinal environment in which people live and conduct their lives, e.g. factors related to place of residence, climate, support (or attitudes) from family and friends, health care system etc. (WHO, 2001)
1.h)	'Disease related factors' is not part of the original ICF classification (see help text for statement above for more info). HOWEVER, disease related factors have on several occasions within the Contextual Factors Working Group been suggested as relevant contextual factors for trials within rheumatology.
1.i)	'Outcome value at baseline' is not part of the original ICF classification (see help text for statement above for more info) AND this may be somewhat in disagreement with the current OMERACT definition of contextual factors, stating that a contextual factor is a "variable that is NOT an outcome of the study, but needs to be recognized (and measured) to understand the study results." (Boers, 2014). HOWEVER, during our interview-study, experts tended to consider the baseline value of the outcome of interest as a potential contextual factor. EXAMPLE: The patients' pain level at the start of a trial (baseline) may modify the treatment effect on pain at the end of the trial. If patients at baseline have very little pain, this leaves less room for improvement from a treatment.
	Questions part 2
2.a)	Please evaluate the section, 'Explanation', above.
2.b)	Please evaluate the section, 'Case scenario', above.
2.c)	Please evaluate the section, 'Criteria for deciding (…)', above.
2.d)	Please consider whether you accept the type of factor described above to be 'contextual factor'.
2.e)	If research shows that the measurement of an outcome (e.g. joint pain) may be distorted for certain subgroups of patients when using certain measurement instruments, this should be taken into account in CLINICAL TRIALS to ensure that the measurement instruments are suitable for the patients of interest. As an example, based on the case scenario above, for a trial investigating joint pain in illiterate patients you may consider using the Numerical Rating Scale (NRS) rather than the Visual Analogue Scale (VAS).
2.f)	When OMERACT working groups select measurement instruments for a core outcome set, it should be investigated whether certain factors have shown to distort the measurements, and, hence, whether certain instruments are not suitable for certain patient subgroups (e.g. literate patients), or whether certain factors need to be standardized (/kept constant) when performing the measurement (e.g. temperature), depending on the type of measurement instrument.

2.g)	Measurement affecting contextual factors may cover many categories of factors that are not relevant for clinical trials. This can be narrowed down by specifying categories that the factors need to fit into: 'personal factors' and 'environmental factors'. These categories are part of a recognized classification system of 'contextual factors' developed by the ICF ('International Classification of Functioning, Disability and Health'). ICF states: PERSONAL FACTORS comprise features of the individual that are not part of a health condition or health states, e.g. gender, race, age, other health conditions, fitness, lifestyle, etc., all or any of which may play a role in disability at any level. ENVIRONMENTAL FACTORS make up the physical, social and attitudinal environment in which people live and conduct their lives, e.g. factors related to place of residence, climate, support (or attitudes) from family and friends, health care system etc. (WHO, 2001)
2.h)	'Measuring method related factors' is not part of the original ICF classification (see help text for statement above for more info). HOWEVER, such factors may be important. E.g., a study found that RA patients receiving both a questionnaire to complete themselves, versus being interviewed by an occupational therapist, reported more difficulties performing self-care activities when using the self-administered questionnaire. (Spiegel, 1985)
	Questions part 3
3.a)	Please evaluate the section, 'Explanation', above.
3.b)	Please evaluate the section, 'Case scenario', above.
3.c)	Please evaluate the section, 'Criteria for deciding (…)', above.
3.d)	Please consider whether you accept the type of factor described above to be 'contextual factor'.
3.e)	Changes in 'outcome explaining contextual factors' during a trial may make us believe that the treatment that is being tested is worse/better than it actually is. EXAMPLE: if a trial is conducted in Europe from winter to summer, improvement in joint pain may partly be explained by warmer during the trial. If somehow the changes in 'outcome explaining contextual factors' are unevenly distributed between groups, this may impact (confound) differences in changes between the groups.
3.f)	OMERACT working groups (that develop core outcome sets) should investigate and list (outcome explaining) contextual factors to be measured and taken into account in clinical trials when interpreting the trial results.
3.g)	Outcome explaining contextual factors may cover many categories of factors that are not relevant for clinical trials. This can be narrowed down by specifying categories that the factors need to fit into: 'personal factors' and 'environmental factors'. These categories are part of a recognized classification system of 'contextual factors' developed by the ICF ('International Classification of Functioning, Disability and Health'). ICF states: PERSONAL FACTORS comprise features of the individual that are not part of a health condition or health states, e.g. gender, race, age, other health conditions, fitness, lifestyle, etc., all or any of which may play a role in disability at any level. ENVIRONMENTAL FACTORS make up the physical, social and attitudinal environment in which people live and conduct their lives, e.g. factors related to place of residence, climate, support (or attitudes) from family and friends, health care system etc. (WHO, 2001)
	Questions part 4
4.a)	If needed, you can go back to previous pages by using the drop down menu in the lower right corner and click 'Go to'.
4.b)	This factor was described on page 1. If needed, you can go back by using the drop down menu in the lower right corner and click 'Go to'.
4.c)	This factor was described on page 2. If needed, you can go back by using the drop down menu in the lower right corner and click 'Go to'.
4.d)	This factor was described on page 3. If needed, you can go back by using the drop down menu in the lower right corner and click 'Go to'.

