Relationship of External Influence to Parental Distress in Decision Making Regarding Children with a Life-Threatening Illness

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Objective To examine the relationship of external influence to parental distress when making a decision about research or treatment for a child with a life-threatening illness and to test potential moderators of this relationship. **Methods** Parents ($n = 219$) who made a decision about research or treatment for a child completed measures of external influence, distress, decision-making preference, and coping. **Results** More external influence was associated with more hostility, uncertainty, and confusion. Decision-making preference and coping style moderated the relationship between external influence and distress: More external influence was associated with more distress when decision-making preference was low and task-focused coping was high. **Conclusions** External influence appears to be related to distress in parents making research and treatment decisions for children with life-threatening illnesses. However, it is important to consider parent characteristics, such as decision-making preference and coping style, when examining the effects of contextual factors on distress during decision making.

Key words decision making; distress; emotion; ethical issues; external influence; informed consent.

Empirical research related to informed consent for research and treatment decisions has generated increasing attention in recent years. This increase coincides with the move from paternalism to patient autonomy as the guiding principle of the clinician–patient relationship (Ende, Kazis, Ash, & Moskowitz, 1989). Prior research related to informed consent has focused on the cognitive aspects of decision making (e.g., decisional capacity, understanding), with less attention paid to the emotional context and consequences of decisions. While patient autonomy is an important policy goal and ethical imperative, it is also essential to recognize that decisions can be burdensome and distressing, especially when uncertainty is high and the potential outcomes are serious. The emotional strain of decision making may be particularly challenging for parents making medical decisions (i.e., informed consent) for their children with life-threatening illnesses (Benedict, Simpson, & Fernandez, 2007; Pyke-Grimm, Stewart, Kelly, & Degner, 2006). In prior qualitative research, parents of children with cancer reported feeling shocked and overwhelmed, which they perceived as interfering with their ability to participate in decision-making about treatment (Pyke-Grimm et al., 2006) or clinical trial enrollment (Kupst, Patenaude, Walco, & Sterling, 2003; Levi et al., 2000).

In this context, clinicians and researchers must balance respect for autonomy with another important ethical principle, nonmaleficence. Nonmaleficence requires that we do not inflict harm, which can include threats to both physical and psychological interests (Beauchamp & Childress, 2001). Research is needed to understand for whom and under what circumstances decisions are related

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to more or less distress, so that the informed consent process can be shaped depending on individual needs and circumstances (Fisher, 2003; Jahng, Martin, Golin, & DiMatteo, 2005), and, ideally, distress can be mitigated while autonomy is maintained.

A number of factors may be related to emotional responses to decision making about research or treatment in medical settings. One such factor is the extent to which the decision maker perceives the presence of external influences from other individuals (e.g., physician, spouse, other family member, community members). Parents making medical decisions for their children may experience unique pressures (Gagnon & Recklitis, 2003), especially because the involved parties may disagree as to what is in the best interest of the child. Prior research suggests that in the context of informed consent, parents feel pressure to concur with the proposed treatment plan (Pyke-Grimm et al., 2006) or perceive that they have few or no choices with respect to treatment decisions (Benedict et al., 2007; Hinds et al., 2000) or clinical-trial enrollment (Levi et al., 2000). In their ethical analysis of the principle of respect for autonomy, Beauchamp and Childress (2001) focus on influence as encompassing persuasion, manipulation, and coercion. Not all influences are necessarily negative or ethically problematic, and some influences may actually be helpful, by providing the decision-maker with needed support or guidance. However, based on the stress and coping theory posited by Folkman (1984), one might hypothesize that some influences increase distress by distracting the individual from decision making, increasing uncertainty, or taxing the decision maker's coping resources. The relationship of external influence to distress may vary depending on a variety of factors, including individual characteristics. Two such characteristics are decision-making preferences and coping style.

