IRB
ETHICS
&
HUMAN RESEARCH

November-December 2015 • Volume 37, Number 6

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A Publication of The Hastings Center

FEATURE ARTICLE

Is Participating in Psychological Research a Benefit, Burden, or Both for Medically Ill Youth and Their Caregivers?

by Lori Wiener, Haven Battles, Sima Zadeh, and Maryland Pao

Limited empirical data exist on how children react to participating in research in medical settings or on their caregivers' reactions to the children's participation. Even less data are available pertaining to the actual or perceived burdens or benefits medically ill children experience from participating in psychological research studies. While behavioral research is generally minimal risk research, some hospital institutional review boards (IRBs) may be reluctant to approve psychosocial studies due to the perceived vulnerability of medically ill children, as well as to concerns about minimal research benefits and potential harms from research participation.[1] With limited empirical knowledge available to guide the process, IRBs are often left to make decisions based on professional experience and informed conjecture about the likely effects on individuals who participate in psychosocial research.[2]

Studies that have systematically investigated the risks or benefits to ill patients and the impact of their participation in psychological research have primarily been conducted with adults. Reported psychological risks include altered self-concept, increased anxiety, receiving information about oneself that is unpleasant, boredom, and inconvenience.[3] A study designed to investigate data collection procedures frequently associated with psychological research, such as audiotaping, questionnaires, and interviews, found that participants had minimal negative reactions to the procedures and thought participation somewhat useful.[4] The risk of emotional distress resulting from psychological research in adults has been specifically investigated in the area of trauma, and little empirical evidence was found that recalling and discussing traumatic events retraumatizes the individual; moreover, the data suggest that studies on violence and trauma may provide some benefit to participants.[5] We found only one study that investigated the risks or benefits experienced through participation in psychosocial research by ill patients who were receiving palliative care.[6] The majority of adult patients reported

Wiener L, Battles H, Zadeh S, et al., "Is participating in psychological research a benefit, burden, or both for medically ill youth and their caregivers? *IRB: Ethics & Human Research* 2015;37(6):1-8.

Table 1.
Measures Administered

Measure	*Description*	*Completed by*	*Approx. time to complete (minutes)*
Burden & Benefit Scale[6]	Measures patient reactions to research participation.	Caregivers and patients	3
Demographic Face Sheet	Provides information on child's age, race, diagnosis, and date of diagnosis, as well as if the child has a psychiatric diagnosis or learning disability. This form also collects information on household income and relationship of the caregiver to the child.	Caregivers	3
Distress Thermometer[20]	Patients rate their emotional distress on a visual analog scale. The screen also includes a problem checklist where raters under age 12 indicate reasons for distress from five separate domains.	Caregivers and patients	5
Brief Symptom Inventory[21]	Identifies psychological distress and psychiatric disorders.	Caregivers and patients aged 18-21	4
Children's Depression Inventory[22]	Identifies psychological distress and psychiatric disorders.	Patients aged 7-17	4
State Anxiety Inventory or State Inventory for Children[23]	Assesses anxiety and tension.	Caregivers and patients	5
Wong-Baker FACES Pain Scale[24]	Assesses pain.	Caregivers and patients	1
Childhood Fatigue Scales[25]	Measures fatigue in pediatric oncology patients.	Caregivers and patients	5

no burden associated with participation and described the experience as moderately to highly beneficial. Research participants reported a sense of contributing to society and appreciated the opportunity to interact with others and to discuss their illness.

The few studies that have provided empirical findings regarding children's appraisals of research participation or their caregivers' appraisals of it are limited by homogeneous samples (e.g., those who have experienced a trauma, witnessed violence, or are affected by family alcoholism) and varied methodological assessment strategies among studies (e.g., qualitative versus quantitative, telephone versus mail-in survey).[7] A feasibility study that consisted of conducting structured diagnostic interviews with preadolescents found that risks were not associated with direct interviewing of children about their own psychopathology.[8] In a study involving children with a traumatic injury, researchers found that participation that assessed acute posttraumatic stress reactions had little risk of generative distress for the pediatric participants or their caregivers.[9] Feeling good about helping others was the most commonly reported positive aspect of research participation. A more recent study involved interviewing 177 adolescents participating in clinical research for a medical or psychiatric illness or as a healthy volunteer and their caregivers. Overall, 90% of the adolescents and caregivers were willing to have the adolescent undergo a few extra blood draws, and 65% were willing to have the adolescent undergo an extra skin biopsy for research purposes. The vast majority felt that the adolescents were making an important contribution to help others.[10]

