NIH Public Access
Author Manuscript
Med Decis Making. Author manuscript; available in PMC 2012 September 1.

Published in final edited form as:
Med Decis Making. 2011 ; 31(5): 730–741. doi:10.1177/0272989X11398666.

The Decision Making Control Instrument to Assess Voluntary Consent

Victoria A. Miller, Ph.D.,
Department of Anesthesiology and Critical Care Medicine, The Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine

Richard F. Ittenbach, Ph.D.,
Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital Medical Center

Diana Harris, Ph.D.,
Center for the Integration of Genetic Healthcare Technologies, University of Pennsylvania School of Medicine

William W. Reynolds, Ph.D.,
Richard Stockton College of New Jersey

Tom L. Beauchamp, Ph.D.,
Kennedy Institute of Ethics, Georgetown University

Mary Frances Luce, Ph.D., and
The Fuqua School of Business, Duke University

Robert M. Nelson, M.D., Ph.D.
Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration

Abstract

Background—The decision to participate in a research intervention or to undergo medical treatment should be both informed and voluntary.

Objective—The aim of the present study was to develop an instrument to measure the perceived voluntariness of parents making decisions for their seriously ill children.

Methods—A total of 219 parents completed questionnaires within 10 days of making such a decision at a large, urban tertiary care hospital for children. Parents were presented with an experimental form of the Decision Making Control Instrument (DMCI), a measure of the perception of voluntariness. Data obtained from the 28-item form were analyzed using a combination of both exploratory and confirmatory factor analytic techniques.

Results—The 28 items were reduced to nine items representing three oblique dimensions of Self-Control, Absence of Control, and Others' Control. The hypothesis that the three-factor covariance structure of our model was consistent with that of the data was supported. Internal consistency for the scale as a whole was high (0.83); internal consistency for the subscales ranged

Correspondence to: Victoria Miller, The Children's Hospital of Philadelphia, 34th St. and Civic Center Blvd., CHOP North Room 1425, Philadelphia, PA 19104. millerv@email.chop.edu. Tel: 267-426-5259. Fax: 267-426-5035.

Note: This is the pre-publication, author-produced version of a manuscript accepted for publication in *Medical Decision Making*. This version does not include post-acceptance editing and formatting. *Medical Decision Making* is not responsible for the quality of the content or presentation of the author-produced accepted version of the manuscript or in any version that a third party derives from it. Readers who wish to access the definitive published version of this manuscript and any ancillary material related to this manuscript (correspondence, corrections, editorials, linked articles, etc…) should go to http://mdm.sagepub.com/. Those who cite this manuscript should cite the published version as it is the official version of record.

NIH-PA Author Manuscript
NIH-PA Author Manuscript
NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

from 0.68 to 0.87. DMCI scores were associated with measures of affect, trust, and decision self-efficacy, supporting the construct validity of the new instrument.

Conclusion—The DMCI is an important new tool that can be used to inform our understanding of the voluntariness of treatment and research decisions in medical settings.

Keywords

voluntariness; decision making control; informed consent; ethics

Introduction

The decision to participate in a research intervention or to undergo medical treatment should be informed and voluntary. The empirical literature has focused largely on understanding (i.e., what a person knows) and decision processing (i.e., how a person uses information) without sufficient attention given to the voluntary nature of consent. Discussions in the psychological literature on intentionality and reasoned action correspond to some features of informed decision making, but little empirical research examines the voluntariness of decisions specifically, and few have investigated the voluntariness of research participation decisions (see 1–3). A 2002 literature review found no shared or well developed model of voluntariness in either the empirical or the ethics literature (4). A general definition is that a voluntary decision is one that reflects the free power of choice without undue influence or coercion (5). However, this definition does not specify what it means for a decision to be free of undue influence and coercion. Wall argues that voluntariness is the degree of control that an individual has over his or her behavior (6). This definition recognizes that, while individuals cannot always control the circumstances that shape their actions, they can attempt to control their behavior within the parameters of those circumstances (6). Similarly, Faden and Beauchamp argue that voluntariness requires that an action be both intentional and under the control of oneself and not others (7).

Whether individuals with serious, life-threatening illnesses are capable of voluntary consent to research has been the subject of debate (8–11). For example, patients may have few options given their situation and may have difficulty resisting enticements or manipulation of hope. Clinical impairments may also impact patient decision making processes (4). While proxy decision makers are not subject to these potential impairments in the same way as patients themselves, they may face the stress and uncertainty of decision making. For example, parents' emotional responses to their child's new medical diagnosis or deteriorating health may compromise the voluntariness of their decisions. Although potential constraints on voluntariness have been discussed at length in the literature, there is little empirical research to inform our understanding of how these constraints actually operate when decisions are made. In addition, we know nothing about how patients and parents perceive their own voluntariness when making health care decisions. One reason for the lack of empirical data in this area is that there are no adequate instruments for measuring voluntariness.

The aim of the present study was to develop an instrument to measure the perceived voluntariness of parents making decisions for their seriously ill children. Consistent with the definitions put forth by Wall (6) and Faden and Beauchamp (7), we have argued that for an action to be voluntary in fact it must be intentional and not under a substantial controlling influence (12). Although voluntary action cannot be measured, a person's perception of whether his or her action is voluntary can be measured by testing for perception of intentionality and noncontrol. In the present study, we assumed that a parent's decision was intentional if the parent indicated that, in fact, he/she had made a decision. A measure of the

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

second condition of voluntary action assesses an individual's perception of the degrees of noncontrol and self-control over the decision that was made. We propose that perception of noncontrol is on a continuum (continuous scale), which allows for fractional amounts (or degrees) of the measured attribute (perception of control)(12). We targeted two different types of parental decisions in the present study. The first type had to do with whether or not to enroll the child in a research protocol, while the second had to do with whether or not to consent to a non-research treatment protocol for the child. Both types of decisions entail interventions for the child and can involve uncertainty, complex information, time pressures, and emotional intensity. A secondary study aim was to test the construct validity of the new instrument by testing associations between scores on the new scale and measures of theoretically-related constructs: decision self-efficacy, affect, and trust. We expected that parents with higher decision self-efficacy, more positive affect (more composed, confident, and clearheaded, versus anxious, unsure, and confused), and greater trust in the physician would perceive greater control over the target decision.