Decision-making preferences are important, because they are likely to shape how the individual appraises and responds to the decision and to attempts by others to influence the decision. Parents vary in the extent to which they desire decision-making autonomy (Gagnon & Recklitis, 2003; Pyke-Grimm, Degner, Small, & Mueller, 1999; Tait, Voepel-Lewis, Munro, & Malviya, 2001), and some may benefit more than others from autonomy (Krantz, Baum, & Wideman, 1980). Prior research suggests that outcomes (e.g., satisfaction, adherence, adjustment) are better when the situation matches the individual's expectations for control (see Krantz et al., 1980; Tait et al., 2001). Results such as these suggest that there are potential benefits to shaping the clinical interaction in a way that matches the individual's preferred style, rather than advocating for patient autonomy regardless of preference (Ende et al., 1989). We might hypothesize that individuals with greater preference for decision-making autonomy would experience external influences as more distressing compared to individuals with a low preference for autonomy, who may actually welcome such influence. Conversely, we might hypothesize that individuals with a low preference for decision-making autonomy would experience external influences as more distressing because of a greater need to perceive interactions with others as benign rather than persuasive or coercive.

An individual's coping style is also relevant to decision making, because it is likely to determine how the decision maker manages the information, context, and emotions related to the decision (Luce, 2005). This is particularly true in high-stakes medical decisions where distress is pervasive and hence coping styles are likely to come into play. In addition, coping style has been identified as a correlate and predictor of distress and adjustment in parents of children with chronic or life-threatening illnesses (Kronenberger, Carter, Morrow, Stewart, & Sender, 1998; Phipps, Dunavant, Lensing, & Rai, 2005; Timko, Stovel, & Moos, 1992). Researchers have identified three general coping styles: task-focused, emotion-focused, and avoidance (Endler, Parker, & Butcher, 1993). Task-focused coping is defined by attempts to alter the situation through direct action, versus limiting the emotional impact of the situation (emotion-focused coping) or distracting oneself from the situation (avoidance coping) (Endler et al., 1993). A task-focused individual is likely to actively engage in the decision by seeking information, setting priorities, and considering different courses of action. Efforts by others to influence the decision may be associated with distress, because the task-focused coper has a need to maintain an active and engaged approach to the situation.

The purpose of this cross-sectional study was to examine the relationship of external influence to distress in parents making decisions about research protocols and non-research treatment protocols for their children with life-threatening illnesses (i.e., in the settings of oncology and intensive care). Both types of decisions had to do with interventions for the child, involved a signed consent form, and occurred in the context of uncertainty, complex information, time pressure, and emotional intensity. While prior research has documented that parents facing these types of decisions can experience high levels of distress (Benedict et al., 2007; Kupst et al., 2003; Levi et al., 2000; Pyke-Grimm et al., 2006), the present study adds to this body of literature by seeking to identify a potential contributor to such distress, perceptions of external influence, and individual characteristics that may make a parent more or less susceptible to distress in the face of such influence. We expected that more external influence would be associated with more distress in five domains: anxiety, hostility, depression, uncertainty, and confusion (Hypothesis 1). We also hypothesized that the relationship of external influence to distress would be moderated by individual traits regarding decision-making preferences (Hypothesis 2) and by ways of coping with major stressors (Hypothesis 3). The rationale for this prediction is that external influences will be experienced as potentially encroaching on the decision process or complicating emotional regulation efforts, by becoming a stressor and/or by interfering with efforts to cope with stressors inherent in the situation.

We predicted that decision-making preference would be an important moderator because this characteristic is directly relevant to the interaction of the decision maker with one particular potential source of external influence, namely physicians, during decision making. Two directions seem possible: (i) parents with high preference for decision-making involvement may experience external influence as more distressing because these parents may be more reactive to any encroachment on their own autonomy, or conversely, (ii) parents with low preference for decision-making involvement may find external influence more distressing because they are particularly reliant on receiving appropriate counsel from others (here, expert physicians) and, hence, may be sensitive to perceptions of inappropriate influence by others. We also predicted that more external influence would be related to more distress for those with high task-focused coping, compared to parents with low task-focused coping, because this coping style reflects a desire to manage one's own distress by maintaining control over the relevant stressful situation. Such a desire should be inconsistent with any perceived encroachment by others.

