Defining and identifying contextual factors within rheumatology:

Protocol for semi-structured interviews of experts and Delphi surveys

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ABSTRACT

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 these challenges of contextual factors in clinical trials.

Objectives: The primary objective is to provide an operationalized definition of contextual factors through a consensus process based on expert inputs. The second objective is to clarify the terminology related to the concept of contextual factors. Furthermore, general methodological guidance will be developed subsequently on how to identify important contextual factors within different fields of rheumatology (i.e. within different OMERACT working groups).

Methods and analysis: In this study, we will utilize semi-structured interviews of clinicians and researchers (e.g. statisticians, methodologists, and trialists), who may be considered experts within the field of contextual factors in clinical trials (or potentially related fields). In parallel with the expert interviews, a patient research partner (PRP) group interview will be conducted. We will conduct the interviews using an interview guide (an adapted version will be used for the PRP group interview), and analyse the data using content analysis. The synthesis will consist of formulating a number of common statements representing opinions expressed during the interviews. A Delphi will be conducted among potential users and relevant stakeholders (including clinicians, researchers, statisticians, methodologists, trialists, patients etc.), in order to reach consensus on a number of statements regarding contextual factors. The statements will be supported by relevant explanations, examples and references, when possible, and a common text will be drafted.

Dissemination: The results will be disseminated through presentations at rheumatology meetings, including OMERACT meetings, and through a publication in an international peer-reviewed journal.

INTRODUCTION

A core outcome (measurement) set is a minimum consensus-based set of outcome domains and instruments that should be measured and reported in all clinical trials for a specific health condition and/or intervention[1 2]. Since 1992, the Outcome Measures in Rheumatology (OMERACT) consensus initiative has successfully developed core sets for many rheumatologic conditions, actively involving patients since 2002[1]. As other initiatives, like the Core Outcome Measures in Effectiveness Trials (COMET) started to formalize the existing methodology, OMERACT's expanding scope required an explicit formulation of its underlying conceptual framework and process to develop core outcome measurement sets for rheumatology[1].

In 2012, the concept of contextual factors was introduced for the first time in the OMERACT process in a preliminary version of the OMERACT Handbook. According to the current principles, core set developers need to specify the setting of the core set, and consider if there are any contextual factors that need to be measured in all trials ('core contextual factors'). However, the research presented in OMERACT 2014 revealed great heterogeneity in understanding, approaching, and identifying contextual factors[3]. To address this, the Contextual Factors Working Group (CFWG) was formed with the objective to provide guidance on how to address contextual factors in clinical trials. At the OMERACT 2016 CFWG SIG session, the participants agreed that the OMERACT Handbook definition should be used as the main operational definition and the definition by the International Classification of Functioning, Disability and Health (ICF) should be used as the conceptual framework[4]. In the current version of the OMERACT Handbook, 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*"[5]. This definition is conceptual and needs operationalization for proper consideration of contextual factors in future research.

Within the ICF framework of functioning and health, contextual factors are defined and further divided into environmental factors and personal factors; "*Environmental factors make up the physical, social, and attitudinal environment in which people live and conduct their lives. Personal factors are the particular background of an individual's life and living, and consist of features of the individual that are not part of a health condition or health states.*"[6]. At the OMERACT 2016 CFWG SIG session, however, it was discussed that contextual factors in trials could also be related to health condition (such as disease duration) and study characteristics (such as multicenter vs. single-center trials), and hence not necessarily covered by the ICF.

Therefore, to achieve consensus on the definition, terminology, identification and analyses of contextual factors relevant for rheumatology trials, an expert-driven approach including qualitative data

collection with a subsequent consensus process among potential users and important stakeholders is needed.

Objectives

The primary objective is to provide an operationalized definition of contextual factors through a consensus process based on expert inputs. The second objective is to clarify the terminology related to the concept of contextual factors. Furthermore, general methodological guidance will be developed subsequently on how to identify important contextual factors within different fields of rheumatology (i.e. within different OMERACT working groups).

METHODS

Protocol

This protocol will be published online on the Parker Institute web page (www.parkerinst.dk) prior to conducting any interviews. The study will be reported according to the Consolidated Criteria for Reporting Qualitative Studies (COREQ)[7].

