Semantic primes theory may be helpful in designing questionnaires such as to prevent response shift

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Abstract

Objectives: The purpose of randomized control trials (RCTs) can be the assessment of the direct effect of treatment on health-related quality of life (HRQL). Response shift (RS) theory considers that a change in HRQL scores observed over time cannot be explained solely by a direct effect of a medical condition, it may also result from a change in the way people appraise their HRQL. The RS effect is a potential bias that is liable to compromise efficient assessment of the effect of treatment on HRQL.

Study Design and Setting: We hypothesize a link between the RS effect on HRQL scores and the level of complexity of HRQL conceptualization.

Results: We discuss how the impact of reconceptualization on scores depends on the complexity of the linguistic definition of a subjective construct and how for reprioritization the impact depends on the dimensionality. The linguistic theory of semantic primes is used to help identify how subjective constructs can be classified according to the complexity of their definitions.

Conclusion: Finally, we suggest that the impact of the RS effect on HRQL scores could be avoided (or lessened) if questionnaires were designed with a rule of "the least semantic and psychometric complexity" in mind.   © 2015 Elsevier Inc. All rights reserved.

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1. Introduction

1.1. The evaluation of the patient perspective in health-related research

Patient-reported outcomes (PRO) are now widely used in health-related research, some of them to assess health-related quality of life (HRQL), usually via self-administered questionnaires [1]. In many medical areas (e.g., oncology, palliative care…), HRQL is measured over time to add relevant information on patients' subjective experience in the course of treatment, to counterbalance objective data such as survival time [2]. Indeed, improvement or deterioration of outcomes such as health status or symptom levels is not always correlated with patients' subjective experience [3].

The current generation of HRQL measures is based on the assumption that the meaning of concepts and measurement scales remains stable in individuals' minds over time and is similar between groups [4]. Thus, HRQL scale scores are assumed to be directly comparable for a given individual over time [5]. As illustrated by what were initially called "paradoxical and counter-intuitive findings" from the 1980s and 1990s [6] (e.g., reports of stable HRQL levels over time by patients with a life-threatening disease [7], reports of better levels of HRQL by patients with advanced stages chronic illness than by others [8]…), these assumptions can be challenged. Indeed, these aforementioned findings were interpreted as evidence that respondents understand the same

What is new?

What is known:

- Patient-reported outcomes (PRO), especially those assessing health-related quality of life (HRQL), are increasingly used as endpoints in randomized control trials (RCTs) to assess the direct effect of a treatment on HRQL.

- Response shift (RS) theory considers that a change in HRQL scores observed over time cannot be explained solely by the direct effect of a medical condition, it can also result from a change in the way people appraise their HRQL.

- Therefore, the RS effect can be a bias, liable to compromise efficient assessment of treatment effect on HRQL.

What this adds to what was known?

- We hypothesize a link between the RS effect on HRQL scores and the level of complexity of HRQL conceptualization.

- We postulate that the linguistic theory of semantic primes can be used to categorize subjective construct definitions in terms of low or high semantic complexity.

- We hypothesize that the impact of reconceptualization on HRQL scores differs according to semantic complexity and that for reprioritization, it depends on dimensionality (in psychometric terms).

What is the implication and what should change now?

- We propose that PRO instruments for use in RCTs should be designed with items of low semantic complexity (i.e., semantic molecules) and should be markedly unidimensional, to avoid (or lessen) the RS effect on scores, and enable straightforward interpretation of changes in HRQL scores that might be observed.

questions differently over time [6,9], a phenomenon which is now known as response shift (RS).

1.2. A brief overview of RS theory

In health-related research, RS was defined in 1999 as "a change in the meaning of one's self-evaluation of a target construct" [6]. It is operationalized in three forms:

- recalibration, which is a change in the respondent's internal standards of measurement (e.g., a person suffering from chronic pain and rating it on a pain scale as 7 of

10 will later rate it as 5 of 10 after experiencing acute pain, despite the chronic pain being the same as before);
- reprioritization, which is a change in the respondent's values (i.e., the relative importance of component domains in the target construct, for example, an athletic person who considers physical functioning as an important part of his/her HRQL may later place emphasis on social functioning after sustaining permanent physical injury);
- reconceptualization, which is the redefinition of a target construct (e.g., an item of a multidomain questionnaire initially assessing the domain of mental health will be later understood by the respondent as assessing another domain, like social functioning) [6].

RS effect is assumed to result from psychological mechanisms that individuals use to deal with life changes, triggered by change in health state (a "catalyst") [6,10]. As illustrated by Fig. 1, when someone is affected by a catalyst (e.g., occurrence of a chronic disease, initiation of chemotherapy…), this catalyst can have a direct effect on HRQL (S_1 pathway in Fig. 1), translating into a change in the person's HRQL assessment. A person's background (e.g., socioeconomic status, personality traits…) can also have a direct effect on HRQL (S_2 pathway) or an effect mediated by the catalyst (S_3 pathway). These effects can be called "standard influences" on HRQL. However, the catalyst can also induce psychological mechanisms (e.g., coping strategies, social comparison…), leading into changes in the way that a person understands and appraises HRQL (R_1 and R_2 pathways) and hence affecting his/her observed scores: RS has occurred.

Thus, there is a need to disentangle RS effect from the effects of the "standard influences" on HRQL [11]. Various methods have been used to detect RS [12–21], although there was in the last years a focus on methods based on structural equation modeling (SEM). Indeed, some recent works were helpful in showing how RS effect can affect observed scores or true attributes (i.e., HRQL itself) and how this effect can be modeled in explaining changes in observed scores or HRQL over time [15,22]. Occurrence of RS has now been documented in a variety of medical conditions [23].

1.3. The particular context of clinical trials

HRQL measurement is increasingly used in the context of randomized control trials (RCTs), as endpoints [24]. In this context, a questionnaire should be designed to allow clear interpretation of the direct effect of treatment on patients' subjective experience. Indeed, it serves as a criterion to enable a decision to be reached between two mutually exclusive options (i.e., the treatment assessed is effective or not) [25].

The initiation of treatment in the different arms of an RCT can be the catalyst of RS effect. For example, experiences of extreme levels of fatigue after chemotherapy can induce recalibration RS when assessing fatigue [26].