Method

Recruitment

This analysis is based on the dataset for a study that was designed to develop a measure of voluntariness in parents making decisions for their children with life-threatening illnesses (Miller et al., 2009; Miller et al., 2011). The purpose of that study was to address the gap in the empirical literature related to informed consent, which has largely ignored the voluntary nature of consent. Participants were recruited from January 2007 through June 2008 at an urban, tertiary care pediatric hospital in the northeastern United States. Eligibility requirements included that the participant was the parent or legal guardian of a child with a life-threatening illness, identified from the clinical settings of oncology, neuro-oncology, bone marrow transplant, and cardiac and pediatric intensive care and that he or she was involved in making one of two types of decisions for the child within the past 10 days. The first had to do with whether or not to enroll the child in a research protocol. The research protocols all involved interventions related to the child's illness and included studies testing new drugs, adjusting the standard of care (e.g., clinical trials in oncology), or comparing two different devices (e.g., different kinds of shunts) or routes of administration for a medication, among others. The second type of decision had to do with whether or not to consent to a non-research treatment protocol for the child; these decisions involved consenting to standard care for the treatment of cancer. Only one parent per child was eligible to participate.

Two hundred and sixty-six parents were invited to participate in the study; 16 (6.0%) declined and 250 (94.0%) agreed. Of those who agreed, 231 (92.4%) returned the questionnaires and 19 (7.6%) did not. Twelve of those who returned the questionnaires were not included in the analysis because they did not complete them within ten days of the decision ($n = 6$) or because items from the primary measure (not reported here) were missing ($n = 6$). The final sample for this analysis consisted of 219 parents. The final sample did not differ in terms of parent gender ($X^2_{[1]} = 2.63$, $p = .105$) or medical unit ($X^2_{[3]} = 4.73$, $p = .193$) when compared to the 47 parents who declined, did not return the questionnaires, or were removed from the analysis.

Procedures

The study was approved by the hospital's institutional review board. Potential participants were approached during an outpatient clinic visit or on an inpatient unit, after they made a decision about a research protocol or non-research treatment protocol for the child. To address concerns about the potential vulnerability of parents who had just made such a decision, study personnel did not approach parents who were having a particularly difficult time according to the floor nurse or other hospital staff. If both parents were present, the parents decided which parent would participate. Study personnel first reviewed the components of informed consent, which included mention of the fact that answering the research questions could be distressing, that their participation was voluntary, and that they could withdraw from the study at any time. Participants then provided verbal consent, and study personnel described the questionnaires and reviewed the instructions. Participants received $20 for their time and effort after completing the questionnaires. Although it was never necessary, study personnel were prepared to refer parents to the physician or research investigator if they expressed second thoughts about the target decision during participation in our study.

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).

External Influence

External influence was assessed with six parent-report items that were developed for the present study (Table I). Items were based on conceptual literature related to the voluntariness of consent (Faden & Beauchamp, 1986; Wall, 2001) and assess influence, persuasion, pressure, manipulation, and coercion. The items assess whether ''others'' tried to influence the decision-maker in various ways and, therefore, do not differentiate between sources of influence (e.g., spouse vs., researcher). Items were reviewed by a multidisciplinary group that included individuals from the fields of philosophy/bioethics, medicine, statistics/methodology, psychology, and decision science. The response format for all items was a 6-point Likert scale ranging from *strongly disagree* (1) to *strongly agree* (6). Items were averaged to yield a score for External Influence; Cronbach's alpha was .92. Higher scores indicate greater external influence. In the present sample, External Influence scores were negatively associated with perceptions of voluntariness, providing support for the validity of this measure.

Distress

Distress was measured with the *Profile of Mood States-Bipolar* (POMS-Bi) (Lorr & McNair, 1988), which yields six scales: Composed/Anxious, Agreeable/Hostile, Elated/Depressed, Confident/Unsure, Energetic/Tired, and Clearheaded/Confused. Lower scores indicate more negative affect. The form requires the administrator to choose among three different time frames that the respondent will address: the past week, including today; right now; or another specified time frame. For this study participants retroactively rated their affect, considering how they felt at the time they made the target decision. The POMS-Bi was chosen for this study because of its versatility with respect to time-frame and the range from positive to negative affective states. Internal consistency values ranged from .84 to .95 in prior research, and test–retest correlations ranged from .43 to .74. The validity of the POMS-Bi has been supported by prior research (McNair & Heuchert, 2005). Furthermore, studies have found convergence between daily ratings of mood and retrospective ratings (Barrett, 1997; Watson & Tellegen, 1999). We analyzed all of the scales except Energetic/Tired, which was not related to our hypotheses.

