

INPLASY PROTOCOL

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None declared.

The impact of response shift on patient-reported outcome measures (PROMs): A systematic review protocol

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Review question / Objective: A recent synthesis of quantitative response shift research provides a comprehensive overview of response shift effects in patient-reported outcome measures (PROMs) (Sawatzky et al., 2022). The current study builds on this previous study by providing a synthesis of the impact of detected response shift effects on change in the target construct (i.e. the PRO of interest), in terms of statistical significance, magnitude, and/or decisions made based on target change. The current synthesis therefore goes beyond the synthesis of effect-size estimates and aims to describe the extent to which response shift leads to different conclusions regarding target change.

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 06 February 2023 and was last updated on 06 February 2023 (registration number INPLASY202320024).

INTRODUCTION

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overview of response shift effects in patient-reported outcome measures (PROMs) (Sawatzky et al., 2022). The current study builds on this previous study by providing a synthesis of the impact of

detected response shift effects on change in the target construct (i.e. the PRO of interest), in terms of statistical significance, magnitude, and/or decisions made based on target change. The current synthesis therefore goes beyond the synthesis of effect-size estimates and aims to describe the extent to which response shift leads to different conclusions regarding target change.

Rationale: Response shift refers to the phenomenon that observed change in PROMs is not fully explained by change in the target construct, due to a change in the meaning of one's self-evaluation. Response shift has received increasing attention in health research, which has resulted in recent theoretical and methodological advances (e.g. Vanier et al., 2021; Sébille et al., 2021; Sawatzky et al. 2021). Overviews of response shift research provide insight into the heterogeneity of the field, where a diverse range of response shift methods are used to study response shift in different patient populations with varying health conditions (e.g. Sajobi et al., 2018). A review on response shift in health-related quality of life concluded that 71% of studies showed evidence of response shift (Ortega-Gómez et al., 2022). However, there is a gap in knowledge about the extent to which the occurrence of response shift also impacts the interpretation of change in the target construct. That is, a statistically significant response shift effect does not automatically imply a difference in statistical significance or magnitude of target change when response shift is taken into account. Therefore, we build on the work of a recent systematic review on response shift effects in quantitative health research (Sawatzky et al., 2022) and will investigate the impact of response shift in more detail. We will use the same 150 studies to investigate the impact of response shift on the interpretation of change in the target construct in terms of 1) statistical significance, 2) magnitude, and/or 3) decisions made based on target change. Investigating the impact of response shift will provide insight into the extent to which response shift leads to different conclusions regarding change.

Through synthesis of how many times and to what extent response shift effects impact target change, we will gain insight into the importance or (clinical) relevance of response shift.

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: We used the same selection of papers as in the recent systematic review on response shift effects (Sawatzky et al., 2022), where 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 Web of Science interface), and d) Dissertations & Theses Global (using the Proquest interface). The searches were limited to English language and 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. All searches were conducted by searching for any of the following terms and abbreviations associated with response shift in all indexed fields: "response shift" OR "longitudinal measurement invariance" OR "retrospective bias" OR "longitudinal differential item" OR "longitudinal DIF". 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. gender, age, country) were extracted as study-level variables. This allows for description of (possible) heterogeneity in terms of impact of response shift 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 for description of (possible) heterogeneity in terms of impact of response shift with regards to intervention.

Comparator: Impact of response shift is operationalized as a difference in change in the target construct (i.e. the PRO of interest) before and after taking into account response shift, in terms of 1) statistical significance; 2) magnitude; or 3) decisions made based on target change. The results on impact of response shift with regards to the different study characteristics will be analyzed descriptively, and by using a multilevel regression. The study-level data that were extracted are described below. Descriptive comparisons of impact of response shift will be based on the following categories of data extracted for each study (for more details see the Reviewer codebook at <https://ln5.sync.com/dl/6bc5503b0/fnm4dad-psxnfn3x-bvdsezvg-hwub8qm3/view/doc/1478925123>): - Population/sample: gender, age, country, health conditions, interventions, sample size;- Study design: observational/experimental, primary/secondary analysis, time between measurement occasions;- Measures: patient-reported outcome measures used for the response shift analysis;- Research design: pathway of response shift examined; type of data for response shift analysis (domains and/or items); whether a hypothesis was stated (yes/no); missing data reporting (yes/no); explanations for response shifts in different groups or in relation to other explanatory variables (yes/no);- Response shift results: descriptive summary; detection (number) of recalibration, reconceptualization, or reprioritization response shifts.

