J Clin Psychol Med Settings (2014) 21:165–172
DOI 10.1007/s10880-014-9392-5

Child Perceptions of Parental Care and Overprotection in Children with Cancer and Healthy Children

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Abstract The primary aims of this study were to: (a) examine child perceptions of overprotection; and (b) explore how these perceptions relate to child health and adjustment. Children with a prior diagnosis of cancer ($n = 205$) and children without a history of serious illness ($n = 76$) reported on parental overprotective and caring behaviors. Children with cancer were recruited from one of four strata based on the elapsed time since their cancer diagnosis (1–6 months; 6–24 months; 2–5 years; >5 years) Children also reported on symptoms of depression, anxiety, and posttraumatic stress. Children with cancer did not differ from healthy children in their perceptions of parental care or overprotection. Child distress was more strongly related to perceptions of care and overprotection than child's health status. Children with cancer do not report their parents approach to care and protection differently than children without a cancer history. These findings mirror prior research examining parental perceptions of overprotection and suggest that, despite the challenges of parenting a child with serious illness, parental protection is not significantly altered.

Keywords Pediatric cancer · Parenting · Overprotection · Depression · Anxiety · Posttraumatic stress

Introduction

A child's chronic or life threatening illness can be a challenge for parenting and leave parents feeling that their child is particularly vulnerable. Perceptions of child vulnerability can, in turn, impede healthy parenting practices (Boyce, 1992). In particular, the heightened fear and anxiety prompted by a child's life threatening illness can induce parenting practices that are deemed overprotective (Thomasgard & Metz, 1996). Parental overprotection, typically characterized as excessive parenting that is inappropriate given the child's developmental stage (Thomasgard, Metz, Edelbrock, & Shonkoff, 1995), has been associated with many negative psychosocial outcomes including child depression (Stein et al., 2000), anxiety (Spada et al., 2012), a decrease in autonomy (Holmbeck et al., 2002), and posttraumatic stress symptoms (PTSS) following a traumatic event (Bokszczanin, 2008). This line of research has underscored the importance of examining factors that may foster overprotective parenting behaviors.

A major determinant of overprotective parenting practices relates to parental perceptions of child vulnerability, which, in turn, has been linked to a child's life-threatening illness (Boyce, 1992; Thomasgard & Metz, 1996). This has led some to suggest that parents of children who have been diagnosed with a serious illness, like cancer, are more likely to perceive their child as being vulnerable, and thus, employ parenting strategies that are deemed overprotective (Hullmann, Wolfe-Christensen, Meyer, McNal-Knapp, & Mullins, 2010; Thomasgard & Metz, 1993).

Research examining parental overprotection from the perspective of the parent has found that parents of children with cancer are not different from parents of healthy children in overprotective parenting practices (Davies, Noll, Destefano, Bukowski, & Kulkarnie, 1991). Differences in

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parental overprotection have also not been established across other types of illness groups (e.g., asthma, Type 1 diabetes, and cystic fibrosis; Hullmann et al., 2010). This research would suggest that parents of children with cancer and other serious illnesses do not differ from other parents in their reports of parental overprotection practices. On the other hand, parents of children with cancer may be underreporting overprotective parenting practices, or may believe these behaviors are appropriate given the context of their child's illness, and not overprotective. This emphasizes the need to consider overprotective parenting behaviors from other informants, particularly children, as these behaviors are consistently linked to their psychological health (Bokszczanin, 2008; Holmbeck et al., 2002; Spada et al., 2012; Stein et al., 2000).

To our knowledge, the only study that has examined parental overprotection from the perspective of the seriously ill child, found that children with cancer reported significantly higher levels of parental overprotection than did children with a history of abuse and healthy controls (Pelcovitz et al., 1998).This is at odds with studies based on parent report, and may suggest a natural discrepancy in parent–child reports of parenting behavior. However, the Pelcovitz et al. (1998) study was quite small (cancer group $n = 23$) and the sample was atypical, in that a high proportion of children in the cancer group (35 %) met criteria for post-traumatic stress disorder (PTSD). Thus, it is not clear from this small sample whether parental overprotection was associated with the cancer diagnosis or if parental overprotection was associated with the child's level of distress.