Decision-Making Preference

The Autonomy Preference Index (API) is a 23-item scale consisting of two subscales: Decision Making and Information Seeking (Ende et al., 1989; Nease & Brooks, 1995). The Decision-Making Scale includes six general items and nine items related to three clinical vignettes, reflecting different levels of illness severity. Higher scores reflect a higher preference for decision-making involvement. We adapted the instrument so that it refers to decisions about the respondent's child's health care. One of the scenarios was changed so that it was relevant to pediatrics (i.e., reference to ''myocardial infarction'' changed to ''asthma attack''). Prior research has demonstrated high test–retest reliability for the subscales (Nease & Brooks, 1995). Cronbach's alpha for the Decision-Making Scale was .74 in the present sample. Evidence for the validity of the Decision-Making scale was demonstrated in prior research by associations with a global item assessing preference for decision-making control and by the finding that adults with diabetes who were highly motivated to perform

Table I. *External Influence Items: Descriptive Statistics and Response Frequencies*

Item: Others tried to...	*M*	*SD*	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
...influence me to make a particular decision.	1.97	1.22	99	77	11	17	13	2
...persuade me to make a particular decision.	1.79	1.02	104	86	10	11	7	1
...manipulate me into making a particular decision.	1.64	0.94	121	75	12	5	4	2
...pressure me about what to decide.	1.69	0.99	116	78	10	8	5	2
...influence my decision inappropriately.	1.48	0.73	131	80	3	1	4	0
...coerce me into making a particular decision.	1.63	0.90	118	82	8	4	7	0

Note. Cronbach's $\alpha = .92$.

self-care scored higher on the Decision-Making scale compared to the general study population (Ende et al., 1989).

Task-Focused Coping

The Coping Inventory for Stressful Situations (CISS) (Endler & Parker, 1990) contains 48 items measuring the three major coping styles of task-focused, emotion-focused, and avoidance. Higher scores indicate higher levels of that style. Cronbach's alpha for the Task subscale was .92 in prior research, and the validity of the measure was supported by associations with measures of personality and emotional distress (McWilliams, Cox, & Enns, 2003).

Data Analytic Plan

We ran Spearman-rho correlations and *t*-tests to determine if demographic variables (parent age, marital status, race, education, income, child age or duration of illness) or decision type were associated with external influence and distress. We ran Spearman-rho correlations to test the hypothesis that external influence would be associated with distress (Hypothesis 1). For the regressions testing the hypothesis that decision-making preference (Hypothesis 2) and coping style (Hypothesis 3) would moderate the relationship between external influence and distress, we first centered the variables of the interactions terms (i.e., the predictor and the moderator), to reduce multicollinearity problems and to facilitate post hoc testing of the simple slopes. This was done by subtracting the sample mean for the variable from all individual scores so that the mean of the variable became zero. Next, we ran hierarchical linear regressions. Demographic and decision variables that were associated with the dependent variables were entered in the first step. Main effects were entered next, followed by the interaction term. We ran separate regressions for the five POMS-Bi scales (Composed/Anxious, Agreeable/Hostile, Elated/Depressed, Confident/Unsure, and Clearheaded/Confused). The first five regressions tested the hypothesis that decision-making preference would moderate the relationship between external influence and distress (Hypothesis 2). The second five regressions tested the hypothesis that task coping would moderate the relationship between external influence and distress (Hypothesis 3). If the interaction term for a regression was significant, post hoc probing of the interaction involved the generation of two new regressions to test the relationship between the predictor and the dependent variable at one standard deviation below the mean of the moderator and one standard deviation above the mean of the moderator (Schubert & Jacoby, accessed March 31, 2010). An examination of the standardized and unstandardized betas and *t*-tests for these regressions allowed us to determine which simple slopes were significantly different from zero and which were not and, therefore, to determine the direction of the moderating effect (Holmbeck, 2002).