The new instrument, called the Decision Making Control Instrument (DMCI), will redress the current imbalance in the assessment of decision-making in medical settings by focusing on the voluntariness requirement of informed consent. A major benefit of the DMCI is that it can be used in future research to explore empirically claims about factors leading to undue influence or coercion over decisions about research and treatment, rather than simply to rely on theoretical statements lacking an empirical foundation. Furthermore, the DMCI can be used to develop empirically-based interventions (e.g., modifying the consent process) that minimize undue influence and optimize decision making in medical settings.

Methods

Recruitment

Participants were recruited from January 2007 through June 2008 at an urban, tertiary care pediatric hospital in the northeastern United States. Participants were eligible if they were the parent of a seriously ill child receiving care at the hospital and made one of the two different target decisions for the child within the past 10 days. The first type of decision was related to research protocols, and the second type was related to non-research treatment protocols requiring written informed consent. Potential participants were identified via multiple clinical settings: oncology, neuro-oncology and bone marrow transplant programs, cardiac and pediatric intensive care units, and the clinical trials office.

A total of 266 parents were invited to participate in this study. Of this number, 16 (6.0%) declined to participate and 250 (94.0%) agreed. Of those who agreed, 231 (92.4%) parents returned the questionnaires and 19 (7.6%) did not. Twelve of the 231 parents who returned the questionnaires were not included in the analyses because they did not complete the questionnaires within ten days ($n = 6$) or because items from the DMCI were missing ($n = 6$). Thus, the final sample for this analysis consisted of 219 participants. A comparison of the final sample of 219 participants to the 47 who declined, did not return the questionnaires, or were removed from the analysis showed that they did not differ in terms of parent gender ($X^2_{[1]} = 2.63$, $p = .105$) or medical unit ($X^2_{[3]} = 4.73$, $p = .193$).

Procedures

The study was approved by the hospital's institutional review board as presenting no more than minimal risk, and written documentation of informed consent was waived under 45 CFR 46.117(c)(2). Potential participants were approached as soon as possible after they had made a decision about a research protocol or non-research treatment protocol, during an outpatient visit or on an inpatient unit. After parents provided verbal informed consent, the

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

researcher described the questionnaires and reviewed the instructions for participation. Following completion of the questionnaires, participants received $20 for their time and effort.

Prior to formal recruitment, the packet of materials was pre-tested with 17 parents. After administration, parents provided specific comments about the DMCI instructions and items that were confusing or ambiguous. Based on this feedback, minor changes were made to the sequence and wording of items and the order in which the questionnaires were administered. Because of these changes, the 17 pre-test participants were not included in the final sample of 219 respondents.

Item Pool for the Decision Making Control Instrument—The experimental item pool for the DMCI was generated from two sources: (a) adaptation of existing instruments and (b) focus group data. A more detailed account of the item development process can be found in Miller et al. (13).

First, we examined existing measures of locus of control, self-efficacy, and decision making that were related, but not identical, to our construct of voluntariness. Relevant instruments included the *Self-Determination Scale* (14), *Rotter Locus of Control Scale* (15), *Multidimensional Health Locus of Control Scale* (16), *General Self-Efficacy Scale* (17, 18), *Decision Self-Efficacy Scale* (19, 20), *Admission Experience Survey- Short Form* (21), and the *Decisional Conflict Scale* (19, 22). We reviewed items from these measures to ensure that we did not leave out potentially relevant control-related themes from the experimental item pool. Although locus of control instruments inspired some of the items in our experimental pool, perceived voluntariness, operationalized as perceptions of noncontrol and self-control, differs from locus of control in several important ways. The locus of control construct has to do with beliefs about outcomes in general or in specific domains (e.g., health), refers to expectancies regarding the future, and is conceptualized as a trait that is stable across time and context. In contrast, perceived voluntariness is concerned with beliefs about the process of decision making related to a specific decision, refers to beliefs about a decision that is currently being made or was recently made, and is expected to vary depending on the specific circumstances.

Second, this study included a qualitative phase involving focus group and individual interviews with: (a) parents who had made decisions about research interventions or protocol-based treatments for their seriously ill children ($n = 15$), (b) physician-investigators involved in obtaining consent from parents ($n = 7$), and (c) study coordinators and research nurses involved in the consent process ($n = 26$). The interviewers included three of the authors (V.M., W.R., and R.N.), all of whom are experienced with qualitative methods and pediatric ethics. Prior to data collection, we developed an interview guide to ensure that key themes related to voluntariness were explored with participants. We began with open-ended questions about the consent process and avoided use of the words ‘voluntariness’ and ‘control’ early in the interview, so that participants would not be biased to view the decision in a particular way and to facilitate the generation of new themes. As each interview progressed, the questions became more specific and prompted for reactions to different definitions of voluntariness that we had identified in the literature. Interviews were audiotaped, transcribed, and analyzed for themes related to voluntariness. Research team members discussed the information obtained from the interviews to generate additional items for the experimental item pool.

