5-level Bolt-ons Have an Improved Psychometric Performance Compared to 3-level Bolt-ons in a Large, Multinational, Longitudinal General Population Sample

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Poster number

Introduction

- The sensitivity of the EQ-5D descriptive system been improved by expanding the response levels from 3 to 5, and, by including additional dimensions: Bolt-ons.
- Approximately 50 Bolt-ons have been developed, and for most, there are both 3-level (**3L**) and five-level (**5L**) versions.
- Little is known about the added value and assumed improvement in measurement performance of the 5L bolt-ons compared to the 3L bolt-ons, and their sensitivity and responsiveness.

Objective

- To compare the psychometric properties of the 5-level versus 3-level bolt-ons for vision, breathing, tiredness, sleep, social relationships and self-confidence when added to the EQ-5D in a general population sample.

Methods

- **POPUP** is an international, observational, longitudinal study collecting data from representative members of the general population (in the US, Canada, UK, Italy, Spain, Germany, Netherlands, Belgium) (**Figure 1**).
- Respondents entered demographic data, provided information on pre-existing medical conditions and filled out a set of PROMs, including the EQ-5D-5L plus 5L bolt-ons, and the EQ-5D-3L plus 3L bolt-ons, Hospital Anxiety and Depression Scale (**HADS**) and HUI-3.
- The following psychometric properties of the bolt-ons were assessed: redistribution properties, ceiling/floor profiles, informativity, divergent and convergent validity, agreement and known group validity.

Abbreviations: EQ-5D-3/5L: EurQol 5-Dimension 3/5-Level, HADS: Hospital Anxiety and Depression Scale, HUI-3: Health Utilities Index-Mark 3, ICC: Intra-class correlation coefficients, LSS: Level Sum Scores, N: Sample size

Disclosures: The material in this poster has not been previously presented or published.

Results

1. Redistribution properties
- The bolt-ons social relationships, tiredness and sleep, had the highest reporting of extreme problems (**Table 1**).
- A low percentage of inconsistent response pairs evidences excellent overall agreement between 3L and 5L bolt-ons.
- The proportion of inconsistent responses between the 3L and 5L pairs increased with the severity of problems.

2. Ceiling effect and Informativity
- There was a ceiling effect for both the EQ-5D-3L and EQ-5D-5L (45.4% and 32.3%, respectively) (**Table 2**).
- All 3L and 5L bolt-ons reduced the ceiling on average with 14% and 22% respectively, with the largest reduction achieved in vision, sleep and breathing.
- All 5L bolt-ons consistently showed higher absolute and relative informativity than 3L bolt-ons; largest improvement was seen for *social-relationships,* the smallest for *breathing*.

3. Agreement between 3L and 5L
- Intra-class correlation coefficients between rescaled Level Sum Scores of the EQ-5D-5L + bolt-ons and the EQ-5D-3L + bolt-ons showed strong agreement (ICC range 0.92-0.97, all p<0.001) (**Table 3**).