Results

Participants

The sample included 219 parents who made one of the two target decisions described above. The mean age of parents was 37.10 years ($SD = 8.10$), and they were 74% female. Sixty-seven percent of the sample was white, 21% Black/African-American, 6% other, 5% Asian, and <1% American Indian or unknown/missing. The majority (74%) of parents were married or living with a partner and almost half (48%) had a college degree or greater. The sample was evenly distributed in terms of income. In terms of the child's illness, 84% of parents had a child with cancer, 11% had a child with congenital heart disease, and 5% had a child with another serious illness. The mean duration since the child's diagnosis of the illness was 11.4 months ($SD = 25.5$).

Setting and Decision Characteristics

The mean duration from making the target decision to participating in this study was 4.2 days ($SD = 2.6$). For 62.1% ($n = 136$) of parents, the target decision had to do with enrolling the child in a research protocol, while 32.9% ($n = 72$) of parents made a decision about a non-research treatment protocol (data missing for 5% of parents). For the parents who made a decision about a research protocol, 128 (94.1%) agreed to enroll the child in the research, while 8 (5.9%) declined the research protocol and chose standard treatment. All of the parents who made a decision about a non-research treatment protocol agreed to the treatment.

Relationship of Demographic and Decision Variables to External Influence and Distress

External influence did not vary according to parent age, race, education, or income, child age or duration of illness, or type of decision. Parents who were married perceived greater external influence than those who were not married [$t(216) = 1.98$, $p < .05$]. There were no differences in distress according to parent race, marital status, or income. Older parent age and older child age were associated with scores on the Composed/Anxious scale of the POMS-Bi, indicating more composed affect for older parents ($r = .15$, $p < .03$) and for parents of older children ($r = .13$, $p = .05$). Higher parent education was associated with higher scores on the Clearheaded/Confused scale ($r = .17$, $p < .02$), indicating more clearheaded affect. Longer duration of the child's illness was associated with more positive affect on all five POMS-Bi scales, with *r*'s ranging from .21 to .36 (*p*'s < .01). Finally, parents who made a research decision had higher scores on the Elated/Depressed scale of the POMS-Bi, indicating more positive affect, compared to parents who made a treatment decision [$t(205) = 2.66$, $p < .01$].

Hypothesis 1: Relationship between External Influence and Distress

Spearman-rho correlations for the primary variables are presented in Table II. More external influence was associated with lower scores on the Agreeable/Hostile ($r = -.22$, $p = .001$), Confident/Unsure ($r = -.23$, $p = .001$), and Clearheaded/Confused ($r = -.28$, $p < .0001$) scales of the POMS-Bi, indicating that parents who perceived more external influence on their decision felt more hostile, unsure, and confused at the time of the decision. External influence was not associated with the Composed/Anxious or Elated/Depressed scales of the POMS-Bi.

Hypothesis 2: Decision-Making Preference as a Moderator of the Relationship between External Influence and Distress

Five regressions were run to test this hypothesis, with each regression testing one of the five POMS-BI scales as the dependent variable. After controlling for demographic and decision variables, two of the five regressions had significant interactions between external influence and decision-making preference, demonstrating that decision-making preference moderated the relationship of external influence to Agreeable/Hostile and Confident/Unsure (Table III). Post hoc probing of the interactions showed that external influence was negatively associated with Agreeable/Hostile and Confident/Unsure when decision-making preference was low (β's ranging from −.32 to −.34), but there was no relationship when decision-making preference was high. In other words, parents who perceived more external influence experienced more hostility and uncertainty if they had low preference for decision-making autonomy, compared to parents with high preference for decision-making autonomy.

Hypothesis 3: Coping Style as a Moderator of the Relationship between External Influence and Distress

Similar to Hypothesis 2, five regressions were run to test this hypothesis, with each regression testing one of the five POMS-BI scales as the dependent variable. After controlling for demographic variables, three of the five regressions had significant interactions between external influence and task coping, demonstrating that task coping moderated the relationship of external influence to Composed/Anxious, Confident/Unsure, and Clearheaded/Confused (Table III). Post hoc probing of the interactions showed that external influence was negatively associated with Anxious/Composed, Confident/Unsure, and Clearheaded/Confused when task coping was high (β's ranging from −.26 to −.37), but there was no relationship when task coping was low. In other words, parents who perceived more external influence experienced more anxiety, uncertainty, and confusion if they were high in task coping, compared to parents who were low in task coping.