We have found no empirical data on whether children undergoing care for a serious illness and their caregivers would perceive participating in psychosocial research as burdensome or beneficial in the outpatient medical setting. Therefore, the objective of this study was to determine whether participation in research that involved approximately 20 minutes of completing self-report questionnaires in an outpatient medical setting was burdensome and/or beneficial to the child and to the caregivers. We also explored whether the level of burden would be related to specific demographic and psychosocial variables such as a child's age, gender, race or ethnicity, disease, self-reported distress level and symptoms such as fatigue, as well as caregiver self-reported distress symptoms.

Study Methods

We recruited a convenience sample of patients between the ages of 7 to 21 years as part of a larger cross-sectional study assessing distress and its correlates. Eligible patients were already enrolled in a treatment trial for cancer, HIV, neurofibromatosis type 1 (NF1), a primary immune deficiency, sickle cell disease, or Li Fraumeni syndrome. One caregiver (primarily the parent) for each patient was also recruited to participate.

A study investigator approached patients aged 18 to 21 and caregivers of patients under the age of 18, described the study, and obtained written consent. The study was described to all minors, who were asked if they would feel comfortable participating. If they answered in the affirmative, they signed a written assent form. The consent or assent process took about 5 to 10 minutes to complete.

Both caregivers and patient-participants completed several validated self-report questionnaires including the State Trait Anxiety Inventory (STAI), Brief Symptom Inventory (BSI) or Children's Depression Inventory (CDI), Childhood Cancer Fatigue Scale (CCFS), and the Burden and Benefit Scale. These and other study instruments are described in Table 1. The outcome of focus for this report was the analysis of the Burden and Benefit Scale,[11] which was based on a literature review that listed common benefits and burdens of research with palliative care patients.[12] It is a brief clinician-administered scale designed to measure patient reactions to research participation. Patient-participants and caregivers were asked, "Was participation burdensome to you in any way?" A five-point Likert scale (0-4) was used with the following response options: "Not at all," "A little bit," "Somewhat," "Quite a bit," and "Very much." In our analysis, we collapsed the last 4 categories (Table 2). Each caregiver and patient-participant who indicated any burden was provided with six follow-up questions to identify what part of participation was burdensome. Examples included "Interfered with my other activities," "The questions were too personal," and "The questions were confusing." A second section assessed whether participation in this study provided any benefit to the participant with the same five-point Likert anchors. If any benefit was endorsed, study participants were provided six possible benefits, including "Addressed issues the health care team doesn't often ask me (or my child) about," "Helped to facilitate treatment for my/my child's emotional distress," and "Helped pass the time/keep my mind busy." Study participants had the option of indicating multiple items for both perceived burden and benefit. Most caregivers completed their study instruments in approximately 20 to 30 minutes, while most patient-participants completed their study instruments in 15 to 25 minutes.

The majority of patient-participants and their caregivers did not find participating in a psychosocial study that consisted of completing a number of self-report measures burdensome.

The principal or associate investigators monitored how study participants responded to the questions about depression, anxiety, and distress measures to identify clinically significant symptoms. If a patient-participant or caregiver disclosed information during completion of the assessment form that suggested that he or she could be a danger to self or others or might need psychiatric intervention, an immediate psychiatric assessment was conducted, and when needed, a referral was made for further assessment by or services with a provider in the participant's home community.