Prior research has demonstrated a relation between a child's distress and their perceptions of overprotective parenting practices. Not surprisingly, developmental research has indicated that parental overprotection leads to child distress, including PTSS (Bokszczanin, 2008). Given the transactional nature between children's difficulties and parenting behaviors (Bagner, Pettie, Lewinsohn, Seeley, & Jaccard, 2012; Gross, Shaw, Burwell, & Nagin, 2009), it is not surprising that other research has documented that child internalizing distress can influence parenting. For example, parents of anxious children were more likely to report overprotective parenting behaviors with their anxious children than a non-anxious sibling (Hudson & Rapee, 2005), suggesting that parents may be altering strategies to suit the needs of the child.

Given the limited studies regarding parental care and overprotection within the pediatric cancer literature, the relation of parenting practices to a child's life threatening illness remains unclear. It appears that child distress may be an important lens from which children perceive parenting practices (e.g., Bokszczanin, 2008; Pelcovitz et al., 1998; Spada et al., 2012; Stein et al., 2000). Thus, the goal for the present study was to examine children's perceptions of parental care and overprotection in a population of children with cancer and a population of children without a history of a serious illness. The role of children's distress was also considered as an important factor to consider in the relation between children's health history and children's perceptions of parental care and overprotection. Consistent with the research documenting parent perceptions of their own parental care and overprotection, we hypothesized that differences between children with a history of cancer and children without a history of serious illness reports of parental care and overprotection would be small, non-significant, and less than what is generally considered a small effect size (i.e. .20; Cohen, 1992). Further, we anticipate that children's distress will be an important correlate for children's perceptions of parental overprotection and care, with distress scores being negatively predictive of parental care and positively predictive of parental overprotection.

Methods

Procedures

Participants were recruited as a part of a larger longitudinal study examining stress, adjustment, and growth in children and families with children who have been diagnosed with cancer. For the patient study group (i.e. families with children diagnosed with cancer), participants were recruited from outpatient clinics at a large children's hospital. Participants were included if they were (a) a least one-month from diagnosis, (b) able to speak and read English, (c) did not have any significant cognitive or sensory deficit, and (d) a parent/legal guardian was willing to participate and provide assent for their child. Patient participants were recruited at random from outpatient clinic visit list using a number generator based on one of four strata derived from elapsed time since their cancer diagnosis (1–6 months; 6–24 months; 2–5 years; >5 years). A total of 378 children with cancer were approached regarding participation in the study, and 258 (68 %) agreed to participate. The primary reasons for declining to participate included being too busy, feeling the questions were too personal, or simply not interested. Participants and nonparticipants did not differ by age, gender, or race/ethnicity, diagnostic category or categorized time since diagnosis. Of those that consented, 3 patients failed to provide usable data, leaving a total of 255 patients with fully usable data.

Control group participants were eligible if they (a) did not have a history of chronic or life threatening illness, (b) able to speak and read English, (c) did not have any significant cognitive or sensory deficits, and (d) a parent/

legal guardian was willing to participate and provide consent for their child. Children were recruited in a two-tier process from elementary, middle, and high schools from a three-state area surrounding the hospital. In the first step, permission slips were distributed through the schools, and returned permission slips included information on child age, gender, race/ethnicity, and parental education and occupation. At that point, parents were not consenting to their child's participation in the study, buy only giving permission for study staff to contact them at a later date should their child provide a good match to a cancer participant based on the collected information. The returned data was used to create a pool of potential control participants, who were subsequently contacted, based on demographic match. An exact percentage of those returning permission slips is not available. However, of 107 who were contacted based on demographic match, 101 (94 %) agreed to participate.

Participants in the study met with trained psychology staff at the hospital's outpatient psychology clinic. Each participant came with one parent or guardian, who also participated as a part of the larger study. The child participant was administered a variety of self-report measures to assess perceptions of parental overprotection and care, anxiety, depression, and posttraumatic stress symptoms. For perceptions of parental care and overprotection, children were asked to report on the parent that was participating in the study. Trained psychology staff members were on hand to assist participants with questions regarding the items.

Participants

Participants included 255 children with cancer and 101 children without a history of significant illness. However, internal reliability estimates were low on several measures for children who were less than 10 years of age. As a result, these children were removed from the final analyses. In the final sample, participants included 205 children with cancer and 76 children without a history of significant illness.

