

## CHALLENGES IN DETERMINING THE COST-UTILITY OF INCONTINENCE TREATMENT: AN ANALYSIS OF THE PROBLEM AND POSSIBLE SOLUTIONS

### Hypothesis / aims of study

A major challenge in economic studies of incontinence is determining the monetary value of improved quality of life resulting from the treatment of incontinence. Placing a monetary value on incontinence-related quality of life is referred to as the cost-utility of treatment. Cost-utility of treatments for different health conditions is the metric used by health economists and decision-makers to gauge whether paying for care is worthwhile. The NICE (National Institute for Health and Clinical Excellence) UK guidelines recommend using the EQ-5D questionnaire as a measure of generic quality of life in economic evaluations. Unfortunately the EQ-5D lacks sensitivity for capturing changes in incontinence-related quality of life (1). In such cases, the NICE guidelines recommend that mapping exercises be undertaken in a transparent manner to fit disease-specific measures onto other generic quality of life measures to gauge the cost-utility of treatment.

The aim of this study was to investigate whether incontinence-specific measures of disease severity, quality of life, or self-efficacy could be mapped onto the SF-12, another generic measure of quality of life, to provide detectable and clinically meaningful changes in SF-6D utilities, from which to calculate cost-utility. We hypothesized that scores on an incontinence-specific quality of life measure would correlate most closely with SF-12 derived utilities compared to severity and self-efficacy ratings.

### Study design, materials and methods

This is a secondary analysis of complete data collected from consecutive new female and male patients seeking care at six urinary incontinence outpatient tertiary care referral centers. Individuals aged 65 years and older with one or more episodes of involuntary urinary loss during the past three months were eligible. Participants were administered the SF-12 generic quality of life measure, the International Consultation on Incontinence questionnaire (ICIQ), the Incontinence Quality of Life Questionnaire (I-QOL) and the geriatric self-efficacy index for urinary incontinence (GSE-UI) prior to their first appointment.

To determine how well the scores from the incontinence-specific measures correlated with generic quality of life ratings, we divided the cohort into two random groups. Using the first group, each participant's health state (SF-6D utility) was calculated from their self-reported SF-12 score with the algorithm validated by Brazier et al (2). Next, we used linear regression models to determine the proportion of variance explained by each of the 3 disease-specific scores (ICIQ, IQOL and GSE-UI 12) on the SF-6D utilities. The 3 IQOL subscores (avoidance and limiting behaviours, psychosocial impacts, and social embarrassment) were also calculated and regressed in univariate analyses on the SF-6D utilities. The models were then applied to the validation cohort to calculate an estimated health state. A Pearson coefficient was computed to assess the correlation between the validation sample's predicted and actual health states. Random allocation to the development group and validation groups, and Pearson coefficient computation were reiterated in a bootstrap method for 1000 times to minimize the effects of hazard on results; regression and correlation parameter estimates were averaged from each serial computation. Statistical calculations were done with RStudio 0.97.248 as an integrated development environment for R.

### Results

Two-hundred-and-twenty-eight individuals (94% female, mean age 73.2 ± 5.8 years) had complete data available for analysis. Table 1 shows the baseline distribution of the incontinence scores and utilities for the development sample.

**Table 1:** Baseline distribution of incontinence scores and utilities for the development sample

Measure (possible range)	Median	Mean	SD	Range
ICIQ (0-21)	11.0	11.4	4.3	3 -21
GSE-UI-12 (0-120)	62.0	60.0	26.8	0 - 118
IQOL total score (24-110)	82.8	79.1	19.0	24 - 110
Avoidance and limiting behavior (8-40)	27.0	26.5	7.1	9 - 40
Psychosocial impact (9-45)	38.6	36.0	8.7	9 - 45
Social embarrassment (5-25)	17.0	16.8	5.0	5 - 25
SF-6D utility (0.35-1.00)	0.80	0.78	0.15	0.35- 1.00

The results of univariate regression of the disease specific measures on the SF-6D values revealed that the total IQOL score and its psychosocial impact subscale explained the greatest proportion of variance in SF-6D utilities (14% and 18% respectively). Compared to the other incontinence-specific measure, the IQOL and its psychosocial impact subscale also yielded the highest correlation between predicted and actual scores in the validation model ( $r=0.37$ ,  $p=0.002$ , and  $r=0.42$ ,  $p=0.001$ , respectively) (Table 2). Adjusting for age did not significantly change the results of the analyses.

**Table 2:** Proportion of explained variance in SF-6D utilities explained by incontinence specific measures, and correlation between predicted and actual SF-6D scores

Measure	Univariate regression Development sample			Pearson correlation Validation sample	
	Beta estimate	p-value	R <sup>2</sup>	r	p-value
ICIQ	-0.009	0.026	0.08	0.26	0.029
GSE-UI-12	0.001	0.078	0.05	0.21	0.073
<b>IQOL total score</b>	<b>0.003</b>	<b>0.001</b>	<b>0.14</b>	<b>0.37</b>	<b>0.002</b>

Avoidance/ limiting behavior	0.006	0.007	0.10	0.31	0.007
<b>Psychosocial impact</b>	<b>0.007</b>	<b>&lt;0.001</b>	<b>0.18</b>	<b>0.42</b>	<b>0.001</b>
Social embarrassment	0.007	0.05	0.18	0.23	0.050

#### Interpretation of results

The IQOL and its psychosocial impact subscale explained the greatest proportion of variance in SF-6D utilities compared to incontinence severity and self-efficacy measures in this sample of older individuals with mild-severe incontinence. Nonetheless, ratings on the disease-specific questionnaire accounted for less than 20% of the variance in generic quality of life scores. IQOL ratings predicted SF-6D utilities with only moderate success, reflecting a large degree of uncertainty in using incontinence disease-specific measures for calculating and comparing cost-utility evaluations in accordance with NICE guidelines. Furthermore, based on the results of our univariate analyses, a clinically meaningful difference of 4-6 points on the IQOL only translates to a 0.012-0.018 point change in SF-6D utility values. Interestingly, a change of 4-6 points on the psychosocial impact subscale of the IQOL would yield substantially larger changes in utility values ranging from 0.028-0.042 points. This difference may be significant when one considers that the formula for calculating cost utility is the incremental cost to achieve an improved health state (numerator) divided by the difference in health utility between the two health states (denominator).

#### Concluding message

The psychosocial impact that incontinence has on a person's self-rated health state is a stronger predictor than incontinence severity or self-efficacy of the scores individuals assign to generic quality of life measures. Future cost-effectiveness research in the field of incontinence needs to consider whether a generic quality of life measure exists that can adequately capture and be responsive to changes in the psychosocial impact of incontinence, or whether incontinence-specific preference-based utility measures need to be developed.

#### References

1. Haywood et al. EuroQol EQ-5D and condition-specific measures of health outcome in women with urinary incontinence: reliability, validity and responsiveness. Qual Life Res. 2008 Apr;17(3):475-83.
2. Brazier JE, Roberts J. The estimation of a preference-based measure of health from the SF-12. Med Care. 2004 Sep;42(9):851-9.

#### Disclosures

**Funding:** No funding to declare. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Review Board of the Institut universitaire de gériatrie de Montréal **Helsinki:** Yes **Informed Consent:** Yes