Study design

In this study, we will utilize a consensus process based on expert inputs. First, semi-structured interviews of experts, as well as a patient research partner (PRP) group interview, will be conducted and analyse the data using content analysis. Next, a Delphi survey will be carried out involving potential users and important stakeholders.

Ethics, permissions and consent

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).

Participants and setting

Contextual factors and applicability issues span a breadth of disciplinary fields that may have different approaches to defining and handling contextual factors in trials. Because we aim for broad relevance of this OMERACT guideline on contextual factors, we want to seek opinions regarding how to define and address contextual factors in trials from different disciplinary perspectives. We will conduct key informant semi-

structured interviews since this is an efficient way to engage diverse stakeholders, and then collect and synthesize their views using content analysis.

The potential participants will initially be selected by purposeful sampling. Participants need to be either clinicians and/or researchers (e.g. statisticians, methodologists, and trialists), who may be considered experts within the field of contextual factors in clinical trials (or potentially similar subjects such as predictive/prognostic factors, effect modifiers, subgroup effects, or stratified analyses/interaction, equity) related field. We will identify participants through our co-authors and the OMERACT Executive as well as lead authors of relevant empirical studies and other guidance documents. We will select participants to maximize variation of disciplines and stakeholder organizations (e.g., academic, industrial, research ethics boards, governmental), as well as gender and geographical representation (i.e. ≥3 continents). We will expand our sample by snowball sampling: an approach to recruit participants that builds on networks by asking each participant to suggest additional contacts[8]. The potential participants will initially be approached by email including an invitation with a brief description of the study and their role as well as informing that participation is voluntary and can at any time be discontinued. Reasons for refusing participation or drop out will be sought, and participants will be asked to identify another relevant expert. Upon acceptance, the participants will be provided with:

- A short overview of the content of the interview guide (**Box 1**)
- The research protocol (excluding the questions)
- A few case scenarios involving contextual factors from OMERACT working groups

The interviews will be conducted through individual calls via Skype.

In parallel with the expert interviews, a PRP group interview will be conducted to obtain the patients' perspectives on contextual factors. The topics discussed will be similar to that of the expert interviews, but the questions will be adapted in collaboration with a PRP (MdW).

Box 1: Content overview of interview questions

- **Defining a contextual factor**
- **Terminology related to (or confused with) contextual factor**
- **Identifying important contextual factors and how to take such into account in trials**
- **Other relevant experts that should be invited for an interview regarding contextual factors**

Data collection

The interviews will initially be conducted using a predefined interview guide (**Box 2**). The content and structure of the interview guide is based on experiences gained from the OMERACT 2016 CFWG SIG session[4], general inputs from the CFWG, experiences gained from an unstructured interview with an expert (BR) (see themes discussed in **Appendix 1**), existing potentially related initiatives, as well as survey results (**Appendix 2**). During the interviews, probing questions will be used (i.e. follow-up questions based on the answers), as well as relevant case scenarios involving contextual factors will be presented if needed (**Appendix 3**).

We will conduct interviews by phone/internet call or face to face and take notes during the interviews as well as tape record the interviews. The interviews are anticipated to last for maximum 45 minutes. The specific questions in the interview guide may be modified along the way based on experiences from the previous interviews and inputs from the CFWG.

The interviews will be conducted by SMN. The personal characteristics of SMN include the credentials BSc and MSc, occupation as a research fellow, and she will undergo informal training and supervision by an experienced qualitative researcher (MUR). MUR has the credentials RN, MPH and PhD, and is occupied as a Post Doc. She has 6 years of experience within qualitative research. It is anticipated that the participants will be aware of the role of SMN within the CFWG (i.e. fellow) and how the interviews will contribute to the work within the CFWG.

The interviews will be transcribed and returned to the participants for comments and/or corrections.