Demographic information for each group is presented in Table 1. The patient and control group did not differ on the child's age (t [279] = 1.22, $p = .22$), gender (χ^2 [1, $N = 281$] = .17, $p = .68$), ethnicity (χ^2 [2, $N = 281$] = .05, $p = .98$), or parent they were reporting on in the study (i.e., mom, dad, other (e.g. grandparent, stepparent) χ^2 [2, $N = 280$] = 4.48, $p = .11$). Using the Barratt Simplified Measure of Social Status (Barratt, 2006) to measure socioeconomic status (SES), an updated adaptation of the Hollingshead index (Hollingshead, 1975), the results revealed significant differences in SES, χ^2 [4, $N = 280$] = 15.52 $p = .004$, with fewer children in the control group from the lower SES strata, in comparison to the cancer group.

Table 1 Demographic information across study groups

	Patient group ($n = 205$)	Control group ($n = 76$)
Gender		
% Female	48.8	46.1
% Male	51.2	53.9
Age		
Mean (SD)	13.6 (2.33)	13.2 (2.36)
Range	10–17	10–17
Race		
% Caucasian	71.9	73.3
% African American	23.2	22.7
% Other	4.9	4.0
SES[a]		
% Group 1	11.7	17.1
% Group 2	13.7	28.9
% Group 3	31.2	31.6
% Group 4	24.4	15.8
% Group 5	18.5	6.6
Parent child reporting on		
% Mom	81.0	88.2
% Dad	13.2	11.8
[b] % Other	5.4	0.0

Diagnosis information for patient participants ($n = 205$)	
Diagnosis	
% Acute lymphoblastic leukemia	22.0
% Acute myeloid leukemia	7.3
% Hodgkin's and non-Hodgkin's lymphoma	14.1
% Solid tumor	40.5
% Brain tumor	16.1
Time since diagnosis	
% <6 months	23.9
% 6 months–2 years	24.9
% 2–5 years	23.9
% >5 years	27.3

SES socioeconomic status

[a] SES groups are ordered highest to lowest, with Group 1 reflecting higher SES strata and Group 5 indicating lower SES strata

[b] Of the other category, 33 % were grandparents, 33 % were aunt/uncle, 25 % were step-parent, and 8 % was other legal guardian

Measures

Parental Care and Overprotection

The *Parental Bonding Instrument* (Parker, Tupling, & Brown, 1979) is a 25-item, child self-report measure. The instrument was slightly modified to assess children's perceptions of their caregiver's current (as opposed to retrospective) parenting practices along two dimensions, care/affection (e.g., "Spoke to me in a warm and friendly voice". to "Speaks to me in a warm and friendly voice".) and protection/overprotection (e.g., "Did not want me to grow up". to "Does not want me to grow up".). Children were asked to rate on a 4-point scale how like or unlike each behavior reflects the attitudes and behaviors of the parent/guardian participating in the study. The *Parental Bonding Instrument* has been used in several research studies examining chronic and life threatening illness (e.g. Agostini, et al., 2010; Barakat, Marmer, & Schwartz, 2010; Garralda, Rangel, Levin, Roberts, & Ukoumunne, 1999; Jenerette & Valrie, 2010) and has been adapted for use in children and adolescents whose age range from 8 to 18 (e.g. Barakat et al., 2010; Borelli, David, Crowley, Snavely, & Mayes, 2013; Garralda et al., 1999; Gau & Chang, 2013). In this study, children were asked to report only on the parent that was also participating in the study. This measure has proved high test–retest reliability and high internal consistency (Wilhelm, Niven, Parker, & Hadzi-Pavlovic, 2004). In the current sample, the internal consistency was also adequate (Care, $\alpha = .84$; Overprotection $\alpha = .77$).

Child Depression

The *Children's Depression Inventory* (CDI; Kovacs, 1992) is a 27-item measure that was used to assess children's reports of their depressive symptoms. Respondents were asked to respond on a three point scale that described him or her best. This measure has provided adequate test and re-test reliability (Kovacs, 1992). In the current sample the internal reliability was adequate ($\alpha = .83$).

Child Anxiety

Screen for Child Anxiety and Related Emotional Disorders (SCARED; Birmaher et al., 1997) is a 41-item scale that was used to assess the likelihood of an anxiety disorder, along different dimensions of anxiety. For the present study, only the overall SCARED score was used. Children were asked to respond on a three point scale (hardly ever true, sometimes true, or often true) how each item reflects the way the participant feels. This measure has adequate psychometric properties including internal consistency, discriminant, and convergent validity (Birmaher et al., 1999). The total scale score was used and showed high internal reliability ($\alpha = .90$) in the current sample.

