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## An Exploratory Study of Response Shift in Health-Related Quality of Life and Utility Assessment Among Patients with Osteoarthritis Undergoing Total Knee Replacement Surgery in a Tertiary Hospital in Singapore

Xu-Hao Zhang, PhD<sup>1</sup>, Shu-Chuen Li, PhD<sup>2</sup>, Feng Xie, PhD<sup>3</sup>, Ngai-Nung Lo, FRCS<sup>4</sup>, Kwang-Ying Yang, FRCS<sup>4</sup>, Seng-Jin Yeo, FRCS<sup>4</sup>, Kok-Yong Fong, FRCP<sup>5,6</sup>, Julian Thumboo, FRCP<sup>5,6,\*</sup>

<sup>1</sup>Department of Pharmacy, National University of Singapore, Singapore; <sup>2</sup>Discipline of Pharmacy and Experimental Pharmacology, School of Biomedical Sciences, University of Newcastle, Newcastle, Australia; <sup>3</sup>Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada; <sup>4</sup>Departments of Orthopaedic Surgery and <sup>5</sup>Rheumatology and Immunology, Singapore General Hospital, Singapore; <sup>6</sup>Department of Medicine, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

### ABSTRACT

**Objective:** To investigate the influence of response shift (RS) on health-related quality of life (HRQOL) and utility assessment among patients undergoing total knee replacement. **Methods:** Consenting patients undergoing total knee replacement were interviewed to determine their HRQOL by using the six-dimensional health state short form, derived from SF-36, and the EuroQol five-dimensional questionnaire at baseline (pretest 1) and the six-dimensional health state short form, derived from SF-36, at 6 (pretest 2) and 18 months after surgery (post-test). RS was studied by using a “then-test” approach by contacting participants 18 months after surgery and asking them to evaluate their HRQOL at baseline (then-test 1) and at 6 (then-test 2) and 18 months after surgery. RS was calculated as the score difference between pretest and then-test scores for a given time point. Relationships between RS and external variables were explored by using univariate and multiple linear regression analyses. **Results:** In 74 subjects (63% response rate, median age 68 years), median (interquartile range) six-dimensional health state short form, derived from SF-36, scores for then-tests at

baseline (0.48 [0.42–0.49]) and at 6 months (0.72 [0.66–0.79]) after surgery were significantly different from respective pretest scores (0.61 [0.58–0.68] at baseline,  $P = 0.000$ ; 0.69 [0.63–0.72] at 6 months,  $P = 0.000$ ), showing RS at both time points. RS at baseline (0.14 [0.08–0.20]) was significantly larger than that at 6 months (–0.05 [0.14 to 0.00],  $P = 0.000$ ). EuroQol five-dimensional questionnaire pretest and then-test scores at baseline also differed significantly (0.69 [0.17–0.73] vs. –0.18 [–0.23 to 0.00],  $P = 0.000$ ). RS at baseline was not affected by assessed demographic or medical variables. RS at 6 months was greater in subjects with more years of education (16% of variance in multiple linear regression,  $P < 0.01$ ). **Conclusion:** RS was present and impacted HRQOL and utility assessment among patients undergoing total knee replacement before and 6 months after surgery.

**Keywords:** health-related quality of life, response shift, total knee replacement, utility assessment.

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### Introduction

Originating from self-report evaluation studies on organizational and educational psychology, a phenomenon termed *response shift* has been increasingly reported in patient-reported outcomes assessment among chronically or terminally ill patients over the last decade [1–3].

In the health-care arena, response shift has been regarded as an instinctive psychological mechanism of patients to adapt to the changes caused by illness or treatment [4]. Sprangers and Schwartz [5] defined *response shift* as a change in the meaning of one's self-evaluation of a target construct as a result of a) a change in the respondent's internal standards of measurement (scale recalibration); b) a change in the respondent's values (scale reprioritization); or c) a redefinition of the target construct (reconceptualization).

Although distinguished as three types of response shift [5], reconceptualization, scale recalibration, and reprioritization are thought to occur in combination [6].

Health-related quality of life (HRQOL) measurement may be affected by response shift because it quantifies patient perceptions, which may change with time because of response shift. Paradoxes such as overestimation of health status or underestimation of treatment effects measured by HRQOL outcomes have been found across various patient groups, including those with cancer, stroke, mental illness, and so on [7–9]. A theoretical model has been built to illustrate the relationship between response shift and HRQOL, in which “changes in an individual's health status may prompt behavioral, cognitive and affective processes necessary for accommodating illness, which may be influenced by antecedents (e.g., sociodemographics, personalities, expectations, etc.) of

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\* Address correspondence to: Julian Thumboo, Department of Rheumatology and Immunology, Singapore General Hospital, Outram Road, Singapore 169608.

E-mail: [julian.thumboo@sgh.com.sg](mailto:julian.thumboo@sgh.com.sg).

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the individual; These processes have the potential to change an individual's standards, values and conceptualization of HRQOL" [7]. The presence of response shift calls into question the assumption that patients would perceive and value a self-reported item with entirely the same internal standards during longitudinal research. In other words, there may be situations where true change measured by HRQOL instruments may not be simply calculated as the difference between respective pre- and postintervention test scores [10,11].

