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None declared.

A synthesis of response shift effects in quantitative health research: A systematic review and meta-regression protocol

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Review question / Objective: **The first aim is to descriptively synthesize evidence about response shift results including prevalence and, where possible, distributions of response shift effect sizes, for different subcategories of response shift methods, populations, study designs, and patient-reported outcome measures (PROMs). The second aim is to identify response shift methods, population characteristics, design characteristics and PROMs that explain variability in: (a) standardized mean differences (for then-test and latent variable methods) and (b) prevalence of response shifts.**
Condition being studied: **The systematic review included all studies on response shifts in PROMs, irrespective of the condition being studied. The type of health condition that each individual study focused on (if applicable), was extracted as a study-level variable.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 September 2022 and was last updated on 07 September 2022 (registration number INPLASY202290033).

INTRODUCTION

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test and latent variable methods) and (b) prevalence of response shifts.

Rationale: Syntheses of response shift effects in PROM studies is scarce. A previous meta-analysis of response shift effects was conducted only on studies that used the then-test method up until 2005 [1]. More recently, Ilie et al. [2] conducted a systematic review of 35 PROM studies examining response shift in cancer patients, while Powden et al. [3] led a systematic review of 9 PROM studies that examined response shift after rehabilitation of orthopedic patients. These latter systematic reviews thus included only studies from a specific patient group. Our previous scoping review, by Sajobi et al. (2018) revealed considerable heterogeneity in characteristics of response shift studies conducted in different populations, using different measurement instruments, and applying different response shift methods. This observation was confirmed in a recent systematic review of response shift in health-related quality of life studies [4]. However, there is a gap in knowledge about the different sources of heterogeneity and their impacts on response shift effects in PROM studies. This systematic review is designed to address this gap in knowledge by contributing a comprehensive synthesis with particular emphasis on describing and explaining heterogeneity of response shift effects in PROM studies.

Condition being studied: The systematic review included all studies on response shifts in PROMs, irrespective of the condition being studied. The type of health condition that each individual study focused on (if applicable), was extracted as a study-level variable.

METHODS

Search strategy: Studies on response shift were identified by searching the following library databases: a) MEDLINE, PSYCINFO, and CINAHL using the EBSCO interface; b) EMBASE using the OVID interface; c) Social Science Citation Index using the Web of Science interface, and d) Dissertations & Theses Global using the Proquest interface. All searches were conducted using the same combination of the following terms and corresponding abbreviations in all indexed fields: "response shift" OR "longitudinal measurement invariance" OR "retrospective bias" OR "longitudinal differential item" OR "longitudinal DIF". The searches were limited to English language and a date of publication before January 1, 2021. For the Social Science Citation Index, an additional limit was applied to exclude meeting abstracts. No other filters were applied to any of the searches. Updated searches will be performed after analyses based on the above search have been completed.

Participant or population: There was no restriction on participant or population characteristics. Rather than a selection criterion, the characteristics of the population of each individual study (e.g., sex, age) were extracted as study-level variables. This allows to describe (possible) heterogeneity in terms of response shift findings with regards to population characteristics.

Intervention: There was no restriction on interventions being studied. Rather than a selection criterion, the type of intervention that each individual study focused on (if applicable), was extracted as a study-level variable. This allows to describe (possible) heterogeneity in terms of response shift findings with regards to intervention.

Comparator: Comparisons of response shift results were based on the following categories of data extracted for each study: 1. Response shift methods: design-based methods, latent variable methods, regression methods, and study-specific methods. 2. Population/sample: sex, age, medical condition, intervention.3. Study design: experimental/observational, primary/secondary analysis, sample size, duration of time between measurement occasions, whether a hypothesis was stated; type of data for response shift analysis (domains and/or items), missing data reporting, whether authors provided explanations for response shifts in different

groups or in relation to other explanatory variables.4. PROMs used for the response shift analysis: name of PROM, type of PROM (generic/disease-specific/individualized/other, where the category individualized supersedes the categories generic/disease-specific), PROM domains.5. Study results: detection (yes/no) and magnitude (see under statistical analyses) of recalibration, reconceptualization, and reprioritization, and dependencies, i.e., whether the response shift effect pertained to a subsample (or group) of an overall sample reported in the same manuscript, or the same or overlapping sample from another study.