Child Post-Traumatic Stress Symptoms (PTSS)

The *UCLA PTSD Reaction Index for DSM-IV* (Pynoos et al., 1998) is a 22-item measure that was used to assess DSM-IV Post-Traumatic Stress Disorder (PTSD) criteria in children. The items are grouped into the PTSD criterion clusters: Re-experiencing/Intrusion (criteria B), Avoidance/Numbing (criteria C), and Arousal (criteria D). Children were first asked to report their most traumatic stressful event they have experienced and answer questions regarding the event. An overall score above 38 on this measure has been used as an indication of clinically significant PTSS (Steinberg et al., 2004). In the current sample approximately 10 % of participants in the patient group and 12 % of participants in the control group met this criterion. The measure has excellent psychometric properties including high internal and test-re-test reliability (Steinberg et al., 2004). Only the overall score was used in the present study and exhibited high internal reliability ($\alpha = .88$).

Statistical Analyses

To address our first hypothesis, that differences in reports of parental care and protection scores between the patient and control group would evidence an effect size less than .20, independent sample *t*-tests were performed. Next, analyses were performed to examine additional indicators of care and overprotection as a preliminary step before addressing the second hypothesis. Specifically, zero-order correlations were performed to examine the relation of parental care and overprotection with demographic variables and patient self-reported distress separately for the patient and control groups. In addition, four one-way analyses of variances were performed separately for the patient and control group to examine if child gender, parent gender, ethnicity, and SES were significantly associated with parental overprotection and care in either group. In addition, diagnostic category and categorized time since diagnosis variables were included in the ANOVAs for the patient group. Finally, to address the second hypothesis that child distress better accounted for variance associated with parental care and overprotection, a set of hierarchical multiple regressions were performed. In step one of each regression, significant demographic variables that emerged during the correlation or ANOVA analyses were entered, to control for the effects of the variables on parental care and protection scores. To control for the possible effects of group status (i.e., patient or control), this variable was entered in step 2. Child distress variables were entered in step 3, to assess if these variables better account for the variance of parental overprotection and care than group status. Finally, step 4 included the interaction between the

Table 2 Correlations among the study variables

	1.	2.	3.	4.	5.	6.	7.
1. Parental care	–	−.43***	−.09	−.12	−.21	−.38***	−.17
2. Parental overprotection	−.37***	–	−.37***	−.01	.28*	.36***	.39***
3. Child age	−.15*	−.15*	–	−.23*	−.04	−.11	−.17
4. SES class	−.10	−.11	−.02	–	.12	.07	.18
5. Child anxiety	−.06	.37***	−.14*	.28****	–	.79***	.69***
6. Child depression	−.30***	.43***	.07	.15*	.66***	–	.69***
7. Child PTSS	−.11	.34***	.09	.26***	.56***	.63***	–
Patient group ($n = 205$) [M(SD)]	29.82 (5.28)	14.41 (6.63)	13.58 (2.33)	3.25 (1.24)	17.31 (11.77)	6.35 (5.44)	17.96 (13.89)
Control group ($n = 76$) [M(SD)]	29.72 (5.78)	14.50 (6.72)	13.20 (2.36)	2.66 (1.14)	20.22 (11.66)	6.63 (5.63)	18.66 (15.85)

Control group correlations are presented above the diagonal, patient group correlations are presented below the diagonal

SES socioeconomic status, *PTSS* posttraumatic stress symptoms

* $p < .05$; ** $p < .01$; *** $p < .001$

child distress variables and group status. Variables were centered prior to computing the interaction.

Results

Patient-Control Comparisons on Parental Care and Overprotection

Independent sample *t*-tests indicate that children in the patient group did not significantly differ from participants in the control group on parental care scores (t [279] = .14, $p = .63$, $d = .02$) or parental overprotection (t [279] = −.10, $p = .74$, $d = .01$). In fact the mean scores of the two groups were nearly identical (Table 2).