Table II. *Intercorrelations, Means, and Standard Deviations for Primary Variables*

			Correlation[a]						
Variable	*M*	*SD*	1	2	3	4	5	6	7
1. External influence	1.70	0.82	–						
2. POMS-Bi PA: Composed/Anxious	41.79	10.35	−.11	–					
3. POMS-Bi PB: Agreeable/Hostile	40.70	10.01	−.22*	.58**	–				
4. POMS-Bi PC: Elated/Depressed	37.72	8.79	−.13	.73**	.55**	–			
5. POMS-Bi PD: Confident/Unsure	45.51	9.38	−.23*	.76**	.55**	.67**	–		
6. POMS-Bi PF: Clearheaded/Confused	45.01	9.34	−.28**	.76**	.62**	.63**	.80**	–	
7. CISS: Task coping	54.51	10.32	−.12	.21*	.28**	.10	.27**	.30**	–
8. API: Decision-making preference	44.08	10.38	.07	.06	−.01	.01	.06	.05	−.02

Note. Correlations are based on Spearman-rho. POMS-Bi: Profile of Mood States-Bipolar; CISS: Coping Inventory for Stressful Situations; API: Autonomy Preference Index.

[a] The pattern of correlations was similar when the sample was restricted to mothers ($n = 162$) and to parents making decisions about research ($n = 136$).

$*p < .01$, $**p < .0001$.

Table III. *Significant Multiple Regression Results for Interactions Between External Influence and the Moderator Variables as Predictors of Parent Distress at the Time of the Decision*

				95% CI for *B*	
Step and variable	ΔR^2	*B*	β	Lower bound	Upper bound
Agreeable/Hostile					
1. Duration of illness	.06	0.003	.24***	0.001	0.01
2. External influence	.05	−2.57	−.21**	−4.11	−1.02
3. Decision preference	.001	−0.03	-.04	−0.16	0.09
4. External influence × decision preference[a]	.02	0.15	.14*	0.01	0.28
Confident/Unsure					
1. Duration of illness	.07	0.003	.25***	0.001	0.01
2. External influence	.04	−2.06	−.18**	−3.52	−0.60
3. Decision preference	.001	0.02	.02	−0.101	0.14
4. External influence × decision preference[a]	.02	0.15	.15*	0.02	0.28
Composed/Anxious					
1. Child age		0.06	.04	−0.24	0.37
Parent age		0.04	.03	−0.18	0.26
Duration of illness	.08	0.003	.24***	0.002	0.01
2. External influence	.01	−1.01	−.08	−2.65	0.63
3. Task coping	.04	0.20	.20**	0.07	0.33
4. External influence × task coping	.03	−0.22	−.19**	−0.37	−0.07
Confident/Unsure					
1. Duration of illness	.06	0.003	.23***	0.001	0.004
2. External influence	.04	−2.15	−.19**	−3.58	−0.73
3. Task coping	.07	0.23	.26***	0.12	0.34
4. External influence × task coping[b]	.03	−0.18	−.17*	−0.31	−0.04
Clearheaded/Confused					
1. Parent education		0.63	.09	−0.18	1.45
Duration of illness	.11	0.004	.30***	0.002	0.01
2. External influence	.05	−2.42	−.22**	−3.78	−1.06
3. Task coping	.08	0.25	.28***	0.14	0.36
4. External influence × task coping[b]	.03	−0.17	−.16*	−0.30	−0.04

Note. *$p < .05$, **$p < .01$, ***$p < .0001$.

[a] These interactions were no longer significant when restricting the sample to mothers ($n = 162$).

[b] These interactions were no longer significant when restricting the sample to research decisions ($n = 136$). In addition, one interaction that was not significant with the combined sample became significant when restricting the sample to research decisions: decision preference as a moderator between external influence and Clearheaded/Confused ($\beta = 0.17$, $p < .04$). *Post-hoc* probing indicated that parents who perceived more external influence experienced more confusion if they had low preference for decision-making autonomy ($\beta = -.41$, $p < .0001$), but not if they had high preference for decision-making autonomy.