Study data were analyzed using SPSS 12.0.1. Descriptive statistics are reported for the primary outcomes (levels of burden and benefit reported by patients and caregivers). Bivariate analyses were conducted using chi-square and Pearson product moment correlations to assess

Table 2.
Patient and Caregiver Perceived Burden and Benefit

		Patient *n (%)*	*Caregiver* *n (%)*
Burden			
	Not at all*	205 (83.0)	243 (93.1)
	A little bit	31 (12.6)	14 (5.4)
	Somewhat, quite a bit, very much	11 (4.4)	4 (1.5)
Benefit			
	Not at all	31 (12.6)	12 (4.8)
	A little bit	65 (24.0)	38 (15.3)
	Somewhat, quite a bit, very much	151 (61.2)	199 (79.9)

*In the analyses, burden and benefit were dichotomized, with "not at all" representing one category and "a little bit," "somewhat," "quite a bit," and "very much" collapsed into the other.

Table 3.
Participant Demographics

Characteristic	*N (%)*
Child's gender	
Male	143 (52.8)
Female	128 (47.2)
Relationship to child	
Mom	202 (74.5)
Dad	52 (19.2)
Aunt or uncle—legal guardian	6 (2.2)
Grandparent	1 (0.4)
Other	1 (0.4)
Race or Ethnicity	
White	161 (59.4)
Black or African American	65 (24.0)
Biracial	17 (6.3)
Latino	15 (5.5)
Asian/Pacific Islander	6 (2.2)
Other	4 (1.5)
Missing	3 (1.1)
Household Income	
Less than $1,000 per month	23 (8.5)
$1,000-$1,999 per month	38 (14.0)
$2,000-$2,999 per month	34 (12.5)
$3,000-$3,900 per month	41 (15.1)
$4,000-$4,900 per month	31 (11.4)
$5,000-$5,999 per month	22 (8.1)
$6,000-$6,999 per month	71 (26.2)
Missing	11 (4.1)

associations between demographic factors, patient distress, and perceived burden or benefit.

Study Results

Between 2009 and 2014, 271 children at two hospital centers met study eligibility and completed study enrollment. The mean age of the patient-participants was 14.5 (range 7 to 21 years). Reported race or ethnicity for most patient-participants was Caucasian (59%) or African American (24%); 53% of the patient-participants were male. The majority (75%) of the participating caregivers were mothers, 19% were fathers, and 3% were other legal guardians. Nine patient-participants over the age of 18 came to their appointment without a guardian present (3%). The breakdown of ages and other demographic data are presented in Table 3.

■ ***Burden of Research Participation.*** The majority of patient-participants (83%) and their caregivers (93%) did not find participating in a psychosocial study that consisted of completing a number of self-report measures burdensome. The most commonly reported factors that caused burden included "questions being confusing or difficult to answer" (4% for patient-participants, 2% for caregivers), "too many questions/took too long" (4% for patient-participants, 3% for caregivers), "questions were too personal" (3% for patient-participants, < 1% for caregivers), and "interfered with other activities" (3% for patient-participants, < 1% for caregivers) (Table 4). Of those who did report burden, 81% of patient-participants and 78% of caregivers also reported that they found participating in the study to be beneficial.

■ ***Benefit of Research Participation.*** The majority of patient-participants (85%) and their caregivers (95%) found at least some benefit to participating in the study. Patient-participants expressed reasons for finding benefit in participation that included feeling good about helping others or contributing to society (59%), providing a task to help them pass the time or keep their mind busy (52%), and finding it helpful or a relief to be asked about issues that affect their life (44%). Almost three quarters of the caregivers also indicated feeling good about helping others (70%) and finding it helpful or a relief to be asked about issues that affect their child's life (63%). Thirty-seven percent of caregivers found benefit in that the study allowed them to address issues the health care team did not often ask about (Tables 2 and 4).

■ ***Differences in Burden.*** A minimal number of differences were found related to patient-participant burden. Caregivers of children with HIV found the study to be more burdensome than caregivers of patients with other conditions (15.5% vs. 5% to 13% for others, $X2 = 8.9$, $p < .05$). Caregivers who reported that their children were anxious on the STAI reported greater levels of burden than caregivers of patients who did not find their children

to be anxious ($r = .17$, $p < .01$). Likewise, caregivers who reported greater fatigue for their children on the CCFS reported greater levels of burden ($r = .17$, $p < .01$). There was no association between caregiver report of socioeconomic status, caregiver or patient report of anxiety or fatigue, and reported level of burden. Patient-participants whose caregivers reported that their own depression was in the clinical range on the BSI (caseness, t-scores > 63) were more likely to find the study burdensome ($X2 = 7.1$, $p < .01$). For all other reported measures (treatment center, patient age, caregiver gender, patient race, or patient distress), no differences were found in reported burden by caregiver or patient-participant.