Demographic Indicators of Parental Care and Overprotection

Correlations, means, and standard deviations among the study variables are presented in Table 2. Correlation analyses revealed a small but significant negative association between age of the child and parental care for the patient group ($r = -.15$, $p = .03$) but not for the control group ($r = -.09$, $p = .43$). Regarding parental overprotection, there was also a small but significant negative correlation with age of the participant for the patient group ($r = -.15$, $p = .03$), and a more substantial negative correlation in the control group ($r = -.37$, $p = .001$). Thus, parental care and overprotection decreased as the age of the participant increased. SES class was not significantly related to parental care or overprotection for either the patient group or control group. Further, several ANOVAs revealed parent care and overprotection scores were not significantly different as a function of the gender of the child, gender of the parent, and race for either the patient or control group. For the patient group, parental care and overprotection scores did not differ based on diagnostic category or time since diagnosis category.

Table 3 Regression analyses predicting children's perceptions of parental care and overprotection

	Parental overprotection		Parental care	
	β	ΔR^2	β	ΔR^2
Step 1		.05***		.02*
Age	−.24***		−.13*	
Step 2		.00		.00
Group status (patient or control)	−.01		−.02	
Step 3		.19***		.12***
Child depression	.31***		−.49***	
Child Anxiety	.03		.17*	
Child PTSS	.14^{t}		.09	
Step 4		.01		.01
Child depression × group status	−.06		−.10	
Child anxiety × group status	−.07		.03	
Child PTSS × group status	.06		.00	

PTSS posttraumatic stress symptoms

^{t} $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$

Two separate hierarchical linear regressions (see Table 3) were performed to examine the contributions of group status (patient vs. control group) and child distress (depression, anxiety, PTSS) to child reports of parental care and overprotection. In both analyses, age was entered in step 1 to control for the effects of age on parental care and overprotection scores, group status was entered in step

2 to control for the possible effects of group status on parental care and overprotection scores, and child depression, anxiety, and PTSS were entered in step 3 to examine if these scores explained significant variance in parental care and protection scores after group status was considered, the interactions between group status and child distress were entered in step 4. Given the high correlation between the child distress variables, multicollinearity diagnostics were assessed. For both parental care and parental overprotection, the variance inflation index (VIF) did not exceed 5 for each variable, suggesting each child distress variable was independently related to the dependent variable.

With perceived parental overprotection as the dependent variable, step 1 explained 5 % of the variance in parental overprotection scores. This change was statistically significant (F [1, 277] = 13.57, $p < .001$) with age as the only indicator of perceptions of parental overprotection ($\beta = -.22$, $p < .001$) in step 1. Group status did not significantly relate to perceptions of parental overprotection ($\beta = -.01$), thus, step 2 did not explain any additional variance ($\Delta R^2 = .00$). The addition of child distress in step 3 explained an added 19 % of the variance in parental overprotection scores and this was a significant change (F change [3, 273] = 21.87, $p < .001$). Specifically, child depression ($\beta = .31$, $p < .001$) was a significant indicator of perceptions of parental overprotection. Further, child PTSS was a marginally significant indicator of perceptions of parental overprotection ($\beta = .14$, $p = .06$). However, child anxiety did not prove to be strongly associated with parental overprotection ($\beta = .03$, $p = .72$). As the final step, the interactions between child distress and group status were not significant.

Parallel findings also emerged in the second regression analysis, when parental care served as the dependent variable (Table 2). Step 1 explained 2 % of the variance in parental care scores. This change was statistically significant (F [1, 277] = 5.094, $p = .03$) with age as the only indicator of perceptions of parental care ($\beta = -.13$, $p = .03$). Group status did not significantly relate to perceptions of parental care ($\beta = -.02$, $p = .70$), and explained <1 % of the variance in parental care scores (F change [1, 276] = .15, $p = .70$). The addition of child distress in step 3 explained 12 % of the variance in parental care scores. This change was statistically significant (F change [3, 273] = 12.93, $p < .001$). Specifically, child depression ($\beta = -.44$, $p < .001$) and child anxiety ($\beta = .17$) were significant indicators of perceptions of parental care. However, child PTSS ($\beta = .09$, $p = .23$) did not prove to be strongly associated with parental care. Finally, the interactions between child distress and group status were not significant.