Once we had a list of potential items for the experimental item pool, we discussed at length the usefulness of each item as an indicator of voluntariness. Items also were reviewed for readability, grammar, technical adequacy, domain representativeness, and cultural

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

sensitivity. The final experimental item pool contained 28 items, all of which assess the parent's perception of control over the target decision about enrolling in a research protocol or consenting to a non-research treatment protocol. The response format for all items was a 6-point Likert scale ranging from *Strongly Disagree* (1) to *Strongly Agree* (6).

Measures

Demographics—Participants completed a demographic form that included questions about the parent (age, gender, race, ethnicity, education, marital status, family income) and the child (age, gender, name of illness, date of diagnosis).

Decision Self-Efficacy—The *Decision Self-Efficacy Scale* (DSE) measures self-confidence in one's decision making abilities with respect to medical treatment (19, 20). For this study, the instructions were edited so that parents rated their confidence in making decisions about medical treatment for their child. Prior research demonstrated an alpha of 0.84 (19) and evidence of validity (23). Higher scores indicate higher perceived self-efficacy.

Affect—The *Profile of Mood States-Bipolar* (POMS-Bi) (24, 25) yields six mood scales, three of which we used to test our hypotheses: Composed-Anxious, Confident-Unsure, and Clearheaded-Confused. In this study participants rated their mood at the time of the target decision. Kuder-Richardson 20 internal consistency values ranged from 0.84 to 0.95 in prior research, and test-retest correlations ranged from 0.43 to 0.74. The validity of the POMS-Bi has been supported by prior studies (26). Higher scores indicate more positive affect.

Trust—The *Trust in Physician Scale* (TPS) assesses patient trust in his/her physician (27). The measure has strong internal consistency reliability, with Cronbach's alphas of 0.85 or greater in two independent phases of item analyses (27). For construct validity, TPS scores were correlated with scores on similar theoretical constructs relating to patient-physician relationships (27). For the present study, we edited the instructions so that the questionnaire referred to "the physician here at the hospital who was most involved in assisting you with making this decision." Higher scores indicate greater trust.

Analytic Plan

Data analysis proceeded in three discrete steps: a descriptive phase, a factor analytic phase, and an initial validation phase.

Descriptive Phase—To understand the characteristics of the scale, measures of central tendency, variability, and association were computed for individual items, and for the 28-item composite score. Because of the ordinal nature of the items, and the potential for a skewed distribution of scores, descriptive indices were computed using both parametric and nonparametric techniques. Item-item and item-total correlations were then calculated using Spearman-rho (r_S) correlation coefficients to identify outliers and potentially redundant correlates of the unrefined, composite score. Composite scores for the instrument as a whole and individual subscales were computed using a simple sum of item scores. Spearman-rho coefficients were deemed most appropriate given the ordinal and sometimes skewed nature of the item distributions.

Factor Analytic Phase—The purpose of this phase was twofold: first, to identify the most appropriate number of underlying factors within the 28-item experimental form, and, second, to identify and describe the same underlying factors using the fewest yet most informative items. A combination of exploratory and then confirmatory factor analytic methods was used. Four different strategies were used to identify the optimal number of

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

underlying factors, including scree plot, number of eigenvalues > 1, parallel analysis, and interpretability of factors. An oblique exploratory factor analytic solution with principal axis factoring and promax rotation was then used to identify conceptually relevant factors for the entire 28-item set. An oblique solution was deemed most appropriate given the potential for several highly correlated factors. Confirmatory factor analytic solutions ($n - 1$, n, and $n + 1$) were then repeated until we obtained a stable set of balanced, meaningful, and conceptually related subscales. Following identification of a preferred solution, the residual covariance matrix was then checked for extreme variations between observed and fitted values. The model was tested using maximum likelihood estimation and a standard likelihood ratio test; our criteria for item selection included a simple structure with no or minimal co-loading of items across factors, primary factor loadings of 0.30 or greater, and a minimum of three primary factor loadings (items) per subscale.

Initial Validation Phase—Three separate analyses were conducted using the newly formed scale to further inform the development process: (a) *reliability estimates* using coefficient alpha for the scale as a whole and for all newly identified subscales; (b) a final set of within-measure item-total, subscale-total, and subscale-subscale correlations (r_s) to document shared variance among DMCI items and scores; and (c) *construct-related validity* estimates using the DMCI, DSE, POMS-Bi, and TPS. These measures provide construct validity information regarding the relationship of the DMCI to established, external measures of decision self-efficacy, affect, and trust. As with the item-level analyses, Spearman-rho coefficients were also used for these analyses, with a Bonferroni-corrected *p*-value of .002 as the criterion for statistical significance.

Power and Sample Size Estimates

Power and sample size estimates were computed at the design stage of the study. Our sample size of $n = 219$ participants placed us above the 183 subjects needed to detect a statistically significant correlation of $r = 0.25$ (with 80% power) and above the 200 participants required for traditional confirmatory factory analysis with moderate communalities and two to three recoverable factors (28). All data were analyzed using SAS v9.1 and STATA v10.0. The external funding sources had no role in the design, analysis, or interpretation of this study.

Results

Participants

The sample included 219 parents who made one of the two target decisions described above. Demographic and illness characteristics are presented in Table 1.

Setting and Decision Characteristics

The mean duration from decision to study participation was 4.2 days ($SD = 2.6$). For 62.1% of parents, the target decision had to do with enrolling the child in a research protocol, while the remaining parents (32.9%) made a decision about a non-research treatment protocol. This information was missing for 5% of parents. About half (46.1%) of the parents had made a past decision about a research protocol or non-research treatment protocol for the child.

Descriptive Phase

Items were reverse-scored prior to calculation of descriptive statistics and frequencies. Table 2 presents these data for the 28 DMCI items. Except for items 3, 18, and 23, each of the six response options was selected by at least one respondent. The response frequencies and

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

item-level summary statistics for all items indicated that a large number of respondents selected response options that indicated greater perceived voluntariness, resulting in negatively skewed item-level distributions. For example, while item-level medians ranged from 5 to 6 (range for each item 1 to 6), item-level means ranged from 4.8 to 5.6 (SDs ranged from 0.7 to 1.7).

