An Exploratory Study to Test the Impact on Three "Bolt-On" Items to the EQ-5D

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A B S T R A C T

Background: Generic preference-based measures were criticized for being inappropriate in some conditions. One solution is to include "bolt-on" dimensions describing additional specific health problems. **Objectives:** This study aimed to develop bolt-on dimensions to the EuroQol five-dimensional questionnaire (EQ-5D) and assess their impact on health state values. **Methods:** Bolt-on dimensions were developed for vision problems, hearing problems, and tiredness. Each bolt-on dimension had three severity levels to match the EQ-5D. Three "core" EQ-5D states across a range of severity were selected, and each level of a bolt-on item was added, resulting in nine states in each condition. Health states with and without the bolt-on dimensions were valued by 300 members of the UK general public using time trade-off in face-to-face interviews, and mean health state values were compared using t tests. Regression analysis examined the impact of the bolt-on variants and the level of the bolt-on items after controlling for sociodemographic characteristics. **Results:** Bolt-on

dimensions had an impact on health state values of the EQ-5D; however, the size, direction, and significance of the impact depend on the severity of the core EQ-5D state and of the bolt-on dimension. Regression analysis demonstrated that after controlling for possible differences in sociodemographic characteristics between the groups, there were no significant differences in health state values between the three bolt-on dimensions but confirmed that the impact depended on the severity of the EQ-5D health state and the levels of bolt-on dimensions. **Conclusions:** The impact of a bolt-on dimension on the EQ-5D depends on the core health state and the level of the bolt-on dimension. Further research in this area is encouraged.
Keywords: bolt-on, EQ-5D, health state valuation, hearing, tiredness, vision.

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Introduction

Generic preference-based measures of health-related quality of life (HRQOL) are commonly used for evaluating the impact of health conditions and their treatments. The advantages of these measures include an ability to capture the impact of conditions or treatment on the overall HRQOL rather than focusing on specific symptoms and an ability to facilitate comparisons across different conditions and disease areas. Furthermore, the "preference-based" aspect of the measures enables the value people place on different health states or aspects of health to be reflected. Consequently, they are widely used for estimating quality-adjusted life-years and for capturing quality-of-life effects in economic evaluations.

The advantages of generic preference-based measures could, however, come at a price. Specifically, they may not capture all important health effects for all conditions and treatments, and therefore there may be circumstances in which these generic

measures of HRQOL are not appropriate for assessing health benefit. Generic measures, including the EuroQol five-dimensional questionnaire (EQ-5D), have been criticized for being insensitive or failing to capture important aspects of health [1,2]. When this arises, it leads to the challenge of how best to obtain health state preference data, particularly if there is a need to estimate quality-adjusted life-years. One possible solution is the development of new dimensions to "bolt-on" to existing generic preference-based measures.

The EQ-5D is a preference-based HRQOL instrument that has been used to measure health status for a wide range of conditions and diseases. Its descriptive system contains five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels of severity and can describe a total of 243 health states [3]. It is commonly used in economic evaluation and to inform health care decision making by organizations such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom [4,5]. From the

outset of the development of the EQ-5D, it was recognized that it could not be "simple" and "comprehensive" at the same time [3]. Since then, the EQ-5D has been validated in a wide range of conditions. It may still not be appropriate, however, for all conditions, and recent reviews found that its performance in some specific disorders is poor [6–8].

There are two possible explanations for the failure of generic preference-based measures in some conditions. The first is that the range or number of descriptions of levels on each dimension of health is not sufficient to capture small changes within that area of health. The second is that descriptive systems may exclude an important dimension of health. The first problem of having too few levels to capture small changes in health may be overcome by increasing the size of the sample in which the data are obtained or increasing the number of levels of the instrument. This latter approach has been taken by the EuroQol Group through the publication of a five-level version of the EQ-5D [9]. The second issue is more problematic, but a potential solution is to bolt on additional item(s) to capture additional elements of HRQOL. The development of these bolt-on item(s) to the EQ-5D could enable researchers to retain the EQ-5D descriptive system as core and select additional dimensions to improve the content validity of the instrument for a particular condition. In the context of economic evaluation, the question of whether a bolt-on dimension is useful will depend on the extent to which values of EQ-5D health states are affected by the inclusion of the dimension. If the bolt-on dimension does not affect values, it would demonstrate that the impairment described by the dimension has little or no impact on health-related utility or that it is already captured by the five EQ-5D dimensions.