Discussion

Parents of children with cancer face many unique challenges. They must balance a need for increased vigilance and protection of their child, while still promoting age appropriate activities and opportunities. These new circumstance can be difficult for parents and have the potential to foster less than optimal parenting strategies. However, the present research suggests that children with cancer perceive their parents care and protection similarly to their peers without a history of serious illness. These findings seem to mirror previous research examining parental perceptions of care and overprotection in similar populations (Davies et al., 1991; Hullmann et al., 2010).

These results contradict the one prior study of children with cancer that assessed parental overprotection form the child's perspective (Pelcovitz et al., 1998). However, it appears that child distress may explain the inconsistent findings. The population of children within the cancer group in the Pelcovitz et al. (1998) exhibited high levels of PTSD (35 %) whereas in the present study approximately 10 % in the patient group met the cutoff for likely PTSD. High levels of child distress has been closely tied parental overprotection in previous literature (Bokszczanin, 2008; Spada et al., 2012; Stein et al., 2000), a finding observed in the present study. In fact, child distress in the present study was more strongly associated with perceptions of parental care and overprotection than child health status. The results of the present research suggest that a child's cancer history does not necessarily foster parenting practices that are overprotective. Rather, children experiencing higher levels of distress tend to perceive greater parental overprotection.

Regarding the relation between demographic variables and parental overprotection, the findings in the present study are consistent with prior research. The present study found that age of child was negatively associated with parental overprotection for both the patient and control group. This finding suggests that a decrease in protection from parents may be a natural part of development. Prior research has also documented higher maternal overprotection scores than paternal overprotection scores in child reports of overprotection (Bokszczanin, 2008; Jelena & Tatjana, 2010). This finding did not emerge in the present research, but the power to detect such a difference was limited given the small number of father participants. Further, child gender differences in reports of parental overprotection were not seen in the current study, which is inconsistent with some prior research (Bokszczanin, 2008; Jelena & Tatjana, 2010), where girls tended to perceive their parents as more protective. This may be explained by age, as the samples in those studies were slightly older than the current sample. Perhaps such gender differences are seen primarily in adolescents.

An important question relates to the direction of the relation among child distress and parental overprotection. Some research has suggested that parental overprotection may lead to child distress (Fedele, Mullins, Wolfe-Christensen, & Carpentier, 2011); whereas other research has suggested that child distress promotes parental overprotection (Hudson & Rapee, 2005). This is difficult to address in a cross-sectional design, and might be examined in future research utilizing a longitudinal design and including both child and parent perceptions of parenting behavior.

The present results should be considered in light of study limitations. As already mentioned, the cross-sectional design of the study only allows for static conclusions to be made about children's perceptions of parenting behavior. It would be interesting to see in future research if parental care and overprotective behaviors change overtime as a function of child's health status. The small sample of fathers was also a limitation in the present study. Increasingly, literature has highlighted the important and unique role fathers contribute to the development of adaptive and maladaptive outcomes (Kane & Garber, 2004). Unfortunately, this could not be appropriately examined in the present study. Additionally, the current study only included child perceptions of parental behavior. Indeed, parental perceptions of their own parenting behavior are an important for consideration when examining the role of parenting behaviors and child outcomes. However, as noted by Fivush (1998), parents are not always the best reporters of their own behavior. Prior research has highlighted the importance of gauging children's perceptions of parenting practices. The history and experiences acquired through parent–child interactions are subjective (Liem, Cavell, Lustig, 2010; Williams, Ciarrochi, Heaven, 2012). Nonetheless, to truly appreciate the transactional pattern between parents and children it is also important to consider parental perspectives of their own behavior. Examining concurrent child and parent reports of parenting behavior as well as child and parent reports of distress is an obvious approach for a future study. Further, examining the role of treatment severity and relapse status might be a fruitful avenue to explore. Finally, with respect to future clinical implications, preliminary evidence from the current study seems to suggest that targeting the transactional pattern between child distress and overprotective parenting practices may serve to reduce child distress as well as overprotective parenting behaviors.

In sum, the present study provides preliminary evidence that parenting strategies do not necessarily change as a function of children's health status. It seems that parents of children with cancer are engaging in the same care and protective strategies as other parents, at least from the perspective of the child.

Acknowledgments This study was funded in part, by a Grant from the National Institutes of Health, R01 CA136782, and by the American Lebanese-Syrian Associated Charities (ALSAC).

Conflict of Interest Rachel Tillery, Alanna Long, Sean Phipps declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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