For the 28 items, item-item correlations ranged from 0.05 to 0.82 (M = 0.50, SD = 0.13, Mdn = 0.49). Item-total correlations ranged from 0.32 to .85 (M = 0.64, SD = 0.15, Mdn = 0.67), representing a range of contributions to the broader scale, with no items duplicative with the scale as a whole. Total DMCI scores on the 28-item composite ranged from 53.0 to 168.0 (M = 141.2, SD = 22.4, Mdn = 145.0).

Factor Analytic Phase

We ran repeated exploratory factor analyses on the initial 28 item experimental pool, removing or retaining items with each iteration. Final item selection was based on a number of different factors, including strength of factor loadings, balance of number of items on each factor, consistency of item loading on the item's primary factor, minimal co-loadings across factors, and conceptual clarity. The goal of these successive iterations was to find the best-fitting solution that was also conceptually interpretable. Three correlated factors based on nine items emerged from the factor analytic methods (Table 3). Good separation was achieved among factors. The Self-Control factor appeared to be strongest (accounting for 55% of the total variance of the items), but not substantially more so than Others' Control (accounting for 44% of the total variance) and Absence of Control (accounting for 43% of the total variance). Only Item 16 co-loaded across factors (0.36 on Self-Control; 0.44 on Others' Control). The hypothesis that a 3-factor covariance structure model was consistent with the data was supported ($X^2_{[12]}$ = 13.42, p = 0.34). The current three-factor model was tested against the saturated model using a standard likelihood-ratio test. Model adequacy was further evaluated using the residual covariance matrix, which yielded no extreme values with respect to the absolute magnitude of the standardized residuals ($|\pm 2\sigma|$). Finally, Kaiser's (29) measure of sampling adequacy supported the application of a simple, common factor analytic technique given a KMO (Kaiser-Meyer-Olkin) value of 0.82 (0.74 to 0.86) (29).

The mean for the DMCI 9-item composite score was 46.12 (SD = 7.0, range: 18 to 54). The means for the subscale scores were 15.11 for Self-Control (SD = 3.20, range: 3.0 to 18), 14.46 for Absence of Control (SD = 3.41, range: 5.0 to 18), and 16.55 for Others' Control (SD = 1.91, range: 5.0 to 18). In general, all response options were endorsed for each of the 9 items, with varying degrees of support. Responses in the direction of greater perceived voluntariness ranged from 78.1 to 98.6% across the 9 items, while responses in the direction of lesser perceived voluntariness ranged from 1.4 to 21.9%.

Initial Validation Phase

Reliability Estimates—Internal consistency for the 9-item composite was high (0.83). Internal consistency for the 3-item subscales was: Self-Control (0.87), Absence of Control (0.69), and Others' Control (0.67).

Item, Subscale, and Composite Correlations—Item-total correlations for the 9-item set ranged from a low of 0.34 for Item 22 to a high of 0.70 for Item 28 (M = 0.56, SD = 0.13, Mdn = 0.55). While item-total correlations for the Self-Control and Absence of Control subscales ranged from 0.37 to 0.70, item-total correlations for the Others' Control subscale were somewhat lower (0.34 to 0.55). Item-subscale correlations were higher: Self-Control (0.73 to 0.77), Absence of Control (0.40 to 0.55), Others' Control (0.44 to 0.58), further supporting the aforementioned indices of internal consistency. Subscale-total correlations

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

were, in general, high (*Mdn* = 0.80): Self-Control = .80, Others' Control = .72, Absence of Control = .88. Subscale-subscale correlations were more moderate in nature (*Mdn* = 0.52, range: 0.51 to 0.52.). Item-item correlations ranged from .27 to .72 (*Mdn* = .45).

Construct-Related Validity—Correlations between the 9-item DMCI composite score, the three DMCI subscale scores, and measures of decision self-efficacy, affect at the time of the decision, and trust are presented in Table 4. Scores on the Decision Self-Efficacy Scale were positively associated with three of the four DMCI scores (*r*s = 0.24–0.25). That is, participants who perceived themselves as efficacious decision makers with respect to their child's medical care also perceived that they were in greater control of the target decision. Scores on two of the three affect scales of the POMS-Bi were associated with DMCI scores (*r*s= 0.21–0.32). These correlations suggest that feeling more confident and clearheaded was associated with greater perceived control over the target decision. Contrary to our hypothesis, feeling more composed (versus anxious) was not associated with greater perceived control over the target decision. Finally, scores on the Trust in Physician Scale were associated with all four DMCI scores (*r*s= 0.22–0.47), indicating that greater trust in the physician who was most involved in the target decision was associated with greater perceived control over that decision.

Discussion

Health care decisions should be perceived by patients and research participants as voluntary. Until now, there have been no adequate tools for measuring perception of voluntariness. Here we describe a new instrument to measure the perceived voluntariness of parental decisions about a research protocol or non-research treatment protocol for their seriously ill child. Factor analysis yielded three correlated factors of Self-Control, Absence of Control, and Others' Control. Confirmatory factor analysis on the same data set supported a 3-factor covariance structure model as most consistent with the data. The three factors and the composite score have internal consistency values ranging from moderate to high. We tested the preliminary validity of the DMCI by examining associations with affect, self-efficacy, and trust. Parents who perceived greater control reported being more confident and clearheaded at the time of the decision, having greater decision self-efficacy, and having greater trust in the physician most involved in the target decision. The correlations were similar for the three subscales of the DMCI. This finding is not surprising, given that each subscale is part of the construct of voluntariness, with higher scores on each indicative of greater perceived control. At this early stage of development, our understanding of the joint contributions of the three subscales of the DMCI is still evolving. However, these associations support the initial construct validity of the DMCI, by demonstrating that it operates in relation to theoretically-related variables in the expected manner. When attempting to validate new measures, it must be kept in mind that virtually all efforts toward validation are preliminary. An instrument is only considered to be truly "valid" after years of documented evidence across multiple groups, settings, and forms. Evidence provided here is only a first step, though admittedly a very positive first step, toward creating a generalizable measure of decision making control for use in biomedical research.