In surgical interventions including total knee replacement (TKR), pre- and postintervention comparisons of HRQOL have been used as a standard method to evaluate patients' improvement in both generic and disease-specific health status, and consequently to determine the cost-effectiveness of the treatment [12,13]. Because of response shift's possible impact on such studies, its exploration has become an emerging area in HRQOL research of surgical interventions [14–16]. There is, however, limited information currently available on the impact of response shift in subjects undergoing TKR, with only one recent publication showing that response shift significantly affected postoperative function 6 months after TKR when measured by using a disease-specific HRQOL questionnaire, the Western Ontario and McMaster Universities Osteoarthritis Index [17]. The impact of response shift on generic HRQOL instruments, however, including preference-based HRQOL instruments (e.g., the EuroQol five-dimensional questionnaire [EQ-5D] or the six-dimensional health state short form, derived from SF-36 [SF-6D]), is not known; if present, this may lead to inaccurate or even invalid results when these instruments are used in utility assessment in this situation. In addition, the evidence of response shift's influence on patients undergoing TKR over a follow-up period longer than 6 months is also lacking. Neither is it clear whether response shift also affects comparisons between two postoperative time points for recovery assessment.

To address these gaps in the literature, the primary objective of the current study was to explore and compare the impact of response shift on HRQOL and utility scores measured by generic HRQOL instruments at baseline and 6 months after TKR when assessed 18 months after TKR. It was hypothesized that response shift at baseline would be larger than that at 6 months following TKR, given that there was no major intervention between 6 months and 18 months postoperatively. If response shift were demonstrated, potential demographic and health-related factors associated with response shift at that time point would be investigated. In addition, the agreement between the SF-6D and the EQ-5D in detecting response shift would also be explored. Based on a comparison study of the EQ-5D and the SF-6D across seven patient groups including those with osteoarthritis, it was hypothesized that the correlation of response shift between the two measures would be moderate as categorized by Cohen's criteria (a correlation coefficient within the range of 0.3–0.5) [18,19].

## Methods

### Subjects and study design

Contactable consenting patients undergoing TKR without cognitive problems seen at a tertiary referral center in Singapore were recruited in this Institutional Review Board–approved study. Because of difficulties in communication during the telephone survey (the third phase as mentioned below), dialect-speaking patients who could not speak either English or Mandarin Chinese ( $n = 19$ ) were excluded. In addition, patients undergoing any additional surgery during the study period were also excluded to obviate any confounding physical and psychological impact caused by this additional surgery.

This Institutional Review Board–approved prospective study was carried out in three phases. Data for the first two phases were retrieved from an earlier Institutional Review Board–approved study, in which generic HRQOL and utility scores were determined by an interviewer by using the SF-6D and the EQ-5D at baseline before the surgery (pretest 1) and using the SF-6D 6 months after surgery (pretest 2) [20]. Response shift was studied by using the “then-test” approach in the third phase, in which eligible Mandarin- or English-speaking patients were interviewed through the telephone 18 months after their surgery. In this telephone interview, patients were asked to give their HRQOL scores for their current health status by using both the SF-6D and the EQ-5D (i.e., post-test scores). They were also asked to give their HRQOL scores at baseline (i.e., then-test 1 scores) and 6 months after TKR (i.e., then-test 2 scores). The rationale of the then-test approach is that at post-test using the same measure, respondents will provide their retrospective judgment of the health status at baseline and 6 months using the same internal standard [21]. In the scoring scheme of the then-test approach, response shift is calculated as the difference between pretest and then-test scores for each time point assessed, in this case at baseline and 6 months after TKR. True change or adjusted treatment effect is calculated as the difference between respective post-test and then-test scores. The difference between respective post-test and pretest scores was considered the observed change or unadjusted treatment effect [22]. Additional data collected during the telephone survey included demographics (age, gender, education level, work status, dwelling type), medical information (presence of acute or chronic illnesses, past knee surgery, number of knees operated), and general satisfaction with knee surgery (on a 0–10 Likert scale).

### HRQOL measures

#### SF-6D

The SF-6D is a preference-based HRQOL measure assessing physical functioning, role limitations, social functioning, pain, mental health, and vitality, with four to six levels per dimension, allowing 18,000 health states to be identified [23,24]. An SF-6D health state is defined by selecting one level from each dimension. The SF-6D score or the SF-6D utility index is scaled from 0.26 to 1.00 continuously, with 0.26 representing the worst health state (all dimensions being at the worst level) and 1.00 representing full health (all dimensions being at full functional level). The validity and equivalence of the SF-6D in English and Chinese versions have been previously demonstrated in a population-based study in Singapore [25].

#### EQ-5D

The EQ-5D is a preference-based HRQOL measure with five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) for respondents to self-classify and rate their health status [26]. For each item, there are three response levels (namely, with no problem, with some problems, and with extreme problems), which allow 243 unique health states to be identified. Scoring methods have been developed to assign each of these health states a utility score, in which 1 represents full health (no problem with all five items) and 0 represents being dead. The range of the final score or the utility index is from  $-0.594$  to 1.00 [27]. The validity of English and Chinese versions of the EQ-5D has been previously demonstrated among patients with rheumatic diseases in Singapore [28].

### Statistical analysis

Data were entered into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA) and analyzed by using SPSS 13.0 (SPSS, Inc., Chicago, IL). All tests were two tailed and conducted at

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