■ *Differences in Benefit.* Based on demographic and psychosocial variables, there were a small number of differences reported in benefit. Patient-participants between 18 and 21 years of age were significantly more likely to find the study beneficial than patient-participants under the age of 18 ($X2 = 14.4$, $p < .001$); this difference was not found between the responses of caregivers for patients 18 to 21 and the responses of caregivers of patients under 18. African-American patient-participants were less likely to report benefit than Caucasian patient-participants ($X2 = 17.1$, $p < .01$); for caregivers, race or ethnicity was not significantly associated with benefit. Caregivers of female patient-participants found the study less beneficial than caregivers of male patient-participants ($X2 = 7.0$, $p <. 01$). No differences were found in caregiver or patient-participant reported benefit with respect to specific diseases or any other reported measures.

Even among those participants who did express some burden, many often also expressed benefit, particularly feeling good about helping others or being relieved to be asked about issues related to their child's life.

Discussion

The current study provides evidence for low perceived burden by medically ill children, adolescents, and young adults and their caregivers participating in a study that involves answering standardized behavioral assessments about mood, pain, fatigue, and overall psychological distress. Patient-participants said they did not experience negative consequences from participating in the study, and their caregivers said the same about having their child participate in the study. On the contrary, patient-participants and their caregivers reported appreciation for being asked about difficult issues and said they benefited from having something to do while waiting at the hospital for medical treatment.

Overall, the participants in this study reported lower burden and more benefit with increasing age, which may be due to improved cognitive understanding of the abstract concepts of burden and benefit. The

Table 4.
Factors Associated with Perceived Burden and Benefit

What did you find burdensome?	*Patient N (%)*	*Caregiver N (%)*
Too weak/feeling too ill	4 (1.5)	1 (0.4)
Too many questions/took too long	11 (4.1)	7 (2.6)
Interfered with other activities	8 (3.0)	2 (0.7)
Questions were upsetting	9 (3.3)	0 (0.0)
Questions were confusing/difficult to answer	12 (4.4)	6 (2.2)
Questions were too personal	9 (3.3)	1 (0.4)
What did you find beneficial?	*Patient N (%)*	*Caregiver N (%)*
Helpful/relief to be asked about issues that affect my/my child's life	118 (43.5)	171 (63.1)
Addressed issues I often don't have an opportunity to discuss with others	71 (26.2)	113 (41.7)
Addressed issues the health care team doesn't often ask me about	61 (22.5)	99 (36.5)
Helped facilitate treatment of my/my child's emotional distress	40 (14.8)	78 (28.8)
Helped pass the time/keep my mind busy	142 (52.4)	63 (23.2)
Made me feel good to help others/contribute to society	160 (59.0)	189 (69.7)

data suggest that caregiver perceptions of burden of participating in this type of research may be illness specific or due to high symptom burden in their children or themselves. We found that caregivers of children with HIV and those who reported that their children were anxious on the STAI or having greater fatigue on the CCFS expressed greater levels of burden than other comparable caregivers. Interestingly, there was no association between patient-participant report of anxiety or fatigue and burden. Patient-participants whose caregiver reported that their own depression was high on the BSI were more likely to find the study burdensome, which is consistent with the literature on the perception of poorer child functioning associated with increased caregiver problems. Clearly, additional research on patient-caregiver interactions with regard to understanding benefit and burden of research participation is warranted.

Worth noting are the 70% of caregivers and 59% of the patient-participants between the ages of 7 to 21 who reported that they felt good about helping others by participating in this research study. This lends support to the idea that altruism can be a source of perceived benefit from (and a motivation for) research participation among children, adolescents, and young adults[13] and those who do not anticipate clinical benefit for themselves.[14] Even among those who did express some burden, many often also expressed benefit, particularly in the areas of feeling good about helping others or being relieved about being asked about issues regarding their child's life, suggesting that the perceived benefit could outweigh risk when both are present.