The DMCI is easy to administer and score, and parents were willing and able to complete the DMCI despite being in a highly stressful medical environment and caring for a seriously ill child. The DMCI can be used to inform our understanding of how parents experience the decision-making process and factors that may influence their perceived voluntariness over specific decisions. This assessment is important, because perceptions of voluntariness may be related to health-related outcomes, such as health status and personal adjustment (see 30), and to aspects of the clinician-patient relationship. The DMCI can also be used to identify

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

individuals who are struggling with medical decisions and in need of additional support and guidance during the consent process.

Although voluntariness of action cannot be measured directly, a person's perception of whether his or her action is voluntary can be measured by testing for perception of intentionality and noncontrol. For measure development, we operationalized voluntariness as the individual's perception of the degrees of noncontrol and self-control over the target decision (12). This approach recognizes that the decision maker's subjective perspective is critical, because whether an influence is "undue" may vary by individual (31). However, the *perception* of voluntariness is different from *being in fact* voluntary. There may be controlling influences that the individual is not aware of, such as when someone intentionally deceives the decision-maker. From a regulatory and ethical standpoint, such a decision in a research or medical setting should be considered non-voluntary, even if the decision-maker's DMCI score reflects a high degree of perceived voluntariness. Although the DMCI does not assess aspects of the *situation* that may render a decision non-voluntary, it provides insight into the individual's perception of the degree to which the decision was self-controlled versus controlled by others. When used alongside an assessment of situational factors, the DMCI may be useful in identifying external conditions that lead to decreased perceived voluntariness.

Appelbaum and colleagues also suggest such a joint approach (31). However, their approach is based on the "legal doctrine of informed consent" and thus presumes that voluntariness is an inherently value-laden concept. In our account, whether an external influence is morally legitimate is conceptually and morally distinct from whether the action taken in response to that influence is voluntary or involuntary (12). In addition, their qualitative empirical approach may be unwieldy and difficult to implement widely in real-world situations (3). An alternative would be to use the DMCI, which is short and easy to administer, on a regular basis and to reserve a more thorough assessment of situational factors for when scores on the DMCI indicate diminished perceived control. This use of the DMCI as a screening measure would require additional research to establish statistically and clinically relevant threshold scores.

This study has several limitations. First, target decisions included those about both research protocols and non-research treatment protocols and the sample size did not permit us to compare measurement models for these two different types of decisions. Our assumption was that the measurement of voluntariness would be similar, because both decisions involve medical interventions for a child's serious illness and occur under conditions of uncertainty. However, the factors related to perceptions of voluntariness may differ for the two types of decisions. Second, our sample had a skewed distribution of DMCI scores, with most participants indicating high perceived voluntariness. This ceiling effect means that the measure may not distinguish between individuals at the high end of the scale, resulting in a lack of sensitivity when testing associations of the DMCI with potential predictors and outcomes. A third limitation is that we used a convenience sample, and those who participated in our research may be different in important ways than those who did not participate. In particular, parents who agreed to participate may have been more likely to perceive that their decisions were voluntary, thus contributing to the ceiling effect. Subgroups that may be susceptible to undue influence, such as those with a lower socioeconomic status or who use publicly-funded insurance, may not have been adequately sampled.

Fourth, our sample was heterogeneous in terms of illness, prognosis, and duration of diagnosis. While this diversity may increase the generalizability of our findings, there may be important differences between subgroups that we could not test. Fifth, we did not collect

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

data on the test-retest reliability of the DMCI; future research using the DMCI should determine the extent to which scores are stable across time. The interpretation of such findings will be complicated by the likelihood that perceptions of voluntariness may change over time, especially if the respondent's emotions and cognitions regarding the decision or the child's health status change over time. Thus, a short retest period (e.g., 1-week) is recommended. For the same reason, the DMCI should be administered as close to the actual decision as possible. Sixth, while the present findings regarding the DMCI are promising, additional research is needed to determine if the factor structure remains stable in other samples, especially when the nine items are presented separately from the original 28-item pool. Seventh, findings from the present study do not address the discriminant and incremental validity of the DMCI. Future research is needed to test the validity of the measure in more depth, including the way in which the DMCI operates in relation to measures of locus of control. Finally, we acknowledge that the DMCI contains one item that co-loads on another factor in the 0.30 to 0.40 range (item 16), and a second item that co-loads just beneath our threshold (item 3). Given that our simple structure is well supported for 7 of the 9 items, and that this is the first of many planned studies in this new area, we are optimistic about these early findings and expect the DMCI to perform well in future studies. As with all validity studies, and in particular with very new instruments such as the DMCI, additional studies will be needed to verify the factor structure of the DMCI and the generalizability of these findings to other populations and settings, including studies that lead toward a refinement of the existing scale.

