### Type of Outcome Measure: Qualiveen Questionnaire

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<tr>
<th>Author ID</th>
<th>Study Design</th>
<th>Setting</th>
<th>Population (sample size, age) and Group</th>
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</table>
| Costa et al. 2001 | Questionnaire | France | Questionnaire development: n=9  
Item reduction: n=281 (218 male, 59 female, 4 missing data)  
Mean age: 41, range 17-87  
Reproducibility: n=46  
Questionnaire development: 4 paraplegic, 3 tetraplegic, 2 conus medullaris syndrome.  
Item reduction: 155 paraplegia, 90 tetraplegia, 24 conus medullaris syndrome, 12 missing data. |
| Qualiveen MANUAL | N/A | France | N=400 (290M, 104F, 6 missing data)  
Mean (sd) age: 41.2 (14.0)  
Mean (sd) DOI: 11.5 (9.6) years  
Type of injury:  
Paraplegia (N=209)  
Tetraplegia (N=109)  
Cauda equine (N=56)  
Missing data (N=26)  
Complete lesion:  
Yes (N=188)  
No (N=115)  
Doesn’t know (N=74)  
Missing data (N=23)  
Method of urinating:  
Self-catheterization (N=165)  
Catheterized by someone else (N=22)  
Percussion (N=111)  
Abdom or manual pressure (N=90)  
Derivation (N=7)  
Indwelling catheter (N=10)  
Other (N=44)  
Family situation:  
Single (N=78)  
Has a partner (N=236)  
Other (N=70)  
Missing data (N=16) |
| Nikfallah et al. 2015 | cross-sectional prospective validation study of | A clinic | N=154, 89M 65F  
Mean age 35.55±9.8  
80 SCI, 74 Multiple Sclerosis |
<table>
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<tr>
<th>Author ID</th>
<th>Internal Consistency</th>
<th>Test-retest, Inter-rater, Intra-rater</th>
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| Costa et al. 2001 | $\alpha = 0.80$
Limitations: $\alpha=0.85$
Constraints: $\alpha=0.80$
Fears: $\alpha=0.81$
Feelings: $\alpha=0.83$
Item-total correlations: | 15-day test-retest ICC ranged from 0.85 to 0.92 for the 4 subscales |
| Nikfallah et al. 2015 | Cronbach’s alpha: 0.95 (overall); 0.82–0.93 (subdomains) | 3 week test-retest ICC = 0.97 (overall); 0.94–0.97 (subdomains) |

2. VALIDITY

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| Costa et al. 2001 | The final decision to reduce the number of items was made by the scientific committee, using their knowledge of the SCI population. Correlations between items in each domain and the domain:
Limitations: $r=0.52$ to $0.65$
Constraints: $r=0.43$ to $0.66$
Fears: $r=0.39$ to $0.60$
Feelings: $r=0.50$ to $0.77$
Correlations between items in each domain and non-corresponding domains:
Limitations: $r=0.29$ to $0.64$
Constraints: $r=0.18$ to $0.59$
Fears: $r=0.12$ to $0.40$
Feelings: $r=0.28$ to $0.57$
The criteria for acceptable discriminant validity is that the “item was more correlated with its own domain than with other domains”

Clinical:
Scores from 4 Qualiveen Scales correlated with 3 items from Subjective Quality of Life Profile (SQLP) related to urination (correlation values are not provided):
How well patients urinate: $P=.0001$
Patient Satisfaction with Urination: $P=.0001$
Time taken to urinate: $P<.05$
| Nikfallah et al. 2015 | Pearson’s $r$ ($p<0.05$):
Qualiveen (Persian) total with Short Form-12 (SF-12) Health Survey - Physical Component Summary: $-0.29$
Qualiveen (Persian) total with SF-12 Mental Component Summary: $-0.32$
Qualiveen and its domains had a moderate to high correlation with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-Urinary Incontinence Short Form) ($0.36 < r < 0.57$) and SF-12 MCS ($-0.51 < r < -0.11$) and SF-12 PCS ($-0.29 < r < -0.19$), indicating good convergent validity. Discriminant validity: |
"patients with higher levels of education had significantly better urinary disorder specific quality of life (P<0.001)"
"patients with good income had better urinary quality of life compared to low and moderate income patients (P<0.05)"
"Participants with normal voiding had significantly lower values for Qualiveen and all its domains (P<0.05)"
"lower Qualiveen scores = better quality of life

3. RESPONSIVENESS

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<th>Responsiveness</th>
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<tbody>
<tr>
<td>Nikfallah et al. 2015</td>
<td>The non-overlap measure for overall Qualiveen score based on ICIQ-UI SF and SF-12 were 65.3 and 27.4%, respectively.</td>
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4. FLOOR/CEILING EFFECT

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<tr>
<th>Author ID</th>
<th>Floor/ceiling effect</th>
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<tbody>
<tr>
<td>Costa et al. 2001</td>
<td>Floor and ceiling effects were minimal, suggesting that the questionnaire adequately covered the range of patient experiences.</td>
</tr>
<tr>
<td>Nikfallah et al. 2015</td>
<td>0% floor &amp; ceiling for overall score 0.7<del>1.3% floor &amp; 0.7</del>3.5% ceiling for “Bother with Limitations”, “Frequency of limitations”, “Fears” subdomains 8.5<del>10.5% floor &amp; 2.0</del>2.8% ceiling for “Feelings” subdomain</td>
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5. INTERPRETABILITY

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<tr>
<th>Qualiveen MANUAL</th>
<th>Mean (SD) Reference scores for Qualiveen domains and overall Index score for different groups:</th>
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<tbody>
<tr>
<td>Group:</td>
<td>Inconvenience domain (0-4):</td>
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<tr>
<td>Men (N=290)</td>
<td>1.36 (0.91)</td>
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<tr>
<td>Women (N=104)</td>
<td>1.50 (0.96)</td>
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<tr>
<td>Age &lt; 30 yrs (N=92)</td>
<td>1.42 (0.90)</td>
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<tr>
<td>Age 30-39 yrs (N=96)</td>
<td>1.42 (0.93)</td>
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<tr>
<td>Age 40-50 yrs (N=100)</td>
<td>1.41 (0.99)</td>
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<tr>
<td>Age &gt; 50 yrs (N=103)</td>
<td>1.32 (0.89)</td>
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<tr>
<td>Paraplegia (N=208)</td>
<td>1.46 (0.89)</td>
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<tr>
<td>Tetraplegia (N=107)</td>
<td>1.34 (0.95)</td>
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<tr>
<td>Cauda equina syndrome (N=56)</td>
<td>1.51 (1.05)</td>
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