Study designs to be included: We included all longitudinal study designs that used a PROM. Studies that did not use a PROM, or used only cross-sectional data were excluded.

Eligibility criteria: Only studies that used quantitative methods to examine response shifts in PROMs were included. The following exclusion criteria were sequentially applied in the following order: 1) Not reported in English; 2) Commentary, editorial, letter, case report, conference abstract; 3) Type of article, (3.1) Narrative or systematic review, (3.2) Conceptual or theoretical paper; 4) Type of study, (4.1) Qualitative study, (4.2) Simulation study; 5) Study design, (5.1) Did not use a PROM, (5.2) Not a longitudinal study; 6) Study objective, (6.1) Did not examine response shift as a study objective, (6.2) No explicit analysis of response shift, though methods are consistent with a response shift analysis; 7) Dissertations (note: searches were conducted to locate studies resulting from relevant dissertations).

Information sources: The following databases were searched: a) MEDLINE, PSYCINFO, and CINAHL using the EBSCO interface; b) EMBASE using the OVID interface; c) Social Science Citation Index using the Web of Science interface, and d) Dissertations & Theses Global using the Proquest interface.

Main outcome(s): The main outcomes are:
1) Prevalence of response shift effects
a. proportion of studies detecting response shift
b. proportion of response shift effects
2) Magnitude of response shift effects
a. distribution of standardized mean difference (SMD)
b. proportion of people classified as having response shift
Each outcome is stratified by response shift pathway (recalibration, reprioritization, reconceptualization) and by different subcategories of response shift methods, populations, study designs, and PROMs.

Additional outcome(s): None.

Data management: We used the EPPI reviewer application to select studies based on our inclusion and exclusion criteria, and to extract all relevant data from the selected studies. The titles and abstracts of each citation were randomly assigned for independent screening by two out of five team members, all of whom were thoroughly familiar with response shift, using the EPPI Reviewer platform [5]. The full text was subsequently retrieved for each citation identified as potentially relevant and each was screened randomly by two of the same team members. Disagreements were reconciled via consensus. Data extraction for each included study was completed by one of three team members. Ambiguities were discussed among team members to achieve agreement. Study-level information was extracted using the EPPI reviewer application and detailed information about each response shift effect was extracted and entered into a separate spreadsheet.

Quality assessment / Risk of bias analysis: We did not perform an assessment of methodological quality or risk of bias of individual studies. The heterogeneity of the included studies with regards to response shift methods, population characteristics, study design and PROMs used, precludes such a straightforward, unambiguous assessment. For example, sample size does not apply as a quality criterion to individual methods.

Rather than weighing different study aspects as an indication of study quality, we made them the focus of our main analyses. For the first aim we describe the prevalence and, where possible, the magnitude of response shift effects stratified by different subcategories of response shift methods, populations, study designs, and PROMs. For the second aim we use all different subcategories of response shift methods, populations, study designs, and PROMs as explanatory variables to explain variability in response shift results.

Strategy of data synthesis: We defined a response shift result as evidence pertaining to the existence or non-existence of a response shift effect, as defined by the authors (e.g., based on statistical significance). Where possible, we determined the magnitude of each response shift effect based on reported statistical information from which an effect size could be derived. We used reported effect sizes, if provided, when insufficient information was available to calculate effect sizes. Standardized mean differences (Cohen's d) were calculated for the then-test and latent variable methods based on information reported in each study based on the difference between baseline ($\bar{X}_1$) and follow-up (then-test) ($\bar{X}_2$) scores as follows: Cohen's d = ($\bar{X}_1$-$\bar{X}_2$)/SD (where SD = standard deviation). For some studies, this meant that we first had to transform medians, interquartile ranges (IQR), and t or z statistics into means and standard deviations [6; 7]. We used the following hierarchy to standardize the mean difference, based on: 1) the standard deviation of the difference, 2) the pooled standard deviation, or 3) the standard deviation of the baseline measurements. For SEM, response shift effects were based on parameter estimates of models that adjust for a lack of longitudinal measurement invariance [8]. All effect sizes were converted to absolute values. For regression-based response shift methods that do use classification, the proportion of people having undergone response shift was extracted as an indication of the magnitude of effects. Information on effect-size magnitudes was synthesized using non-parametric statistics, including medians and IQRs for continuous effect sizes and percentages for classification.