The DMCI can be used in future research to address several important questions. First, the DMCI can explore the potential causes of decreased perceived voluntariness for treatment and research decisions. Factors such as disease state (32, 33), prognosis (34), clinical setting (35, 36), and substance abuse (37) can influence decisions, but whether these factors create an undue influence is unclear. Similarly, we know little about the impact of inducements on perceived voluntariness, or whether patients are unduly influenced when their own physicians request their participation in research. Second, future research should employ cross-sectional and longitudinal methodologies to assess the influence of perceptions of voluntariness on outcomes, including satisfaction with the decision, clinician-parent communication, health status, and adjustment. Finally, the DMCI should be tested with populations that may be particularly vulnerable to undue influence, such as children and adolescents, those who are economically disadvantaged and/or lack access to health care, and individuals with mental illness. It is our hope that research utilizing the DMCI will provide the empirical foundation for the development of guidelines to enhance the voluntariness of decisions in a variety of medical settings and for different subgroups of patients.

Acknowledgments

Financial support for this study was provided entirely by grants from the National Science Foundation (SES-0527618; Drs. Nelson, Luce, and Beauchamp) and the National Institutes of Health/National Cancer Institute (R21CA118377-01A1; Dr. Nelson) and an Institutional Development Grant to The Center for Research Integrity, Department of Anesthesiology and Critical Care Medicine, The Children's Hospital of Philadelphia. The funding agreements ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The work reported in this article was conducted prior to Dr. Nelson joining the U.S. Food and Drug Administration and does not represent the views and/or policies of the Food and Drug Administration or the Department of Health and Human Services.

References

1. Lidz, CW.; Meisel, A.; Zerubavel, E.; Carter, M.; Sestak, RM.; Roth, LH. Informed Consent: A Study of Decisionmaking in Psychiatry. New York: Guilford Press; 1984.

NIH-PA Author Manuscript NIH-PA Author Manuscript NIH-PA Author Manuscript

2. Sugarman J, McCrory DC, Hubal RC. Getting meaningful informed consent from older adults: A structured literature review of empirical research. Journal of the American Geriatrics Society. 1998; 46:517–524. [PubMed: 9560079]

3. Appelbaum PS, Lidz CW, Klitzman R. Voluntariness of consent to research: A preliminary empirical investigation. IRB: Ethics & Human Research. 2009; 31(6):10–14. [PubMed: 20034185]

4. Nelson RM, Merz JF. Voluntariness of consent for research: An empirical and conceptual review. Medical Care. 2002; 40(9):V69–V80. [PubMed: 12226588]

5. Anonymous. Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No 10, Nuremberg, October 1946-April 1949. Washington, DC: Government Printing Office; The Nuremberg Code; p. 1949-1953.

6. Wall E. Voluntary Action. Philosophia. 2001; 28(1–4):127–136.

7. Faden, RR.; Beauchamp, TL. A History and Theory of Informed Consent. New York: Oxford University Press; 1986.

8. Daugherty CK, Siegler M, Ratain MJ, Zimmer G. Learning from our patients: one participant's impact on clinical trial research and informed consent. Annals of Internal Medicine. 1997; 126:892–897. [PubMed: 9163291]

9. Logue G, Wear S. A desperate solution: autonomy and the double-blind controlled experiment. Journal of Medicine and Philosophy. 1995; 20:57–64. [PubMed: 7738459]

10. Minogue BP, Palmer-Fernandez G, Udell L, Waller BN. Individual autonomy and the double-blind controlled experiment: the case of desperate volunteers. Journal of Medicine and Philosophy. 1995; 20:43–55. [PubMed: 7738458]

11. Volume One Report. Washington, DC: Government Printing Office; 1982 October. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Making Health Care Decisions.

12. Nelson RM, Beauchamp TL, Miller VA, Reynolds WW, Ittenbach RF, Luce MF. The concept of voluntary consent. Submitted for publication.

13. Miller VA, Reynolds WW, Ittenbach RF, Luce MF, Beauchamp TL, Nelson RM. Challenges in measuring a new construct: Perception of voluntariness for research and treatment decision making. Journal of Empirical Research on Human Research Ethics. 2009; 4(3):21–31. [PubMed: 19754231]

14. Sheldon KM, Ryan RM, Reis H. What makes for a good day? Competence and autonomy in the day and in the person. Personality and Social Psychology Bulletin. 1996; 22:1270–1279.

15. Rotter JB. Generalized expectancies for internal versus external control of reinforcement. Psychological Monographs. 1966; 80:1–28. [PubMed: 5340840]

16. Wallston KA, Wallston BS, DeVellis R. Development of the multidimensional health locus of control (MHLC) scales. Health Education Monographs. 1978; 6:160–170. [PubMed: 689890]

17. Bosscher RJ, Smit JH. Confirmatory factor analysis of the general self-efficacy scale. Behavior Research and Therapy. 1998; 36:339–343.

18. Sherer M, Maddux JE, Mercadante B, Prentice-Dunn S, Jacobs B, Rogers RW. The Self-Efficacy Scale: Construction and validation. Psychological Reports. 1982; 51:663–671.

19. Bunn H, O'Connor A. Validation of client decision-making instruments in the context of psychiatry. Canadian Journal of Nursing Research. 1996; 28:13–27. [PubMed: 8997937]

20. Cranney A, O'Connor AM, Jacobsen MJ, et al. Development and pilot testing of a decision aid for postmenopausal women with osteoporosis. Patient Education and Counseling. 2002; 47:245–255. [PubMed: 12088603]

21. Gardner W, Hoge SK, Bennett N, Roth LH, Lidz CW, Monahan J, et al. Two scales for measuring patients' performance and perceptions of coercion during hospital admission. Behavioral Sciences and the Law. 1993; 20:307–321. [PubMed: 10150233]

22. O'Connor AM. Validation of a decisional conflict scale. Medical Decision Making. 1995; 15(1): 25–30. [PubMed: 7898294]

23. O'Connor AM. User Manual- Decision Self Efficacy Scale. 1995 In.

24. Lorr, M.; McNair, DM. Profile of Mood States: Bipolar Form (manual). San Diego, CA: Educational and Industrial Testing Service; 1988.