Glossary list

Baseline	The initial assessment at the start of a 'study'. The effect of an intervention (e.g. a new tablet) can be determined by comparing baseline scores to follow up scores. *(OMERACT glossary[1])*
Confounding (/confounder)	Variables which might confuse the association that is seen in a study. E.g. there seems to be an association between alcohol and lung cancer. But this does not mean alcohol causes lung cancer. The link is really between smoking and lung cancer - alcohol confounds or confuses the issue because people who drink alcohol are more likely to smoke and therefore get lung cancer. *(OMERACT glossary[1])*
Contextual factors	According to the current OMERACT definition, a contextual factor is defined as a "*variable that is not an outcome of the study, but needs to be recognized (and measured) to understand the study results. This includes potential confounders and effect modifiers*"[2]. However, this definition is considered rather broad, unspecific and confusing to many. Therefore, the Contextual Factors Working Group (CFWG) aims to update this definition to make it useful for OMERACT working groups and rheumatology clinical trials. This is done by first interviewing patients, clinicians and researchers about their views on contextual factors. From this, we identified three different subtypes of contextual factors that may be relevant to consider in clinical trials. Finally, a Delphi survey is conducted (*the one you are participating in*) to collect opinions from stakeholders on several aspects, to fully make the three types of contextual factors useful.
Delphi survey	The Delphi Process is a means of reaching consensus through structured consultation between a group of people who may have very different perspectives and fields of expertise. It is particularly useful where there is little or no published information on the subject under consideration. Unlike more familiar consultation methods such as steering groups, the Delphi Process doesn't need participants to physically meet together and there is no limit on how many people can be involved. Since the process is anonymous, it avoids 'power struggles' because there is no opportunity for a strong individual to unduly influence the group and people can change their minds without losing face. The process also enables a combination of many opinions into a group response and can be completed in as short a time as possible. To ensure anonymity, the Delphi Process uses questionnaires. These involve a number of statements to which participants respond using a ranking system. Reponses are analysed centrally and then fed back to all participants, enabling individuals to change their mind and re-rank their answers if they wish, in light of opinions expressed by the group. The process is repeated until consensus is reached. At the end, a statistical response is arrived at for each statement that equates to the strength of opinion felt by the group. The result can then be used as a benchmark for developing good practice. *(OMERACT glossary[1])* I*n the Delphi survey you are participating in, we anticipate three rounds.*
Effect modifier	Effect modification is present when the effect of an intervention varies according to patient subgroups. [3] The (baseline) characteristics describing the patient subgroups (or environment) are effect modifiers. E.g. if the effect of a treatment is different for men and women, then sex is an effect modifier. Effect modifiers are assessed by performing a statistical test for interaction.
Generalizability (of trial results)	Refers to whether the results of a trial can be generalized to real world patients in clinical practice.
Literate (/literacy)	Definitions of literacy varies from being broad to narrow. When UNESCO estimates worldwide adult illiteracy rate, literacy was defined as a person's ability to "*both read and write with understanding a short simple statement on his/her own life*". The International Literacy Association defines literacy as "*the ability to identify, understand, interpret, create, compute, and communicate using visual, audible, and digital materials across disciplines and in any context"* [4]. [5]