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 Web of Science interface), and d) Dissertations & Theses Global (using the Proquest interface).

Main outcome(s): We will extract a narrative summary of the results with regards to impact of response shift for each study. Using this information, we aim to provide a synthesis of whether and how impact of response shift is investigated, the way that impact of response shift is reported (e.g. relating to statistical significance, magnitude, or decisions based on target change), and the magnitude of impact of response shift, if applicable.

The primary outcomes are:

- 1) Impact of response shift effects
 - a. proportion of studies that investigate impact of response shift in at least one of the three defined ways;
 - b. proportion of studies that evidence impact of response shift in at least one of the three defined ways;
 - c. magnitude of impact of response shift, if applicable.

Each outcome is stratified by type of target construct (PRO domain) and type of

response shift method (the statistical method used to detect or measure response shift effects).

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 (see Sawatzky et al., 2022).

Data extraction of response shift impact using the previous included studies was done by two independent reviewers using the EPPI reviewer application. Data extraction categories were agreed upon and defined in advance. After submission of this registry, we will further refine the data extraction categories and finalize the data extraction process. Ambiguities will be discussed in the larger author group of reviewers to achieve agreement.

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, would result in an inconsistent and incomplete reporting of risk of bias, and precludes such a straightforward, unambiguous assessment. Rather than weighing different study aspects as an indication of study quality, we made them the focus of our main analyses. That is, we stratified the results of the impact of response shift across the different subcategories of population characteristics, research methods, and/or PROMs; some of which may be taken to be related to study quality (e.g. whether a hypothesis was stated, missing data was reported, and explanations for response shift were investigated).

Strategy of data synthesis: We will describe the results with regards to the impact of response shift on target change, using the same 150 papers that were selected for the previous systematic review on response shift in quantitative health research

(Sawatzky et al., 2022). We infer evidence of impact of response shift on target change – as per author’s conclusion – in the following ways: 1) by a statistically significant difference in target change before and after taking into account response shift, 2) a difference in magnitude of target change before and after taking into account response shift (e.g. change in effect-size magnitude, or above a threshold of ‘minimal importance’), or 3) a different decision after response shift is taken into account.

Objective 1: To provide a descriptive summary of results on impact of response shift, we will describe the number of studies that investigated impact of response shift, the methods that were used to investigate impact of response shift, the number of times that impact of response shift was evidenced, and the magnitude of impact of response shift itself (if available). We will stratify the results based on the type of response shift method, and the PRO investigated. In addition, we will describe the heterogeneity of findings in relation to different populations/samples, study designs and PROMs.

Objective 2: To identify population characteristics, research methods, and PROMs that explain variability in results on impact of response shift using multilevel regression.

Subgroup analysis: We will describe results on impact of response shift across the overall sample of studies and across subgroups (e.g., based on different population characteristics, research methods, and/or PROMs).

Sensitivity analysis: Sensitivity analyses will be conducted with regards to the inclusion of results from related (dependent) studies and samples. Studies that involved analyses of the same sample are classified as dependent, with the first study identified as the primary study and all subsequent studies identified as secondary. Samples within studies are considered unrelated (independent) if there were no subsamples or overlapping samples within the study. For studies that include subsamples, the overall sample (if available) is identified as

the independent sample. For studies with subsamples but no overall sample, the subsamples are treated as independent.

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

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

Other relevant information: This work is part of The Response Shift-in Sync Working Group Initiative (Sprangers et al., 2021).

Keywords: Response shift; impact; health; patient-reported outcomes; systematic review; multi-level regression.

Dissemination plans: The results of the systematic review will be provided in an article that will be submitted to an international peer-reviewed journal.

Contributions of each author:

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