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

25. Lorr M, McNair DM, Fisher S. Evidence for bipolar mood states. Journal of Personality Assessment. 1982; 46(4):432–436. [PubMed: 7120016]
26. McNair, DM.; Heuchert, JP. Profile of Mood States: Technical update. North Tonawanda, NY: Multi-Health Systems; 2005.
27. Anderson LA, Dedrick RF. Development of the Trust in Physician Scale: A measure to assess interpersonal trust in patient-physician relationships. Psychological Reports. 1990; 67(3, Pt2): 1091–1100. [PubMed: 2084735]
28. MacCallum RC, Widaman KF, Preacher KJ, Hong S. Sample size in factor analysis: The role of model error. Multivariate Behavioral Research. 2001; 36(4)
29. Kaiser JF. An index of factorial simplicity. Psychometrika. 1974; 39(1):31–36.
30. Skinner EA. A guide to constructs of control. Journal of Personality and Social Psychology. 1996; 71(3):549–570. [PubMed: 8831161]
31. Appelbaum PS, Lidz CW, Klitzman R. Voluntariness of consent to research: A conceptual model. Hastings Center Report. 2009; 39(1):30–39. [PubMed: 19213193]
32. Siminoff LA, Fetting JH, Abeloff MD. Doctor-patient communication about breast cancer adjuvant therapy. Journal of Clinical Oncology. 1990; 7:1192–1200. [PubMed: 2671280]
33. Tabak N. Decision making in consenting to experimental cancer therapy. Cancer Nursing. 1995; 18:89–96. [PubMed: 7720055]
34. Gallo C, Perrone F, De Placido S, Giusti C. Informed versus randomised consent to clinical trials. Lancet. 1995; 346:1060–1064. [PubMed: 7564786]
35. Du Mont J, Stermac L. Research with women who have been sexually assaulted: examining informed consent. Canadian Journal of Human Sexuality. 1996; 5:185–191.
36. Faden RR, Gielen AC, Kass N, O'Campo P, Anderson J, Chaisson R, et al. Prenatal HIV antibody testing and the meaning of consent. AIDS Public Policy J. 1994; 9:151–159. [PubMed: 11654177]
37. McCrady BS, Bux DAJ. Ethical issues in informed consent with substance abusers. Journal of Consulting and Clinical Psychology. 1999; 67:186–193. [PubMed: 10224728]

Appendix

Decision-Making Control Instrument

Sometime in the last ten days, you made a decision about enrolling your child in a research intervention or protocol-based treatment. We are interested in learning more about how you made this decision. Please respond to the following items and circle the one answer that best fits your opinion about this decision.

		Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1	I was powerless in the face of this decision.	1	2	3	4	5	6
2	Someone took this decision away from me.	1	2	3	4	5	6
3	I made this decision.	1	2	3	4	5	6
4	I was passive in the face of this decision.	1	2	3	4	5	6
5	The decision about the protocol was inappropriately influenced by others.	1	2	3	4	5	6
6	I was not in control of this decision.	1	2	3	4	5	6
7	Others made this decision against my wishes.	1	2	3	4	5	6

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

		Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
8	I was not the one to choose.	1	2	3	4	5	6
9	The decision was up to me.	1	2	3	4	5	6

Scoring Instructions

1. Reverse-score all items except 9.
2. Total Score = sum of all nine items
3. Subscales:
    a. Self-Control subscale = sum of 3, 8, 9
    b. Absence of Control subscale = sum of 1, 4, 6
    c. Others' Control subscale = sum of 2, 5, 7

© The Children's Hospital of Philadelphia. For permission to use the Decision Making Control Instrument, please contact Victoria Miller, The Children's Hospital of Philadelphia, 34th St. and Civic Center Blvd., CHOP North Room 1425, Philadelphia, PA 19104. Email: millerv@email.chop.edu. Tel: 267-426-5259.

NIH-PA Author Manuscript
NIH-PA Author Manuscript
NIH-PA Author Manuscript

Table 1

Demographic and Illness Characteristics

Variable	*N* (%) or *M (SD)*
Parent age (years)	37.1 (8.1)
Parent gender (female)	162 (74%)
Parent race	
Black or African-American	46 (21%)
American Indian/Alaskan Native	1 (< 1%)
Asian	10 (5%)
White	147 (67%)
Other	14 (6%)
Unknown/ missing	1 (< 1%)
Marital status of parent	
Married/Living with Partner	163 (74%)
Single	32 (15%)
Separated	10 (5%)
Divorced	10 (5%)
Widowed	3 (1%)
Other	1 (<1%)
Parent's highest education	
Some high school	12 (6%)
Completed high school	32 (15%)
Vocational or some college	72 (33%)
College degree	56 (26%)
Some post-graduate education	12 (6%)
Professional or graduate degree	34 (16%)
Family income	
Less than $19,999	26 (12%)
$20- 39,999	39 (18%)
$40-59,999	35 (16%)
$60-79,999	40 (18%)
$80-99,999	27 (12%)
More than $100,000	49 (22%)
Unknown/ missing	3 (1%)
Child's illness	
Leukemia	65 (30%)
Lymphoma	19 (9%)
Solid tumor	91 (41%)
Unspecified cancer	9 (4%)

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Variable	*N* (%) or *M (SD)*
Congenital heart disease	24 (11%)
Other (non-cancer)	11 (5%)
Duration of illness (months)	11.4 (25.5)