The National Research Council has pointed out that there are limited data on how much IRBs over- or underestimate risks of participating in research. It has been noted that IRB members generally make assessments of risk based on their own experience, with almost no information on research participants' perceptions of the probability, magnitude, duration, and consequences of these risks.[15] It is understandable that IRB members are concerned that asking a chronically or seriously ill child about psychological issues such as depression or anxiety may provoke negative reactions. Another potential risk of psychological research is concern by individuals who share personal information.[16] Yet 44% of patient-participants found it helpful or a relief to be asked about issues related to their life, and 63% of caregivers in the study found it helpful or a relief to be asked about issues related to their child's life. And it appears that sensitivity to psychosocial evaluation was not a major concern since few study participants thought the questions were too personal (3% of patients, less than 0.5% of caregivers). These findings suggest that IRB concerns that research participants will have negative reactions to certain questions in psychosocial research may be unwarranted in straightforward survey research using standardized instruments. Furthermore, an Institute of Medicine panel reexamined low-risk human research protections and concluded that IRBs are placing unnecessary work burdens on themselves by not exempting social and behavioral research when federal regulations permit them to do so.[17] While the federal regulations do not permit exemption of minimal-risk research involving minors, the findings from our study demonstrating low burden and high benefit with pediatric psychosocial research suggest that when human subjects protection and the integrity of research methods are not of concern, IRBs may consider using the expedited review process.

We note several important limitations to our study. First, the study assessed the burden and benefit of participating in a specific cross-sectional study in an outpatient research setting. Burden and benefit associated with participating in psychosocial research might differ with longitudinal studies, where measures are repeated over time. Follow-up assessment might augment our understanding of any longer-lasting benefits or perceived burden from participation in psychosocial research. Second, our study included specific self-report measures. Future investigations should ascertain whether burden or benefit changes with different study methodologies, including studies that involve interviews in addition to questionnaires. Third, our participants reported lower burden and more benefit associated with increasing age. Empirically based understanding of risks associated with psychological well-being and social behavior at different developmental stages is needed. Fourth, our study participants were already participating in clinical research and therefore may have been more likely to find lower burden and more benefit participating in psychosocial studies. Lastly, the findings also suggest that research participants might experience burdens and benefits from participating in research. Future studies might ask whether participants are likely to participate in similar research again to better ascertain the degree of perceived burden.

A strength of this study was our ability to address limitations noted in earlier studies,[18] including small sample size, narrow age limit, and focus on one particular condition (e.g., cancer), each of which limits the generalizability of the findings. We focused on youth across a 14-year age span who were living with many types of chronic and acute illnesses. The National Research Council recommended that researchers build questions into their

studies in order to collect perceptions of risk and harm in behavioral research.[19] By investigating the burdens and benefits of psychosocial research participation, we sought to better understand the nature of risks associated with this type of study. Additionally, earlier studies had not attempted to address potential differences in burden and benefit as a function of race or ethnicity. We were able to note some small differences to which researchers should remain attentive.

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Acknowledgments

This work (NCT#00824278) was supported in part by the Intramural Research Programs of the NIH, National Cancer Institute, Center for Cancer Research, and the National Institute of Mental Health. The authors acknowledge the support of several individuals who helped make this work possible. We thank Brigitte Widemann, MD; Katherine Warren, MD; Melinda Merchant, MD, PhD; Andrea Baldwin, PNP; Andy Gillespie, RN; and Donna Bernstein, RN, for their ongoing enthusiasm for our study. We also thank Janet Osherow, LCSW, Mary Lane, LCSW, and Denise Garner, LICSW, for their clinical and administrative support at Georgetown University. Mostly, we thank the children, adolescents and young adults for openly sharing their time and opinions with us.

Human Subjects Protection Statement

This study was approved by the Institutional Review Boards at the National Institutes of Mental Health and at Georgetown University, where patients and their caregivers gave informed consent to participate.

