**Initial Development and Validation of a Fecal Incontinence-Specific Quality of Life Measure**

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**Introduction**

Fecal incontinence (FI) can be psychologically and socially debilitating to both child and family. It can create a magnitude of stress on the caregiver. Fear of such episodes of fecal incontinence limits the child’s involvement in activities. We seek to provide the data that shows significant improvement in Quality of Life (QOL), and how that is measured, in association with fecal incontinence.

**Objectives**

- To develop and validate a tool for QOL specific to the colorectal patient with FI
- Identify what psychometrical questions are appropriate for measurement of QOL in the colorectal patient
- Obtain Data showing actual improvement in QOL, as compared to before and after a bowel management program
- Provide a tool to allow for simple administration within the PCP office to providing immediate feedback

**Methods**

- IRB submission and approval to collect data for validity
- 222 families consented
- Inclusion/Exclusion Criteria
  - Child must be 3-12 years of age
  - Caregiver must be able to read English
- Development of CINCY-40 (cincinnati fecal incontinence score)
  - Items for Measure/ Psychometric Questions—mental state, personality, and thought process
    - Literature Review
    - Expert Consensus
    - Initial pilot testing (8 families)
    - Parent Interviews
    - Four factor solution:  
      - Physical
      - Emotional
      - Social
      - Total score
  - Validity by correlation:  
    - PedQL
    - Parenting Stress Score
    - Fecal Incontinence Severity Score (FISS)

**Demographics**

<table>
<thead>
<tr>
<th>AGE</th>
<th>GENDER</th>
<th>DIAGNOSIS</th>
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</table>
| 8.40 +/- 2.70 | Male 130 61.30% | Hirschsprung Disease 30 13.50%
|          | Female 86 38.70% | Anorectal Malformation 88 39.60%
|          |                    | Spina Bifida 39 17.60%
|          |                    | Idiopathic Constipation 63 28.40%
|          |                    | Other 2 0.90%
|          |                    | Marital Status/Caregiver
|          |                    | Single 9 4.10%
|          |                    | Married 200 90.10%
|          |                    | Living With Person 3 1.40%
|          |                    | Separated 3 1.40%
|          |                    | Divorced 7 3.20%
|          |                    | RACE
|          | Caucasian 204 91.90% | Caucasian
|          | African American 9 4.10% | African American
|          | Asian 2 1% | Asian
|          | American Indian 2 1% | American Indian
|          | Other 5 2.30% | Other

<table>
<thead>
<tr>
<th>Household Income</th>
<th>Education Level / Caregiver</th>
</tr>
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<tbody>
<tr>
<td>$5,000 to $14,999</td>
<td>Some High School 5 2.30%</td>
</tr>
<tr>
<td>$15,000 to $24,999</td>
<td>General Equivalency 3 1.40%</td>
</tr>
<tr>
<td>$25,000 to $49,999</td>
<td>High School Degree 11 5.00%</td>
</tr>
<tr>
<td>$50,000 to $74,999</td>
<td>Some College 33 14.80%</td>
</tr>
<tr>
<td>$75,000 to $99,999</td>
<td>Associate Degree 36 16.20%</td>
</tr>
<tr>
<td>$100,000 to $199,999</td>
<td>Bachelor’s Degree 69 33%</td>
</tr>
<tr>
<td>$200,000 to $399,999</td>
<td>Graduate Coursework 12 5.40%</td>
</tr>
<tr>
<td>$400,000 to $599,999</td>
<td>Master’s Degree 42 18%</td>
</tr>
<tr>
<td>$600,000 to $799,999</td>
<td>Professional Degree 44 6.30%</td>
</tr>
</tbody>
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**The Tool For Measurement**

**CinCy-FIS on a scale of 0-10, 0= Never and 10 = Often**

- Activity Limitations/Composite Score (Max: 30): Above 22 is worse symptoms than average population.
  - Avoids going out
  - It is difficult to get out and do things
  - How often does child miss out on hobbies, play, parties

- Physical Quality of Life/Composite Score (Max: 40): Above 30 is worse symptoms than average population.
  - Limits movement because of stomachaches, pain, or bloating
  - Feels pain, bloating or acheing in stomach
  - Hard time eating because of the bloating, pain, acheing or feeling full

- Social Quality of Life/Composite Score (Max: 30): Above 24 is worse symptoms than average population.
  - Avoids visiting friends
  - Harder to make friends
  - Feels left out

- Emotional Quality of Life/Composite Score (Max: 40): Above 30 is worse symptoms than average population.
  - Feels depressed
  - Worries about others smelling poop on him/her
  - Feels like he/she is not a healthy person
  - Enjoys life less

**Parenting Stress/Composite Score (Max: 40): Above 28 is worse symptoms than average population.
  - Avoids traveling
  - Child’s poop problems always on my mind
  - How is family affected
  - Child’s poop problems have a negative influence on my family

**Results**

Overall and sub-scale quality of life scores are presented using a normalized scale of 0-100 (higher scores represent increased quality of life).

**Conclusions**

- The CINCY-FIS is a reliable and valid assessment of fecal incontinence-specific quality of life and parenting stress
- The measure is self administered and does not require a specialist to interpret
- The score is highly sensitive to patient changes making it suitable for both clinical and research purposes
- QOL scores improved just 2 weeks following initiation of a bowel management program