NIH-PA Author Manuscript NIH-PA Author Manuscript NIH-PA Author Manuscript

Table 2

Item Descriptive Statistics for Experimental Item Pool

				Response frequencies					
Item	***M***	***SD***	***Mdn***	**1 Strongly Disagree**	**2 Disagree**	**3 Somewhat Disagree**	**4 Somewhat Agree**	**5 Agree**	**6 Strongly Agree**
1. The decision about the protocol was mine.	4.9	1.1	5.0	4	7	8	38	84	78
2. I was powerless in the face of this decision.*	4.7	1.6	5.0	16	14	18	17	58	96
3. Someone took this decision away from me.*	5.5	0.8	6.0	2	0	7	9	52	149
4. I was actively involved in this decision.	5.2	1.0	6.0	4	2	5	24	74	110
5. I made this decision.	5.0	1.2	5.0	4	7	12	30	71	95
6. The decision about the protocol was pressured by others.*	5.2	1.2	6.0	4	4	18	14	68	111
7. It didn't matter what I decided.*	5.2	1.2	6.0	7	4	10	12	68	118
8. I was not free to decide what I wanted.*	5.3	1.1	6.0	5	7	5	10	67	125
9. The decision was made by another person.*	5.0	1.3	5.0	6	10	19	9	78	96
10. I was helpless in the face of this decision.*	4.9	1.4	5.0	6	16	17	12	71	97
11. I was the one to choose.	4.8	1.3	5.0	6	14	13	35	78	73
12. The decision about the protocol was my choice.	4.8	1.2	5.0	8	8	8	44	78	73
13. I was passive in the face of this decision.*	4.7	1.4	5.0	5	24	14	22	77	77
14. I had an influence on the decision about the protocol.	4.2	1.7	5.0	21	33	18	23	67	57
15. The decision about the protocol was inappropriately influenced by others.*	5.4	0.9	6.0	2	2	7	7	85	116
16. I was not in control of this decision.*	5.0	1.3	5.0	8	10	13	10	71	107
17. I had no role in making the decision about the protocol.*	5.2	1.2	6.0	6	6	10	14	64	119
18. Others made this decision against my wishes.*	5.6	0.7	6.0	2	1	0	5	54	157
19. I was not the one to choose.*	5.2	1.2	6.0	6	9	11	6	74	113
20. Others were in control of this decision.*	4.9	1.4	5.0	5	15	22	10	64	103
21. I was able to express my point of view about the decision.	5.2	0.9	5.0	3	3	3	18	94	98
22. I was free to decide what I wanted.	5.1	1.1	5.0	4	6	10	13	90	96

Med Decis Making. Author manuscript; available in PMC 2012 September 1.

NIH-PA Author Manuscript
NIH-PA Author Manuscript
NIH-PA Author Manuscript

				Response frequencies					
Item	***M***	***SD***	***Mdn***	**1 Strongly Disagree**	**2 Disagree**	**3 Somewhat Disagree**	**4 Somewhat Agree**	**5 Agree**	**6 Strongly Agree**
23. The decision about the protocol was manipulated by others.*	5.3	0.9	6.0	0	6	6	13	79	115
24. The decision was up to me.	4.9	1.2	5.0	5	7	12	30	84	81
25. The decision was beyond my control.*	4.8	1.4	5.0	7	14	18	15	79	86
26. I was in control of this decision.	4.8	1.2	5.0	3	14	10	38	78	76
27. The decision was out of my hands.*	5.0	1.3	5.0	5	13	12	12	80	97
28. I chose whether or not to agree to the protocol.	5.2	1.1	5.0	3	6	8	19	85	98

*Item was reverse-scored prior to calculation of descriptive statistics and frequencies.

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Table 3

Factor Loadings of the Final DMCI Items

Item	Self-Control	Absence of Control	Others' Control	Uniqueness[a]
5. I made this decision.	**.82**	.08	−.01	.28
19. I was not the one to choose.*	**.76**	.03	.21	.23
24. The decision was up to me.	**.75**	.04	.05	.38
2. I was powerless in the face of this decision.*	.06	**.93**	−.14	.17
16. I was not in control of this decision.*	.36	**.44**	.16	.43
13. I was passive in the face of this decision.*	−.02	**.40**	.15	.78
18. Others made this decision against my wishes.*	.12	−.13	**.97**	.06
15. The decision about the protocol was inappropriately influenced by others.*	−.09	.16	**.46**	.73
3. Someone took this decision away from me.*	.15	.29	**.34**	.62

*Item was reverse-scored prior to factor analysis.

[a]Uniqueness refers to the proportion of an item's total variance that is not accounted for by the factors.

NIH-PA Author Manuscript
NIH-PA Author Manuscript
NIH-PA Author Manuscript

Table 4

Bivariate Correlations

Variable	*M*	*SD*	1	2	3	4	5	6	7	8
1. DMCI Total Score	46.1	7.0	-							
2. DMCI Self-Control	15.1	3.2	.80**	-						
3. DMCI Absence of Control	14.5	3.4	.88**	.51**	-					
4. DMCI Others' Control	16.6	1.9	.72**	.52**	.52**	-				
5. POMS-Bi PA (Composed/Anxious)	41.8	10.4	.15	.09	.16	.09	-			
6. POMS-Bi PD (Confident/Unsure)	45.5	9.4	.27**	.21*	.25*	.23*	.76**	-		
7. POMS-Bi PF (Clearheaded/Confused)	45.0	9.3	.32**	.22*	.31**	.31**	.76**	.80**	-	
8. Trust in Physician Scale	45.8	6.0	.39**	.43**	.22*	.47**	.06	.24*	.21*	-
9. Decision Self-Efficacy Scale	86.7	13.3	.24*	.25*	.16	.25*	.13	.27**	.25*	.28**

Note. Correlations are based on Spearman-rho.

Abbreviations: DMCI= *Decision Making Control Instrument*; POMS-Bi= *Profile of Mood States, Bipolar*

* p <.002,

** p< .0001

Med Decis Making. Author manuscript; available in PMC 2012 September 1.