Data analysis and sample size

Sample size will be determined by theoretical saturation, defined as when subsequent interviews contribute no new data, and is anticipation to occur at 10-13 interviews[9]. The transcribed interviews will be analysed using content analysis[10] conducted by SMN, supported by MUR. In the first stage, the transcripts from the interviews will be read multiple times and relevant pieces will be coded in the margins. The codes from each of the transcripts will be collected onto a clean set of pages, and will be reduced and refined by removing duplicates and merging overlapping codes. In the second stage, conceptually-related codes will be grouped into categories and subcategories. Categories may include the following themes Definition, Terminology, Importance, Analysis or similar.

Box 2: Pre-defined interview guide

Part A: Definition and terminology

In the OMERACT Handbook, a contextual factor is conceptually 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".

This definition needs operationalization for further application.

1. In the context of randomized clinical trials:
    a. Which criteria need to be fulfilled before a "factor" can be considered a contextual factor?
    b. Can a contextual factor vary or be time-varying – or is it always constant during the trial period (e.g. as assessed at baseline)?
    c. How would you describe a contextual factor in lay terms to a patient?
    d. Please provide a few examples of contextual factors and of variables that are clearly not contextual factors*.
2. How do you consider contextual factors to be the same or different from:
    a. Predictive factors? (please explain)
    b. Prognostic factors? (please explain)
    c. Effect modifiers? (please explain)
    d. Subgroup effects? (please explain)
    e. Stratified analysis and interaction? (please explain)
3. Can you think of other terms that may be the same as contextual factors?
4. Can you think of other terms that may be confused with contextual factors, and which need to be clarified when explaining contextual factors to trialists, researchers, statisticians, methodologists, clinicians, patients etc.?

Part B: Identifying important contextual factors

We intend to develop a set of 'important' generic contextual factors that need to be considered as potentially 'core' in rheumatology trials.

1. What elements would make a contextual factor important across multiple disease areas within rheumatology?
    a. Which general or conceptual criteria need to be fulfilled?
    b. Which statistical criteria need to be fulfilled?
2. *In addition to the set of important generic contextual factors, each OMERACT working group may wish to add specific contextual factors when defining their 'core contextual factors' for a specific core outcome set for a rheumatic condition.* What would prove that a specific contextual factor is important?
3. What caveats or conditions would *you* anticipate in the pursuit of important contextual factors?
4. How should important contextual factors be taking into account in future research? (e.g. when designing, analysing and reporting trials, and when summarizing evidence from existing literature)

Part C: Snowballing

1. Can you name other clinicians or researchers, who you would recommend us to interview as well?

*Possible probing questions will be inspired survey results (Appendix 2)

Synthesis and consensus

The synthesis will consist of formulating a number of common statements representing opinions expressed during the interviews. The statements will be drafted by SMN and reviewed by members of the CFWG.

Based on the statements, a Delphi will be conducted among potential users and relevant stakeholders (including clinicians, researchers, statisticians, methodologists, trialists, patients etc.), allowing for expressing degree of agreement and suggest rephrasing. The first round of the Delphi survey will be piloted by members of each stakeholder group, including 2-3 patient research partners (PRPs), to specifically make sure that all terms, language, comprehension of the questions and introduction texts are understandable for patients. A separate concise protocol stating the exact Delphi survey questions and further details will be written for this purpose, prior to initiating the Delphi.

The result of the Delphi will include consensus on a number of statements regarding contextual factors. The statements will be supported by relevant explanations, examples and references, when possible, and a common text will be drafted.

In order to ensure clarity and applicability of the common text, the text will be reviewed by members of the CFWG as well as a small group of 4-6 PRPs. This will be done through separate online one hour group discussions, where the findings (i.e. the text) will be provided to the participants on beforehand as well as being presented prior to the interview. The participants will be asked if it makes sense from their perspective and if they immediately understand what is meant. The results of this interview might lead to minor changes in formulations in the text. Furthermore, the text will be circulated among the chairs of the OMERACT working groups, which will be encouraged to comment on the formulation of the statements, and may as well lead to minor changes in formulations in the text.

Patient involvement

Following common OMERACT recommendations, at least two PRPs (MdW and MSV) have been involved during the whole process in the same way as other members in the CFWG's activities. Following the EULAR recommendations for patient involvement[11], the contribution of the PRPs are, and will continue to be, recognized, and any inputs from the PRPs are considered important. Both PRPs are well experienced in the OMERACT methodology, and hence, will not receive any training. In addition to this, patients are involved as important stakeholders in the interviews and Delphi survey.