References

1. Jaffe AE, DiLillo D, Hoffman L, et al. Does it hurt to ask? A meta-analysis of participant reactions to trauma research. *Clinical Psychology Review* 2015;40:40-56; Emanuel EJ, Fairclough DL, Wolfe P, et al. Talking with terminally ill patients and their caregivers about death, dying, and bereavement: Is it stressful? Is it helpful? *Archives of Internal Medicine* 2004;164:1999-2004; Institute of Medicine. *Approaching Death: Improving Care at the End of Life*. Washington, DC: National Academy Press, 1997.

2. Kassam-Adams N, Newman E. The reactions to research participation questionnaires for children and parents. *General Hospital Psychiatry* 2002;24:336-342; Ceci SJ, Peters D, Plotkin J. Human subjects review, personal values, and the regulation of social science research. *American Psychologist* 1985;40:994-1002; Newman E, Kaloupek DG, Keane TM, et al. Ethical issues in trauma research. In: Kantor GK, Jasinski JL, eds. *Out of the Darkness*. London: Sage, 1997, pp. 271-281.

3. Prentice ED, Gordon BG. Institutional review board assessment of risks and benefits associated with research. In: National Bioethics Advisory Commission. *Ethical and Policy Issues in Research Involving Human Participants*, vol. II, Bethesda, MD, 2001; Hermeren G. Human and social consequences of research. *Progress in Clinical Biological Research* 1983;128:359-79.

4. Vaughan SC, Marshall RD, MacKinnon RA, et al. Current psychotherapy research methodology applied to psychoanalysis: A feasibility study. *Journal of Psychotherapy Practice and Research* 1994;3:334-340; Marshall R, Spitzer RL, Vaughan SC, et al. Assessing the subjective experience of being a participant in psychiatric research. *American Journal of Psychiatry* 2001;158(2):319-321.

5. See ref. 2, Newman et al. 1997; Newman E, Walker EA, Gefland A. Assessing the ethical costs and benefits of trauma-focused research. *General Hospital Psychiatry* 1999;21:187-196.

6. Pessin H, Galietta M, Nelson C, et al. Burden and benefit of psychosocial research at the end of life. *Journal of Palliative Medicine* 2008;11:627-632.

7. Ondrusek N, Abramovitch R, Pencharz P, et al. Empirical examination of the ability of children to consent to clinical research. *Journal of Medical Ethics* 1998;24(3):158-165; Reich W, Kaplan L. The effects of psychiatric and psychosocial interviews on children. *Comprehensive Psychiatry* 1994;35(1):50-53; Abramovitch R, Freedman JL, Henry K, et al. Children's capacity to agree to psychological research: Knowledge of risks and benefits and voluntariness. *Ethics & Behavior* 1995;5(1):25-48.

8. Zahner GE. The feasibility of conducting structured diagnostic interviews with preadolescents: A community field trial of the DISC. *American Academy of Child & Adolescent Psychiatry* 1991;30(4):659-668.

9. Kassam-Adams N, Newman E. Child and parent reactions to participation in clinical research. *General Hospital Psychiatry* 2005;27:29-35.

10. Wendler D, Abdoler E, Wiener L, et al. Views of adolescents and parents on pediatric research without the potential for clinical benefit. *Pediatrics* 2012;130:692-699; Grady C, Wiener L, Abdoler E, et al. Assent in research: The voices of adolescents. *Journal of Adolescent Health* 2014;54(5):515-520.

11. See ref. 6, Pessin et al. 2008.

12. Kristjanson LJ, Hanson EJ, Balneaves L. Research in palliative care populations: Ethical issues. *Journal of Palliative Care* 1994;10:10-15.

13. See ref. 4, Marshall et al. 2001.

14. See ref. 10.

15. Singer E, Levine FJ. Protection of human subjects of research: Recent developments and future prospects for the social sciences. *Public Opinion Quarterly* 2003;67:148-164.

16. Labbott SM, Johnson TP. Psychological and social risks of behavioral research. *IRB: Ethics & Human Research* 2004;26;3:11-15.

17. Maloney DM. Institutional review boards and social science research. *Human Research Report: Protecting Researchers and Research Subjects*. 2003;18(7):1-2.