4. Validity and Sensitivity
- Spearman's coefficient only showed strong correlation between the domain *Anxiety/Depression* and the bolt-ons *Social Relationships* (3L, 0.610; 5L, 0.642)*, and between *Self-confidence* and *Social relationships* (3L, 0.604; 5L, 0.658).
- Both the 3L and 5L breathing bolt-ons showed strong correlation with relevant items of other instruments (r=0.66-0.68), except for vision (r=0.12-0.37).
- Longitudinal data showed that 5L bolt-ons picked up more changes over time – both improvements and worsening, compared to 3L bolt-ons (**Table 4**).
- EQ-5D-5L + 5L bolt-ons showed improved sensitivity, with more Pareto changes (improvements, worsening, mixed) over time than the EQ-5D-5L + 3L bolt-ons (**Table 5**).
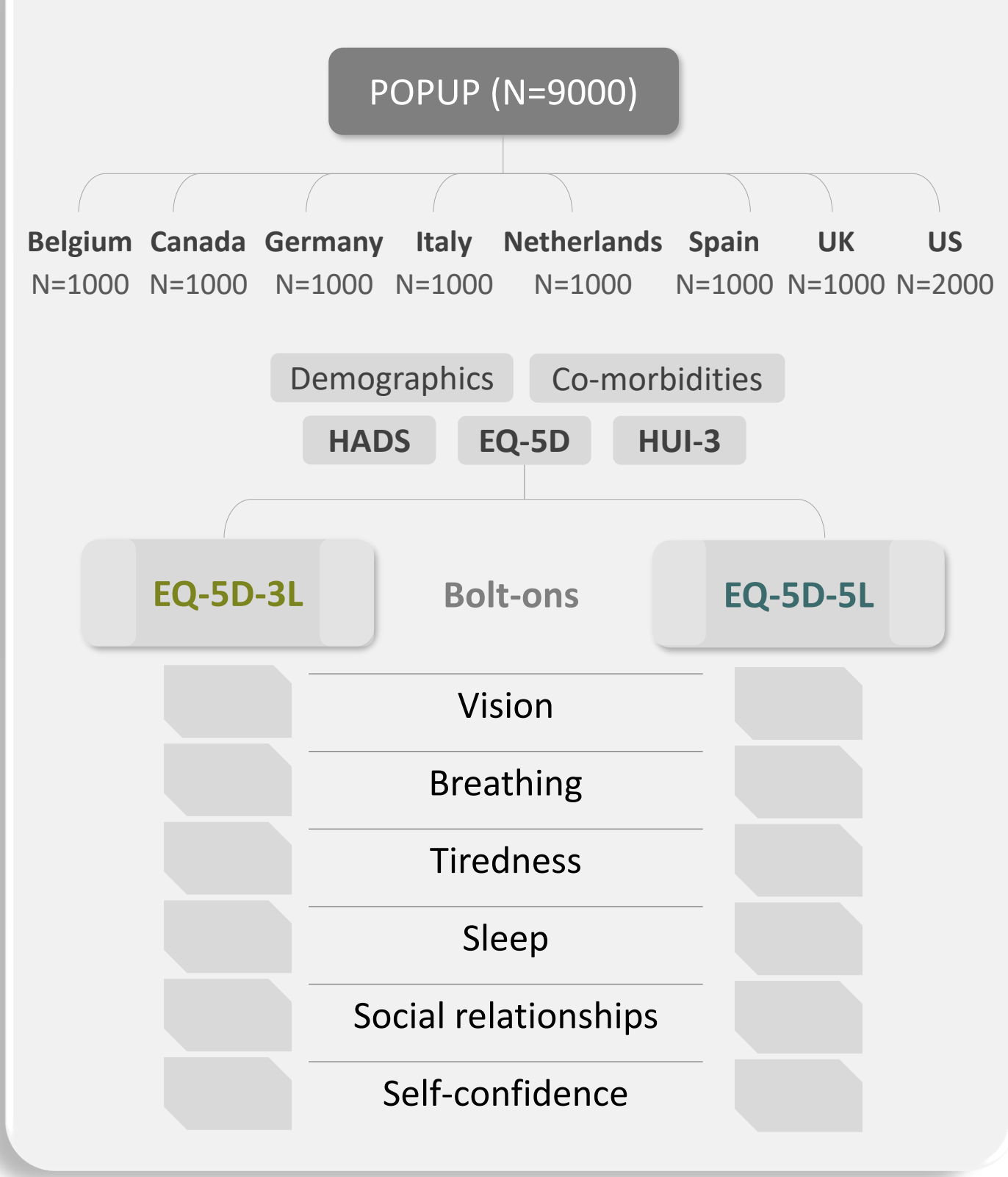
Figure 1. POPUP study

Table 1. Redistribution

EQ-5D-5L Bolt-ons

Vision	1	2	3	4	5	% inconsistent 3L and 5L pairs
1	39.7%	16.1%	4.2%	0.5%	0.1%	
2	1.4%	19.4%	15.5%	1.8%	0.1%	6.7%
3	0.1%	0.2%	0.1%	0.5%	0.3%	
Total	6,002	5,201	2,906	419	69	N=14,597
Breathing						
1	77.2%	6.0%	0.6%	0.1%	0.1%	
2	1.3%	9.0%	4.1%	0.6%	0.1%	2.5%
3	0.1%	0.1%	0.1%	0.4%	0.3%	
Total	11,472	2,204	705	158	58	N=14,597
Tiredness						
1	47.6%	9.8%	1.0%	0.2%	0.1%	
2	0.7%	20.5%	13.4%	2.6%	0.1%	2.8%
3	0.1%	0.1%	0.5%	2.1%	1.3%	
Total	7,066	4,433	2,165	718	215	N=14,597
Sleep						
1	40.7%	13.9%	1.1%	0.2%	0.1%	
2	1.7%	22.4%	13.0%	2.6%	0.2%	4.2%
3	0.0%	0.2%	0.6%	1.9%	1.3%	
Total	6,201	5,326	2,150	683	235	N=14,597
Social relationships						
1	55.5%	11.0%	1.5%	0.2%	0.1%	
2	1.2%	13.7%	9.8%	2.6%	0.2%	3.9%
3	0.1%	0.1%	0.4%	1.8%	1.8%	
Total	8,287	3,617	1,705	674	312	N=14,597
Self-confidence						
1	66.6%	8.7%	1.1%	0.2%	0.1%	
2	1.7%	10.2%	6.6%	1.7%	0.2%	4.0%
3	0.2%	0.1%	0.5%	1.2%	1.1%	
Total	9,987	2,772	1,198	445	196	N=14,597

(EQ-5D-3L Bolt-ons)

Table 2. Informativity and ceiling effects

EQ-5D-3L + 3L bolt-on	Shannon H'	Shannon J'	Ceiling
EQ5D	3.24	0.41	45.4%
Vision	4.22	0.44	33.8%
Breathing	3.79	0.40	43.7%
Tiredness	4.20	0.44	36.8%
Sleep	4.11	0.43	37.7%
Social relationships	4.03	0.42	40.3%
Self-confidence	3.96	0.42	41.8%
EQ-5D-5L + 5L bolt-on			
EQ5D	4.89	0.42	32.6%
Vision	6.51	0.47	19.7%
Breathing	5.74	0.41	30.9%
Tiredness	6.41	0.46	24.1%
Sleep	6.34	0.45	23.6%
Social relationships	6.22	0.45	26.5%
Self-confidence	6.05	0.43	28.6%
Relative increase with 5L	**153%**	**105%**	