For the first descriptive aim, response shift results and effect sizes were summarized at different levels of analysis (study- and effect-levels) and for the response shift pathways (recalibration and reprioritization/reconceptualization) separately. Accordingly, the synthesis focused on describing prevalence and magnitude of response shift effects, based on a) the proportion of studies detecting response shift (study-level), and b) the proportion of response shift effects identified (effect-level) within the subcategories of response shift methods, population characteristics, study design characteristics, and PROMs. Corresponding with the descriptive aim and given the expected heterogeneity in effect sizes, effect sizes were not pooled. Analyses were conducted twice: 1) including all response shift effects from all studies, and 2) including only response effects from unrelated studies and samples that do not overlap with samples from the same (e.g., subsamples) or other studies.

For the second explanatory aim, meta-regression analysis will be employed to identify response shift methods, population characteristics, design characteristics, and PROMs that explain variability in: a) Standardized mean differences (for then-test and latent variable methods), using multilevel linear regression, and 2) Prevalence of response shifts, using multilevel logistic regression.

Subgroup analysis: It is our aim to provide a descriptive synthesis of heterogeneity across different study and sample characteristics. That is, the number of response shift effects investigated and detected will be described across different response shift methods, different populations, study designs and PROMs.

Sensitivity analysis: Sensitivity analyses will be conducted with regard to dependencies among studies, i.e., whether studies are related. Studies are considered related when analyses from different studies are

conducted on the same or overlapping samples, or when the same results are reported in multiple manuscripts. For related studies, only the first (original) study is counted. Independent samples do not have overlap with other samples. When samples are overlapping, only the overall sample is counted (subsamples are not counted). Analyses will be conducted twice: 1) including all response shift effects from all studies, and 2) including only response effects from unrelated studies and samples that do not overlap with samples from the same (e.g., subsamples) or other studies.

Language restriction: Only documents written in English are included in the synthesis.

Country(ies) involved: Canada, France, The Netherlands, United Kingdom.

Other relevant information: This work is part of The Response Shift-in Sync Working Group Initiative.[9]

Keywords: Response shift; patient-reported outcomes; systematic review; meta-regression analysis; prevalence; effect sizes; classification.

Dissemination plans: The results of the systematic review and meta-regression analyses will be provided in two separate articles and submitted to international peer-reviewed journals.

Contributions of each author:

Author 1 - Richard Sawatzky - Conceiving the review; Designing the review; Writing the protocol; Coordinating the review; Data collection; Data management; Analysis of data; Interpretation of data; Writing the review.

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Author 2 - TT Sajobi - Conceiving the review; Designing the review; Preliminary analysis to inform protocol development; Interpretation of data; Critical revision of the review.

Author 3 - L Russell - Data collection; Data management; Interpretation of data; Critical revision of the review.

Author 4 - OA Awosoga - Conceiving the review; Designing the review; Preliminary analysis to inform protocol development; Interpretation of data; Critical revision of the review.

Author 5 - A Ademola - Conceiving the review; Designing the review; Preliminary data collection and analysis to inform protocol development; Interpretation of data; Commenting on the review.

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Author 7 - O Lawal - Designing the review; Preliminary data collection and analysis to inform protocol development; Commenting on the review.

Author 8 - A Brobbey - Designing the review; Preliminary data collection and analysis to inform protocol development; Commenting on the review.

Author 9 - LM Lix - Conceiving the review; Interpretation of data; Critical revision of the review.

Author 10 - A Anota - Data collection; Preliminary data collection and analysis to inform protocol development; Commenting on the review.

Author 11 - V Sébille - Conceiving the review; Designing the review; Data collection; Interpretation of data; Critical revision of the review.

Author 12 - MAG Sprangers - Conceiving the review; Designing the review; Data collection; Interpretation of data; Writing the review.

Author 13 - MGE Verdam - Conceiving the review; Data collection; Data management; Interpretation of data; Critical revision of the review.

Author 14 - Response Shift-in Sync Working Group - Commenting on the review.

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