18. Currier JM, Hermes S, Phipps S. Brief report: Children's response to serious illness: Perceptions of benefit and burden in a pediatric cancer population. *Journal of Pediatric Psychology* 2009;34(10):1129-1134.

19. National Research Council. *Protecting Participants and Facilitating Social and Behavioral Sciences Research*. Washington, DC: National Academies Press: 2003.

20. Patel S, Mullins W, Turk A, Dekel N. Time efficient distress screening and psychosocial services in the pediatric oncology setting. Paper presentation at the Psychosocial and Neurocognitive Consequences of Childhood Cancer: A Symposium in Tribute to Raymond K. Mulhern. St. Jude Children's Research Hospital, Memphis, TN, 2006.

21. Derogatis LR, Fitzpatrick M. The SCL-90-R, the Brief Symptom Inventory (BSI) and the BSI-18. In M.E. Maruish, ed. *The Use of Psychological Testing for Treatment Planning and Outcome Assessment*. Mahwah, NJ: Lawrence Erlbaum Associates, 2004.

22. Kovacs M. *Children's Depression Inventory Manual*. North Tonawanda, NY: Multi-Health Systems, Inc., 1992.

23. Spielberger CD, Reheiser EC, Owen

AE, et al. Measuring the psychological vital signs of anxiety, anger, depression, and curiosity in treatment planning and outcomes assessment. In M.E. Maruish, ed., *The Use of Psychological Testing for Treatment Planning and Outcome Assessment*. Mahwah, NJ: Lawrence Erlbaum Associates, 2004.

24. Wong D, Baker C. Pain in children: Comparison of assessment scales. *Pediatric Nursing* 1988;14(1):9-16.

25. Hockenberry M, Hinds P, Barrera P, et al. Three instruments to assess fatigue in children with cancer: The child, parent and staff perspectives. *Journal of Pain and Symptom Management* 2003;25:319-328.

Annotations

Solomon, AJ, Klein, EP, Corboy JR, et al. Patient perspectives on physician conflict of interest in industry-sponsored clinical trials for multiple sclerosis therapeutics. *Multiple Sclerosis Journal* 2015:17. DOI: 10.1177/1352458515569101 • Solomon and colleagues conducted an online study involving 597 participants who have multiple sclerosis. The goal of the study was to understand these patients' attitudes about information disclosed in the consent process regarding potential physician-industry conflicts of interests in an industry-sponsored study. The participants in this study thought it was important for doctors involved in a research study to disclose whether they receive compensation from industry sponsors, how such funds are allocated, and what prior relationships the doctor had with pharmaceutical companies. The authors suggest that to avoid or minimize potential conflicts of interests in industry-sponsored clinical trials, standardized and transparent disclosure practices for physicians involved in multiple sclerosis research should be developed. These practices could be a model for disclosure of conflicts of interests for other types of industry-sponsored clinical trials.

Weiss EM, Joffe S. Promoting informed decision making for comparative effectiveness randomized trials. *JAMA Pediatrics* 2015;169(9):803-804. • The authors contend that the Office for Human Research Protections should reconsider the draft guidance it issued to researchers about how they should define and describe to prospective research participants the risks of comparative effectiveness randomized clinical trials (CE-RCTs) that compare treatments within accepted standards of care. The draft guidance states that if the purposes of a study examining standards of care include identifying risks associated with those standards, then the identified risks associated with those standards of care under evaluation that are different from the risks of standards of care at least some of the participants would be exposed to outside of the study "are generally considered . . . to be reasonably foreseeable risks of research." Weiss and Joffe claim that following this guidance will impede rather than promote informed decisions about whether to participate in research because researchers and institutional review boards are likely to mischaracterize in consent documents the disadvantages of the study treatments compared with one another as foreseeable risks of participation, thus unnecessarily dissuading patients from enrolling in the study. The authors argue that OHRP should aim to promote disclosures about CE-RCTs organized around four core questions: What is the purpose of the trial? What are the alternatives to joining the study? What are the comparative risks and benefits of each study treatment? Are there any other risks or discomforts from joining the trial?