Table 3. Agreement between 3L and 5L Bolt-ons

Bolt-on	ICC between rescaled LSS of the EQ-5D-5L+ bolt on and rescaled LSS of the EQ-5D-3L + bolt-on	95% lower confidence bound	95% upper confidence bound
Vision	0.920	0.918	0.922
Breathing	0.963	0.962	0.964
Tiredness	0.970	0.969	0.971
Sleep	0.968	0.967	0.969
Social relationships	0.946	0.945	0.948
Self-confidence	0.956	0.955	0.957

Table 4. Comparison of longitudinal changes between 3L and 5L bolt-ons

Change Wave 2 - Wave 1	Vision 3L	Vision 5L	Breathing 3L	Breathing 5L	Tiredness 3L	Tiredness 5L	Sleep 3L	Sleep 5L	Social Relationships 3L	Social Relationships 5L	Self-confidence 3L	Self-confidence 5L
-4		0.1%		0.0%		0.1%		0.1%		0.1%		0.1%
-3		0.4%		0.1%		0.3%		0.2%		0.4%		0.5%
-2	0.1%	2.5%	0.1%	1.0%	0.2%	2.7%	0.3%	2.1%	0.4%	2.2%	0.4%	2.0%
-1	13.4%	17.4%	6.3%	8.9%	13.0%	16.6%	12.4%	15.4%	10.3%	14.1%	10.1%	10.9%
0	**74.4%**	**61.4%**	**87.1%**	**80.0%**	**75.7%**	**62.1%**	**72.7%**	**59.6%**	**79.6%**	**68.5%**	**80.8%**	**72.7%**
1	11.9%	15.7%	6.4%	8.7%	10.8%	15.9%	14.4%	19.4%	9.3%	12.4%	8.3%	11.1%
2	0.2%	2.3%	0.1%	1.3%	0.3%	2.0%	0.3%	2.8%	0.4%	1.9%	0.5%	2.3%
3		0.2%		0.0%		0.4%		0.3%		0.4%		0.4%
4		0.0%		0.0%		0.1%		0.1%		0.0%		0.1%
Mean change in rescaled LSS	0.10	0.04	0.22	0.17	0.05	0.07	0.39	0.40	0.14	0.05	0.09	0.18
Correlation (Δ 3L rescaled LSS ; Δ 5L rescaled LSS)	0.519		0.565		0.586		0.584		0.588		0.583	

Table 5. Comparison of Pareto class changes between the EQ-5D-3L + 3L and EQ-5D-5L + 5L bolt-ons

For all respondents who are worse than 11111(1)	EQ-5D 3L	EQ-5D 5L	EQ-5D + Vision 3L	EQ-5D + Vision 5L	EQ-5D + Breathing 3L	EQ-5D + Breathing 5L	EQ-5D + Tiredness 3L	EQ-5D + Tiredness 5L	EQ-5D + Sleep 3L	EQ-5D + Sleep 5L	EQ-5D + Social Relationship 3L	EQ-5D + Social Relationship 5L	EQ-5D + Self-Confidence 3L	EQ-5D + Self-Confidence 5L
Improved	40%	38%	38%	31%	41%	37%	40%	36%	41%	35%	41%	36%	42%	37%
Mixed	9%	18%	15%	15%	12%	23%	14%	25%	13%	25%	13%	25%	14%	25%
No change	30%	19%	26%	28%	25%	16%	24%	13%	22%	13%	23%	14%	23%	15%
Worsened	21%	24%	22%	26%	22%	24%	22%	25%	25%	26%	23%	24%	22%	24%
Difference Improved	-2%		-7%		-4%		-4%		-5%		-4%		-5%	
Difference Mixed	9%		0%		11%		12%		12%		12%		11%	
Difference No Change	-10%		2%		-9%		-11%		-9%		-9%		-8%	
Difference Worsened	4%		4%		2%		3%		2%		1%		2%	

Key findings

3-level	5-level

Average ceiling effect
45% → **32%**
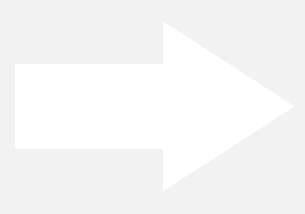
Inconsistent responses
63% → **41%**

Agreement between 3L and 5L
Excellent (ICC range: 0.92-0.97)

Informativity
Absolute	Relative
+53%	**+5%**

Sensitivity
5L bolt-ons have markedly improved sensitivity to change over time

Conclusion

- This is the first study in the literature to psychometrically validate a set of 3-Level and 5-Level bolt-ons in parallel.
- All 12 bolt-ons showed good measurement performance in assessing the health status of the general population, with the 5-Level bolt-ons showing superior psychometric performance.
- Our findings are useful for informing future bolt-on development, selection and testing, as well as instrument development beyond the EQ-5D