	In the case scenario illustrating 'measurement distorting contextual factors', patients were considered illiterate if they did not know how to read or write Portuguese (the study was conducted in Brazil), and they were also innumerate (i.e. unable to use mathematics).
Numeric rating scale (NRS)	A commonly used scale for rating pain. *See Figure 1.*
Outcome	The effect of treatment on a patient, which may be measured in a number of ways. Objective measures (outcomes) are independent of the opinion of the patient, e.g. radiologic joint damage (X-rays), biological blood tests (rheum factor, serum levels of MMPs, ECR and CRP). More subjective outcomes are based on the experience or opinion by the patient, e.g. questionnaires like HAQ. Outcome expectancy is a belief that certain behavior will lead to a certain outcome (e.g. pacing one's lifestyle will lead to reduced fatigue) and is based on the patient's knowledge of RA management. *(OMERACT glossary[1])*
Placebo	A sham treatment. If the treatment is a tablet or capsule it will contain no active ingredient. The best placebos are identical to the real drug and help to maintain blinding in either single or double blind trials. Placebos are used to help separate the real effect of the active ingredient from any benefit (or side effects) that the subject may experience by chance or purely by the acting of taking tablets. *(OMERACT glossary[1])*
PROs	A patient reported outcome, often shortened to PRO, is any consequence of an illness reported by patients. Examples include pain, disability, inability to work normally, becoming fatigued, etc. *(OMERACT glossary[1])*
Random variability (random error, 'noise')	When a measurement instrument produces results that are imprecise. E.g. if a scale for measuring body weight sometimes randomly measures 5 kg too much and other times measures 2 kg too little. Random error (noise) reduces the reliability of the measurement instrument. *See 'Test-retest reliability'.*
Statistical interaction	Effect modifiers are assessed by performing a statistical test for interaction. In the case of contextual factors, one would investigate whether the factor and the treatment provided in the trial are 'interacting', i.e. whether the effect of the treatment is dependent on the factor (e.g. men vs women). In practice, this is done by formulating a specific statistical model when analyzing the data. If the model shows that there is an interaction present, we can conclude that the factor investigated is an effect modifier (and, hence, an 'effect modifying contextual factor').
Systematic error (bias)	When a measurement instrument systematically produces results that are either too high or to low (i.e. the measurement results are biased in a certain direction). E.g. if a scale for measuring body weight consistently measures 5 kg too much. Systematic error (bias) reduces the validity of the measurement instrument. *See 'Validity (internal)'.*
Personalized medicine (/personalized care)	Personalized medicine seeks to target therapy and make the best decisions for groups of patients according to certain characteristics. E.g. if evidence shows that a certain treatment has a better effect in certain groups of patients (e.g. women, elderly, those with long disease duration etc.), the treatment could be restricted (or "personalised") to those who will benefit the most – i.e. personalized care. [6]
Reliability	Also called 'precision'. *See 'Test-retest reliability'.*
Responsiveness	The ability of an instrument (methods, questionnaire etc.) to measure a significant change in disease-activity over time. The ACR and the Eular recommend different response criteria (or improvement criteria). Their criteria have comparable validity in RA. See also: Anke M. van Gestel et al. "ACR and Eular improvement criteria have comparable validity in RA trials", J. Rheumatol 1999;26:3:705-711. *(OMERACT glossary[1])*
Test-retest reliability	Reliability is defined as "*the degree to which the measurement is free from measurement error*". Test-retest reliability is "*the extent to which scores for patients who have not changed*

	are the same for repeated measurement (…) over time" [7], or in other words, the ability to provide consistent scores over time in a stable population.
Treatment effect in trial (/effect size)	The degree of improvement (or otherwise) of a particular therapy after any placebo effect has been accounted for. The treatment effect can be presented in several ways, e.g. as the difference in change in an outcome between groups (i.e. treatment group vs placebo group), or as the difference in proportions of responders between groups etc. *(OMERACT glossary[1])*
Validity (external)	The extent to which the research findings can be generalised to the wider population of interest and applied to different settings. (Bowling, 1997). *OMERACT glossary[1])*
Validity (internal)	The ability of an instrument (method, questionnaire) to measure what it has to measure (or what we think or expect to measure). This is what is called "truth" in the OMERACT filter. The validity of an instrument is not obvious. For example: RA patients do have high scores on some depression questionnaires. Not because they are depressed, but as the results of questions like: "I always have a slow start in the morning", "I often feel tired" and "I can't do the same as before". For this reason one has to conclude that such a questionnaire is not valid for RA patients. *OMERACT glossary[1])*
Visual Analogue Scale (VAS)	A commonly used scale for rating pain. *See Figure 1.* A VAS is a way of measuring by asking a person to put a mark on a line, for example a 100 mm. VAS, without scale indication. Only the endpoints are given, for example: no pain at all and extreme pain. In this way you can measure different criteria, like morning stiffness, fatigue or general well being. A VAS can be made by the consultant as well as by the patient. *(OMERACT glossary[1])*

