Measuring Voluntary Consent Among Parents of Seriously Ill Children

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New Directions for the 21st Century
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Purpose

To present the development of a measure of voluntary consent within the context of an empirical bioethical framework, one that incorporates a theoretical, developmental, and analytical approach to measurement.
Outline

- Measuring Ethical Actions
- Science and Measurement
- Why Measure?
- Rationale for Voluntary Consent
- Research Strategy Used to Measure Voluntary Consent
- Lessons Learned
Measuring Ethical Actions

Can we measure ethical and/or bioethical actions?

Yes . . . but it requires bridging the traditionally disparate worlds of ethics and scientific measurement.
Many different conventions, method of inquiry depends upon several factors:

- presenting problem
- discipline of origin
- interest and skill set of investigator and team

Conceptualization of an event/object/set of processes

How we study something depends in large part on ‘what’ we see, ‘how’ we see it, and the boundaries we set on its manifestation.

Fundamental to the overarching study design and analyses is the operationalization of an idealized phenomenon.
Science and Measurement

Science is about...

- Discovery...uncovering natural laws
- Understanding our world well enough to intervene
- Hypothesis testing—challenging the status quo with our own ideas
- Right method = correct answer, right analyses = correct solution

Perhaps...

- Not simply about discovery, not about us
- Intervention really does depend upon understanding
- Transformation of experiences into measurable events
Why Measure?

- To derive estimates for comparison across a common dimension.

- Basic requirements\(^1\)
  - Presence of a one-dimensional abstraction
  - Ordered continuum with linear magnitude onto which events may be organized
  - Unit of measurement is determined by a process that is invariant over the range of the continuum

- Measurement models connect the construct of interest with the observable indicators (items) of a given trait or condition

- Enter observation and experimentation

Rationale for Voluntary Consent

Case example: voluntary consent

- National Commission (1974) authorized by congress to develop guidelines that would govern conduct of human subjects’ research
- Applications of basic ethical principles (inf consent, fair selection, risk/benefit ratio)

Influential factors

- Respect for persons serves as the moral basis for informed consent
- “Free power of choice without undue influence or . . . coercion’ (Voluntariness, Belmont Report)
- Voluntariness must be evaluated with respect to: influence, control, intention
  - Influence: persuasion, coercion, and manipulation
  - Controlling factors: internal, external
  - Intention: congruence between action and capacity to act

Empirical Study of Voluntariness

- Goal: identify vulnerable individuals or conditions that might result in vulnerability
- DMCI: measure of decision making control

Research Strategy

Voluntary Consent

Decision Making Control Instrument

Challenges
Theoretical

Analytical

Developmental

Research Strategy
Concept of Voluntary Consent

- Voluntary consent (VC) is one of 3 foundational notions in the protection of human research participants
- VC is the least carefully examined in the literature
- Proposed the following:
  - VC must be understood f(intentionality, freedom from controlling influences)
  - Reject the notion of authenticity as a necessary condition of VC
  - Examined VC within a value-laden and non-value-laden set of analysis

Instrument is needed to provide data that would help establish appropriate policies and procedures for obtaining VC with respect to intentionality and perceived self-control
Challenges of Measuring a New Construct

- Refine the construct definition (perception of voluntariness) and operationalize the construct
- Congruence between theory and analyses
- Strategies used
  - literature review
  - focus groups
  - identification of concrete indicators
  - creation of new/adaptation of existing items
  - mapping items to theoretical content
  - multidisciplinary team

Decision Making Control Instrument

Purpose: To inform our understanding of the voluntariness of treatment and research decisions in medical settings.

- *N* = 219 parents completed questionnaires (CICU, NICU, Onc; *M* = 4.2 d, *SD* = 2.6 d) relative to involving their child (62% research protocol, 33% non-research treatment protocol, 5% missing).

Results

- 28 items → 9 item scale representing dimensions of Self-Control, Absence of Control, and Others’ Control
- Preliminary validity was evidenced through statistically significant correlations with measures of affect, trust, decision self-efficacy.
- Internal consistency (*Mdn* = 0.83; 0.68 to 0.87 across subscales)