PERSPECTIVES AND DISSEMINATION

This qualitative study will provide consensus on how to define and identify contextual factors related to rheumatology trials, as well as among potential users and important stakeholders. We anticipate that this will be an important step towards taking contextual factors into account in future research, which could potentially bring us closer to personalized medicine. The study will be disseminated through presentations

at rheumatology meetings, including OMERACT meetings, and a publication in an international peer-reviewed journal.

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APPENDIX 1: Themes discussed in an unstructured interview (used for designing of the interview guide)

- Definition and related terminology
    - Predict the treatment response
    - Stratified medicine
    - Prognostic factors
    - Predictive factors
    - Not an outcome of the study
    - Effect modification
    - Heterogeneity of effects
    - Subgroup effects
    - Interaction (quantitative interactions and qualitative interactions)

- Classification
    - Patient-level, intervention-level, trial-level.
    - ICF, Environmental factors and Personal factors
    - Health condition or health states.

- Challenges when specifying and analysing important contextual factors
    - Focus is usually on main effects (risk of type-2 errors, only qualitative interactions may be detectable)
    - Consistent reporting may generate power for meta-analyses
    - Important contextual factors could be variables traditionally reported in table 1 of trial reports
    - Many contextual factors may in general not make a difference on the outcome
    - Field/outcome specific important contextual factors

APPENDIX 2: Inputs from survey of OMERACT working groups (used for designing of the interview guide)

Survey question (optional part of the survey):
The next upcoming study within the CFWG aims at providing a **clear and elaborated (operationalised) definition of contextual factors.** This will be done through **semi-structured interviews of experts** (incl. statisticians, methodologists, and trialists) who may be considered experts within a contextual factor (or potentially similar subjects such as predictive/prognostic factors, effect modifiers, subgroup effects, or stratified analyses/interaction) related field.
If you have any specific and/or general issues regarding contextual factors from your working group, which you recommend us to get addressed in the interviews, fell free to state them below (*e.g. definition, related terminology, classification, handling of contextual factors in planning and analysis of trials etc.*):

Regarding contextual factors, we recommend that the experts address the following issue(s): Write your answer here

Answers:
Issues recommended to get addressed in the interviews of experts

Working Group (self-reported name)	**Issues recommended to get addressed in the interviews of experts**
Glucocorticoid impact	"Glucocorticoid impacts are probably modified by diagnosis for which they are prescribed, dose, and duration of prescription."
Hand OA	"In addition to what is named above: analysis of contextual factors in existing literature.
Medication Adherence	"Whether medication adherence should be a key contextual factor in all drug trials of different rheumatic conditions."
Vasculitis	"Disease duration, experience of investigator, geographic location, access to newer/expensive biologic agents, social/family support."
Extra*	"Need to consider effect of disease diagnosis per se as a contextual factor (e.g. PsA vs RA; SSc vs SLE); obviously, need to consider the context of country or region - China, Japan, Europe, North America."

*Not representing any OMERACT working group.

APPENDIX 3: Case scenarios involving contextual factors

The primary objective of the survey of OMERACT working groups was to collect examples of case scenarios (trial settings) involving contextual factors with an important impact on the trial outcome. The answers were reviewed for any erroneous entries by one researcher (SMN) supported by another researcher (RC), and, if needed, mails were sent with clarifying questions to the respective co-chairs of the working group. Of the case scenarios, at least three case scenarios were selected based on:

- The disease involved; preferably, the case scenarios should involve different diseases
- The type of contextual factors involved; at least one example should involve environmental contextual factors
- Method of handling contextual factors; a variety in methods between the case scenarios will be aimed for
- General value for future studies within the CFWG (i.e. the semi-structured interviews of experts)

Preference were given though, to potentially core contextual factors if more than one working group indicated that this generic construct applies across multiple conditions/interventions (e.g. sex, age, and comorbidities).