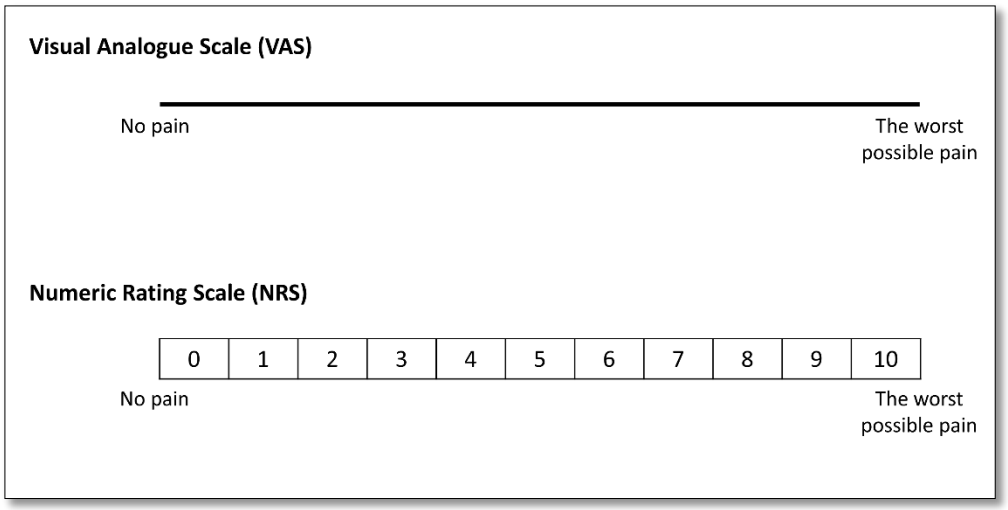

Figure 1: Visual Analogue Scale (VAS) and Numeric rating scale (NRS). *Figure inspired by Ferraz et al. (1990)* [8]

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Email invitation

EMAIL TOPIC: OMERACT Delphi survey regarding Contextual Factors

Dear *[name here]*

Most people find 'Contextual Factors' rather confusing – even us within the OMERACT Contextual Factors Working Group! However, one thing that most seem to agree on is that ***contextual factors need to be taken into account in clinical trials***. Why? Because they can influence the interpretation of trial results and potentially lead to inappropriate conclusions about effectiveness and/or safety. OMERACT therefore requires that core set developers consider contextual factors.

Interestingly, our latest research suggests that the confusion is likely due to the fact that when we talk about 'contextual factors' we may actually be talking about ***different types of contextual factors***.

Curious about what these factors are and what it means for you as an OMERACT member?

In this Delphi survey you will review our proposed definitions and we welcome your input into how contextual factors in the future should be understood and considered within OMERACT:

https://delphimanager.liv.ac.uk/ContextualFactors/

Estimated time for answering based on pilot test is approx. **25 minutes**.
Notice, some reading is needed, so it is **NOT** suitable for answering with your smartphone.

This survey is relevant for all OMERACT members – we need your opinion!

Bonus: If you answer the survey right away you will get the chance to win a traditional Danish souvenir. One winner will be found for each of the three stakeholder groups (i.e. patients, clinicians, and 'others'). Further, we offer to write your name in the acknowledgement section (with your consent of course) if you complete all Delphi rounds.

Thanks in advance for your participation

With kind regards,

Peter Tugwell (co-chair), **Lyn March** (co-chair), **Robin Christensen** (co-chair), **Maarten de Wit** (PRP), **Marieke Voshaar** (PRP), and **Sabrina Mai Nielsen** (fellow)

On behalf of the Contextual Factors Working Group

Demographic questionnaire

This is an overview of what will be used in the online DelphiManager program:

Name	[textbox]*
E-Mail address	[textbox]*
Confirm Email	[textbox]*
Stakeholder group	[dropdown menu, 3 options]* Patients Clinicians, who are currently involved in rheumatology patient care (such as physicians, nurses, physiotherapists, occupational therapists etc.) Others (such as biostatisticians, methodologists, researchers or trialists etc., currently NOT involved in patient care)
If your stakeholder group is 'other', please specify	[textbox]
Age	[textbox]*
Sex	[radio buttons, 3 options]* Female Male Other/Do not want to declare
Country of residence	[textbox]*
Which working group(s) are you involved in?	[checkboxes, 46 options]* (2) *Currently not part of any working group* *Disease - ANCA Vasculitis (Core Set)* *Disease - Axial Spondyloarthritis (Core Set)* *Disease - Behçet's Syndrome (Core Domain Set)* *Disease - Calcium Pyrophosphate Deposition (CPPD)* *Disease - Chronic Nonbacterial Osteomyelitis (CNO)* *Disease - CTD-ILD (Core Domain Set)* *Disease - Fibromyalgia (Core Set)* *Disease - Flares in OA* *Disease - Foot & Ankle Disorders* *Disease - Glucocorticoid-Related Adverse Events* *Disease - Gout* *Disease - Hand OA (Core Domain Set)* *Disease - Hip & Knee Osteoarthritis (Core Set)* *Disease - Juvenile Idiopathic Arthritis (Core Domain Set)* *Disease - Large Vessel Vasculitis* *Disease - Myositis (Core Domain Set)* *Disease - Osteoporosis (Core Set)* *Disease - Polymyalgia Rheumatica (PMR) (Core Domain Set)* *Disease - Psoriatic Arthritis (Core Domain Set)* *Disease - Rheumatoid Arthritis (Core Set)* *Disease - Shoulder Pain Outcome Measures (Core Domain Set)* *Disease - Sjogren's* *Disease - Systemic Lupus Erythematosus (Core Set)* *Disease - Systemic Sclerosis - Raynaud's* *Imaging & Biomarkers - Gout - Biomarkers* *Imaging & Biomarkers - Juvenile Idiopathic Arthritis MRI (JAMRI)* *Imaging & Biomarkers - MRI Taskforce* *Imaging & Biomarkers - Study grouP for xtrEme-Computed Tomography in Imaging & Biomarkers - Rheumatoid Arthritis (SPECTRA)* *Imaging & Biomarkers - Synovial Tissues in RCT* *Imaging & Biomarkers - Ultrasound* *Instrumentation Across Diseases - Adherence* *Instrumentation Across Diseases - Pain* *Instrumentation Across Diseases - Shared Decision Making*

Instrumentation Across Diseases - Stiffness
Instrumentation Across Diseases - Work Productivity
Methods - Composite Outcomes
Methods - Consensus for Consensus
Methods - Contextual Factors
Methods - Health Equity
Methods - Patient Outcomes in Longitudinal Observational Studies (POLOS)
Methods - Patient preferences to value health outcomes for RCT's
Methods - Remission in RA-patient perspective
Methods - Safety
Methods - Surrogate Outcome - Serum Urate Biomarker in Gout
CURRENTLY NOT PART OF ANY WORKING GROUP
NOT LISTED – please specify

If not listed, please specify [textbox]

How many years have you been involved in OMERACT? [radio buttons, 4 options]*
- <1 year
- 1-5 years
- 6-10 years
- >10 years

What is your primary rheumatic condition? (for patients only) [radio buttons, 22 options]* (2)
- I AM NOT A PATIENT
- ANCA Vasculitis
- Axial Spondyloarthritis
- Behçet's Syndrome
- Calcium Pyrophosphate Deposition (CPPD)
- Chronic Nonbacterial Osteomyelitis (CNO)
- CTD-ILD (i.e. Connective Tissue Disease-associated Interstitial Lung Disease)
- Fibromyalgia
- Osteoarthritis (OA)
- Gout
- Juvenile Idiopathic Arthritis (JIA)
- Large Vessel Vasculitis
- Myositis
- Osteoporosis
- Polymyalgia Rheumatica (PMR)
- Psoriatic Arthritis (PsA)
- Rheumatoid Arthritis (RA)
- Shoulder Pain
- Sjogren's syndrome
- Systemic Lupus Erythematosus (SLE)
- Systemic Sclerosis - Raynaud's
- NOT LISTED – please specify

If not listed, please specify [textbox]

Are we allowed to contact you regarding your answers (i.e. if we find any comments/suggestions unclear)? [radio buttons, 2 options]*
- Yes
- No

I agree to participate in, and receive email notifications regarding this study [checkbox]*

**Mandatory to answer these questions*

References:

1: 1. United Nations. Member States. 2020. https://www.un.org/en/member-states/index.html [Date accessed: 2020 January 27].

2: OMERACT. Working Groups. 2020. https://omeract.org/working-groups/ [Date accessed: 2020 January 28].