Measuring Voluntariness of Consent

Table 2: Item Descriptive Statistics for Experimental Item Pool

<table>
<thead>
<tr>
<th></th>
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<td>1.1</td>
<td>5.0</td>
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<td>7</td>
<td>8</td>
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<td>78</td>
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<td>1.6</td>
<td>5.0</td>
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<td>14</td>
<td>18</td>
<td>17</td>
<td>58</td>
<td>96</td>
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<td>6.0</td>
<td>2</td>
<td>0</td>
<td>7</td>
<td>9</td>
<td>52</td>
<td>149</td>
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<td>5.2</td>
<td>1.0</td>
<td>6.0</td>
<td>4</td>
<td>2</td>
<td>5</td>
<td>24</td>
<td>74</td>
<td>110</td>
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<td>5.</td>
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<td>1.2</td>
<td>5.0</td>
<td>4</td>
<td>7</td>
<td>12</td>
<td>30</td>
<td>71</td>
<td>95</td>
</tr>
<tr>
<td>6.</td>
<td>5.2</td>
<td>1.2</td>
<td>6.0</td>
<td>4</td>
<td>4</td>
<td>18</td>
<td>14</td>
<td>68</td>
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<tr>
<td>7.</td>
<td>5.2</td>
<td>1.2</td>
<td>6.0</td>
<td>7</td>
<td>4</td>
<td>10</td>
<td>12</td>
<td>68</td>
<td>118</td>
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<tr>
<td>8.</td>
<td>5.3</td>
<td>1.1</td>
<td>6.0</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>10</td>
<td>67</td>
<td>125</td>
</tr>
<tr>
<td>9.</td>
<td>5.0</td>
<td>1.3</td>
<td>5.0</td>
<td>6</td>
<td>10</td>
<td>19</td>
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<td>78</td>
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<td>10.</td>
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<td>16</td>
<td>17</td>
<td>12</td>
<td>71</td>
<td>97</td>
</tr>
</tbody>
</table>

The ‘Voluntariness’ Construct

Table 3  Factor Loadings of the Final DMCI Items

<table>
<thead>
<tr>
<th>Item</th>
<th>Self-Control</th>
<th>Absence of Control</th>
<th>Others’ Control</th>
<th>Uniquenessa</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. I made this decision.</td>
<td>0.82</td>
<td>0.08</td>
<td>-0.01</td>
<td>0.28</td>
</tr>
<tr>
<td>19. I was not the one to choose.</td>
<td>0.76</td>
<td>0.03</td>
<td>0.21</td>
<td>0.23</td>
</tr>
<tr>
<td>24. The decision was up to me.</td>
<td>0.75</td>
<td>0.04</td>
<td>0.05</td>
<td>0.36</td>
</tr>
<tr>
<td>2. I was powerless in the face of this decision.</td>
<td>0.06</td>
<td>0.93</td>
<td>-0.14</td>
<td>0.17</td>
</tr>
<tr>
<td>16. I was not in control of this decision.</td>
<td>0.36</td>
<td>0.44</td>
<td>0.16</td>
<td>0.43</td>
</tr>
<tr>
<td>13. I was passive in the face of this decision.</td>
<td>-0.02</td>
<td>0.40</td>
<td>0.15</td>
<td>0.78</td>
</tr>
<tr>
<td>18. Others made this decision against my wishes.</td>
<td>0.12</td>
<td>-0.13</td>
<td>0.97</td>
<td>0.06</td>
</tr>
<tr>
<td>15. The decision about the protocol was inappropriately influenced by others.</td>
<td>-0.09</td>
<td>0.46</td>
<td>0.73</td>
<td></td>
</tr>
<tr>
<td>3. Someone took this decision away from me.</td>
<td>0.15</td>
<td>0.29</td>
<td>0.34</td>
<td>0.62</td>
</tr>
</tbody>
</table>

Note: Values in bold typeface indicate onto which factor each item loaded.

Voluntary Consent

The Decision Making Control Instrument to Assess Voluntary Consent

Victoria A. Miller, PhD, Richard F. Ittenbach, PhD, Diana Harris, PhD,
William W. Reynolds, PhD, Tom L. Beauchamp, PhD, Mary Frances Luce, PhD,
Robert M. Nelson, MD, PhD

Challenges in Measuring a New Construct: Perception of Voluntariness for Research and Treatment Decision Making

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Richard Stockton College of New Jersey
Richard F. Ittenbach
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Research Strategy

The Concept of Voluntary Consent

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Tom Beauchamp, Georgetown University
Victoria A. Miller, University of Pennsylvania School of Medicine
William Reynolds, Richard Stockton College of New Jersey
Richard F. Ittenbach, Cincinnati Children's Hospital Medical Center
Mary Frances Luce, Duke University
Lessons Learned

(1) Challenging the notion that Voluntariness and one’s degree of decision making control can be effectively measured.

(2) Off-set our own biases by premising our work on a conceptual/theoretical foundation with multiple analytic strategies and an interdisciplinary team.

(3) Although statistical rules and conventions were important, they never informed and complimented our thinking.

(4) More attention is needed within the area of pediatrics.
Acknowledgments

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Mary Frances Luce  Duke University
Victoria Miller  CHOP, University of Pennsylvania
Robert (Skip) Nelson  U.S. Food & Drug Administration
William Reynolds  Stockton College of New Jersey