Discussion

This research addresses a gap in prior research by examining a potential correlate of parental distress during decision making, external influence, and two individual characteristics that may moderate this relationship. In sum, individual characteristics were of importance in this high-stakes medical encounter where distress is of obvious concern. Perceptions of more external influence were associated with more hostility, uncertainty, and confusion in parents making decisions about research or treatment for their children with life-threatening illnesses. However, these relationships were moderated by decision-making preferences and coping style. Specifically, perceptions of more external influence were associated with more distress when decision-making preference was low and when task coping was high.

These findings highlight the importance of parent characteristics when examining the relationship of contextual factors to distress during decision making. We found evidence for two factors that increase risk of susceptibility to the negative association of perceived external influence with distress. First, individuals who perceive external influence are more likely to feel uncertain and hostile if they are also low in their desire to make autonomous medical decisions for the child. This finding suggests that these individuals are emotionally sensitive to influences from others, perhaps because they feel unable to participate in the decision or ill-equipped to withstand influence from others. Second, individuals who perceive external influence are more likely to feel uncertain, confused, and anxious if they also have a task-focused coping style. This is, perhaps, because efforts by others to influence the decision may interfere with the task-focused decision maker's ability to engage in their preferred coping strategy, which may derail coping efforts and result in more distress. In addition, external influence may itself require coping resources to manage and, consequently, may interfere with successful coping efforts.

Attention to the specific emotions that are moderated by decision-making preferences and coping style may be instructive. External influence was associated with more hostile, uncertain, and confused feelings. The relationship between external influence and hostile and uncertain feelings was moderated by decision-making preferences, while the relationship between external influence and anxious, uncertain, and confused feelings was moderated by task-focused coping. It seems logical that decision-making preference, which is concerned with interpersonal interactions in decision making, should moderate hostility (which is often other-directed) while task coping, which involves preferences regarding the management of one's own emotional states, should moderate anxiety (which is more generalized and not necessarily other-directed). It is also notable that uncertainty, which lies conceptually at the intersection of emotional and cognitive reactions to decisions, was the only measured emotional state to show influence of both moderators.

Like prior research with similar samples (e.g., Gagnon & Recklitis, 2003; Pyke-Grimm et al., 1999; Tait et al., 2001), the range of scores for decision-making preference suggests that the parents in our study did not rate themselves as high in decision-making preference. Scores ranged from low to moderate, with few or no parents desiring to make health care decisions on their own. Consequently, the range of scores reflects, on the low end, those who prefer that the physician take the lead in making decisions about the child's medical care (and, hence, who may be particularly sensitive to the quality of interpersonal interactions regarding decision making) and, on the high end, those who desire physician input but are relatively more willing to take an active role in the decision (and, hence, who may be more able to withstand the effects of perceived external influence).

In our sample, we included parents making decisions about enrolling in a research protocol, as well as parents making decisions about protocol-based treatments. These decisions share certain features in our context, such as interventions for a life-threatening illness, uncertainty, complex information, time pressure, and emotional intensity, but they also have important differences. For example, decisions about research participation may involve different motivations to consent (e.g., altruism; concern that the child's medical care will be affected negatively if the parents decline), have more institutional oversight, may entail concepts that are particularly difficult for parents to understand, such as randomization (Kodish et al., 2004), and may bring additional sources of external influence to the decision-making situation, such as study coordinators and clinician–investigators. Exploratory analyses showed that the pattern of findings in the present study was similar for the combined sample and for the sub-sample of parents making research decisions (see footnote in Tables II and III), suggesting that perceptions of external influence and distress operate similarly in research and treatment contexts. However, this study was not designed to test this hypothesis. Additional research is needed to explore more fully the effects of decision features, such as whether the decision is about research or treatment, on perceptions of external influence and distress.