Case scenario 1

WORKING GROUP

Gout

CONTEXTUAL FACTORS

Personal contextual factor:

Previous urate-lowering vs. ULT-naive

Environmental contextual factor:

NA

REFERENCE

Title and reference:

The urate-lowering efficacy and safety of febuxostat in the treatment of the hyperuricemia of gout: the CONFIRMS trial.

Becker MA et al. Arthritis Res Ther. 2010;12(2):R63.
https://www.ncbi.nlm.nih.gov/pubmed/20370912

TRIAL SETTINGS

Population:

Patients with gout

Intervention:

Urate-lowering treatment

Outcome:

Rate of flares

EXPLANATION

In the CONFIRMS trial, patients previously treated (even in a previous trial) showed lower rate of flares

Case scenario 2

WORKING GROUP

Chronic pain

CONTEXTUAL FACTORS

Personal contextual factor:

Early rheumatoid arthritis trial vs trial in established rheumatoid arthritis

Environmental contextual factor:

NA

REFERENCE

Title and reference:

Biologic interventions for fatigue in rheumatoid arthritis.
Almeida C et al. Cochrane Database Syst Rev. 2016 Jun 6;(6):CD008334.
https://www.ncbi.nlm.nih.gov/pubmed/27271314

TRIAL SETTINGS

Population:

Rheumatoid arthritis

Intervention:

Biologics

Outcome:

Fatigue

EXPLANATION

In this meta-analysis, there was statistically significant heterogeneity. Sensitivity analysis showed that early RA trials produced larger effect size than trials in patients with established disease

Case scenario 3

WORKING GROUP

Total joint replacement (TJR)

CONTEXTUAL FACTORS

Personal contextual factor:

NA

Environmental contextual factor:

Community poverty

REFERENCE

Title and reference:

Disparities in TKA Outcomes: Census Tract Data Show Interactions Between Race and Poverty
Goodman SM et al. Clin Orthop Relat Res. 2016 Sep;474(9):1986-95.
https://www.ncbi.nlm.nih.gov/pubmed/27278675

TRIAL SETTINGS

Population:

Black patients with knee osteoarthritis

Intervention:

Total knee arthroplasty

Outcome:

WOMAC pain and function 2 years after surgery

EXPLANATION

Observational study linking individuals to community socioeconomic factors including poverty, demonstrating that blacks in wealthy neighbourhoods have the same outcomes as their white peers, but have worse outcomes if they live in impoverished neighbourhoods

Case scenario 4

WORKING GROUP

Total joint replacement (TJR)

CONTEXTUAL FACTORS

Personal contextual factor:

Education college or above

Environmental contextual factor:

Community poverty

REFERENCE

Title and reference:

Education mitigates the effect of poverty on total knee arthroplasty outcomes
Goodman SM et al. Arthritis Care Res (Hoboken). 2017 Nov 22. doI: 10.1002/acr.23442.
https://www.ncbi.nlm.nih.gov/pubmed/29164795

TRIAL SETTINGS

Population:

Patients with knee osteoarthritis

Intervention:

Arthroplasty

Outcome:

WOMAC pain and function at 2 years

EXPLANATION

Patients undergoing knee arthroplasty with < college education from impoverished neighbourhoods have worse 2 year outcomes, but those with at least some college do as well as those from wealthier neighbourhoods

Case scenario 5

WORKING GROUP

Shoulder Pain

CONTEXTUAL FACTORS

Personal contextual factor:

Medical Comorbidities as measured by the functional comorbidity index (FCI)

Environmental contextual factor:

NA

REFERENCE

Title and reference:

Do Medical Comorbidities Affect Outcomes in Patients With Rotator Cuff Tears?
Gagnier JJ et al. Orthop J Sports Med. 2017 Aug 21;5(8):2325967117723834.
https://www.ncbi.nlm.nih.gov/pubmed/28856169

TRIAL SETTINGS

Population:

Patients with rotator cuff tears

Intervention:

Surgical repair and rehabilitation

Outcome:

Western Ontario Rotator Cuff (WORC) index

EXPLANATION

The study is a cohort study within an established registry. Quote ”Across the entire sample, regression analysis revealed that increased FCI score was associated with worse baseline WORC score”