Previous studies have sought to investigate the addition of extra dimensions to the EQ-5D, including a cognition dimension [10] and sleep [11]. In addition, early work of the EuroQol Group examined the EQ-5D with an energy/tiredness dimension added on [12]. The added cognition dimension showed a significant impact on health state values of EQ-5D states, whereas the energy/tiredness and sleep dimensions did not.

The aim of this exploratory study was to test the impact of adding three potential bolt-on items to the EQ-5D and to quantify the effect each has on EQ-5D health state values. The three clinical areas addressed by the bolt-on items were identified as part of a larger Medical Research Council-National Institute for Health Research–funded project to examine the use of generic and condition-specific measures in NICE decision making. A series of systematic reviews to examine the validity and responsiveness of generic measures of HRQOL found that the performance of the EQ-5D was poor in hearing-related conditions [13] and in some specific vision disorders [6]. Therefore, hearing and vision disorders were selected as bolt-on dimension candidates for further consideration. A third area of "tiredness" was also selected because concerns about the ability of the EQ-5D to reflect energy, particularly cancer-related fatigue, has been highlighted in a recent review of how NICE measures the value of health care interventions [14].

Methods

The overall study design involved allocating a representative general population sample into four groups, each valuing a set of EQ-5D states, with three groups valuing states with one of the bolt-on dimensions (vision, hearing, or tiredness) and the fourth group valuing EQ-5D states without bolt-on. This allowed a series of comparisons and regression analyses to be performed to estimate the effect of bolt-on variants and the levels they take.

Development of the Three Bolt-On Items

Each dimension of health in the EQ-5D has a heading (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), and the usual activities dimension has a clarification in parentheses: "Usual activities (e.g. work, study, housework, family or leisure activities)." Based on a brief review of existing quality-of-life and health status measures related to hearing, vision, and tiredness and the opinions of the research team, each bolt-on dimension was given a heading subtitle (hearing, vision, or tiredness). In addition, the bolt-on questions related to vision and hearing included clarifications in parentheses. This referred to glasses or contact lenses in the vision bolt-on—"Vision (using glasses or contact lenses if needed)"—and to hearing aids as an example in the hearing bolt-on—"Hearing (using equipment if needed, e.g. hearing aids)."

The description of severity levels of the bolt-on items follows the approach used for the three-level EQ-5D. The description of bolt-on items is presented in Figure 1.

Selection of Health States for Valuation

Three EQ-5D health states were chosen as "core" states for valuation. The health states were selected after consideration of three criteria: 1) to cover a range of severity levels; 2) to select from the set of 43 states that have previously been valued in the Measurement and Valuation of Health (MVH) study, which was used to generate the social tariff of EQ-5D values for the United Kingdom [15,16]; and 3) to include combinations of problems that are not implausible or rare. This third criterion was assessed by examining health states that occur with a relatively high frequency in the Health Survey for England [17]. The final selection included a "mild" state (11121), a "moderate" state (22222), and a "severe" state (22233). The classification of mild, moderate, and severe was based on observed utility values resulting from the MVH study, and the three states have a logically determined

Hearing (using equipment if needed, e.g. hearing aids)

I have no problems hearing ☐

I have some problems hearing ☐

I have extreme problems hearing ☐

Vision (using glasses or contact lenses if needed)

I have no problems seeing ☐

I have some problems seeing ☐

I have extreme problems seeing ☐

Tiredness

I am not tired ☐

I am moderately tired ☐

I am extremely tired ☐

Fig. 1 – The three bolt-on items.