From an ethical standpoint, it is important not only to promote parental autonomy, but also to safeguard against the potential negative effects of decision making in a stressful medical environment. While coercive or manipulative behaviors of researchers or clinicians are normatively wrong, the present findings suggest that they may also increase parental distress. The possibility that parents are experiencing such influences should be explored and addressed during informed consent, so that the principle of nonmaleficence can be realized.

This study has several limitations. First, our measure of external influence does not distinguish between sources of influence, which may have different relationships with distress. We also measured *perceptions* of external influence, which may or may not coincide with *actual* influences that occur in the context of research and treatment decision making. Furthermore, the items were developed for this study and have not been subject to rigorous psychometric and validity testing. However, the high Cronbach's α and the finding that the measure operated in relation to other variables as expected support its use. Second, data from this study are cross-sectional, so we cannot determine the causal direction of effects between the tested variables. While we assume that external influences lead to greater distress, it is equally plausible that those who are more distressed perceive the situation more negatively and, hence, view the decision as being manipulated or coerced by others. Third, the sample was primarily female and Caucasian. There may be important differences in how the variables operate in male samples or in samples with greater minority representation. Similarly, the sample may be biased in that those who agreed to participate in a study about decision making may differ in important ways from those who chose not to participate. Fourth, we did not document any features of the research protocols or the non-research treatment protocols, which prevented us from describing the context of decision making in more detail and testing whether characteristics of the protocols were related to our primary variables. Finally, most participants in our sample did not perceive high levels of external influence. Although this did not impede our ability to find significant associations between external influence and distress, it is possible that the pattern of findings would be different if external influence scores were more evenly distributed.

There are several clinical implications of these findings, with respect to ameliorating the distress that may result from the process of informed consent for parents in high-stakes medical situations. Although a certain level of distress may be inevitable, high levels of distress may interfere with decision making and thus, should be addressed. First, it may be useful for researchers or clinicians to engage parents in a discussion about their experience of the decision-making process, either during or immediately after informed consent. This discussion could include attention to sources of influence and their potential impact on the decision. This process may alleviate some of the effects of external influence on distress level, but it should be approached in such a way that the parent does not experience increased regret, decisional conflict, or distress. Second, researchers and clinicians should be aware that parents who prefer a passive role in decision making or have a task-focused coping style will be susceptible to distress in the face of external influence. These parents may benefit when clinicians or researchers tailor their communication to the parent's preferred coping and decision-making styles, which may, in turn, mitigate their distress. Additional research is needed to determine how to identify such parents in real-world settings and effective approaches for tailoring communication to parental characteristics. Finally, although demographic effects on distress were not a primary focus of the study, it is instructive, and not surprising, that parents of children with a shorter duration of illness experienced more distress. These and other parents may benefit from an informed consent process that more closely attends to their emotional state, via providing more time for decision making, exploring emotional reactions to the child's diagnosis, and facilitating a sense of control where appropriate. Training clinicians and researchers about how to conduct the process of informed consent, including fostering an emotionally supportive environment, is one promising model of intervention (Yap et al., 2009).

Areas for future research include examining the relationship between external influence and distress in different contexts and populations. For example, additional research is needed in the context of lower-stakes medical decisions (e.g., nontherapeutic, minimal risk research) and with parents from racially and ethnically diverse backgrounds, who may experience external influences differently than our primarily Caucasian sample of parents. In addition, research in this area should examine decision-specific factors that may relate to perceptions of external influence and distress, such as the perceived importance of the decision, whether the decision has to do with research or treatment, and the perceived risks and benefits related to the decision. Future research should also seek to identify additional moderators of the relationship between external influence and distress, such as trait anxiety, trust in physicians, and illness severity. Such research may enhance our ability to tailor informed consent to the needs and characteristics of individual parents. Finally, additional research is needed to improve the measurement of external influence, by developing measures that differentiate between sources (e.g., spouse, clinician or researcher, family members) and types (e.g., coercion, manipulation, persuasion) of influence and consider the effects of nonperson influences, such as the Internet and incentives for research participation. These influences may be experienced by parents differently; for example, influence from a spouse may be benign, while influence from a researcher or extended family member may be difficult to manage. A more comprehensive approach to the measurement of external influence will enable us to tease out these effects more carefully and shape intervention strategies in a more targeted way.

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