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# Youth and Parent Appraisals of Participation in a Study of Spontaneous and Induced Pediatric Clinical Pain

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## Abstract

The current study examined youths' and their parents' perceptions concerning participation in an investigation of spontaneous and induced pain during recovery from laparoscopic appendectomy. Youth (age range 5-17 years) and their parents independently completed surveys about their study participation. On a 0 (very negative) -to-10 (very positive) scale, both parents 9.4(1.3) [mean(SD)] and youth 7.9(2.4) rated their experience as positive. Among youth, experience ratings did not differ by pain severity and survey responses did not differ by age. Most youth (83%) reported they would tell another youth to participate. Ethical issues regarding instigation of pain in youth for research purposes are examined.

### Keywords

Ethics; induced pain; experimental pain; acceptability; children; adolescents

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## Introduction

Unrecognized, ignored, inadequately assessed, and poorly managed clinical pain in children and youths are widespread problems (National Pharmaceutical Council and Joint Commission on Accreditation of Healthcare Organizations, 2001; World Health Organization, 2012). Failures to provide children with relief from pain have been attributed to: (1) incorrect assumptions about pain and its management; (2) individual and social attitudes toward pain; (3) the complexity of assessing pain in youth; and (4) inadequate training of health care professionals (Walco, Cassidy, & Schechter, 1994). Similar observations are made in the American Pain Society and the American Academy of Pediatrics position statements concerning children's pain (Palermo et al., 2012; American Academy of Pediatrics, 2001). These challenges would diminish with a stronger research base and a better common understanding of children's pain. Fortunately, there have been unprecedented advances in understanding and the capacity to control youth's pain (McGrath et al., 2014; Walco, 2008), reflecting rapidly mounting research efforts over the past 35 years (Case et al., 2006).

Countering these successes have been challenges in including children in clinical investigations, even though inclusion would enhance understanding and protect children's safety and well-being. The International Association for the Study of Pain's (IASP) *Core Curriculum for Professional Education in Pain* states that individuals should "be aware that some groups, such as children…are vulnerable to unfair exclusion from pain research" (Charlton, 2005). Fost (Fost, 2001) has similarly argued that overprotecting youth in pediatric research has been an obstacle to advancing medicine. Prejudging studies of pain in children and youths as too aversive or harmful and presuming that children and their parents would be unwilling to participate may contribute to decisions to not undertake much-needed research. Efforts to protect children have led to their exclusion from research, leading to a lack of data and treatments for children appropriate to their developmental status. Although there has been a substantial increase in research interest in pediatric pain over the past several decades, we remain substantially in need of a better understanding (Caes et al., 2016). A balance is needed between the need to protect children and the need to include them in research (Samuel, Black, Avard, & Knappers, 2009).

Ethical standards for research participation provide a basis for judgments concerning involvement of children in research, seeking to minimize risk to children but supporting the benefits of advancing knowledge. It is recognized that children and youths may be vulnerable research participants who cannot represent their own views and interests, with authority to decide on research participation typically assigned to parents or legal guardians. Developmentally-sensitive standards are needed that provide age-specific approaches to judgments of risk, recruitment, privacy, and confidentiality, and to consider how permission or consent and assent apply to parents and youth (Berde et al., 2012). Unobtrusive observation of clinical pain would not appear to raise ethical concerns, whereas exacerbating clinical pain in children suffering pain requires justification within regulatory standards. US federal regulations state that (a) "Research involving children must be restricted to 'minimal' risk or a 'minor increase over minimal' risk absent a potential for direct benefit to the enrolled child [20] (US Food and Drug Administration, 2016)" or (b) "must present risks that

are justified by anticipated direct benefits to the child; the balance of which is at least as favorable as any available alternatives[21] (Office for Human Research Protections, 2009)".

Acceptability of pediatric pain research with patients in clinical settings appears to be related to the type of study performed. Questionnaire studies generally are not seen as problematic. As well, there has been little hesitation to unobtrusively observe youth subjected to medical procedures required for prophylactic, diagnostic, or treatment purposes (e.g., immunization injections, bone marrow aspirations, acupuncture), provided ethical standards, including assent and consent are satisfied. Controlled studies of induced pain in clinical settings are more difficult for a variety of reasons: there is substantial reluctance to expose children and youths to pain; there may be no immediate benefit to the child; there is a risk of further compromising health status; comparison conditions are difficult to generate; there may be considerable within- and between-person variation in the nature of the underlying causes of and reactions to pain; and clinical settings are difficult to standardize (Birnie, Caes, Wilson, Williams, & Chambers, 2014; Birnie, Noel, Chambers, von Baeyer, & Fernandez, 2011; LeBaron, Zeltzer, & Fanurik, 1989; Wilson, Holley, & Palermo, 2013). Nevertheless, studies that instigate pain permit: (a) standardized control over characteristics of the stimuli and environmental context and (b) opportunities to extensively interrogate the complexity of the painful experience (sensory, affective, cognitive, behavioral, and social features). Current mandated ethical review of research protocols indicates that participation in research with more than minimal risk must be justified by potential direct benefit to the individual child (Edwards, 2012).

The importance of securing informed consent from parents or guardians and assent from youth in advance of participation is widely recognized (Birnie et al., 2011; Solodiuk & Charles, 2012). In contrast, there has been minimal effort to systematically evaluate children and youths' appraisals of their research participation experiences at the end of studies. Additional information is needed to better inform the public, researchers, and research ethics committees on the ethical conduct of research with this vulnerable population (Crane & Broome, 2017).

Given this gap in knowledge, the present study queried youths' and their parents' feelings about participating in a study that evaluated an innovative approach to assessment of post-operative pain (Sikka et al., 2015). In this study, both spontaneous, ongoing pain following surgery (including breakthrough pain) and pain induced by pressure on the abdomen adjacent to the surgical wound (pain pressure task) were evaluated because: (a) they are common experiences among children in post-operative recovery; (b) they have distinct physiologies in the post-operative setting (Bennett, 2012); and (c) they have different implications for medical management (Bennett, 2012; Sikka et al., 2015; Srikandarajah & Gilron, 2011). Induced pain (the pain pressure task) did not exceed that which was already occurring during routine physical examinations. In our evaluation of youth and parent participants' experiences, we evaluated reasons for participating in the research, best and least liked aspects of the research, overall experience (positive, neutral, or negative), and whether they would refer others for participation. Our ad hoc hypothesis was that our research protocol, which included induced pain, would be well tolerated by pediatric and parent participants.

# Methods

## Participants

All participating youth and their parents attending the final study visit of a primary study examining new technologies for assessment of pain (described below under procedure) were given the opportunity to provide data appraising their participation in the primary study. Sixty-one neurotypical youths, aged 5-17 years, who required laparoscopic appendectomy at a pediatric tertiary care center had provided assent for the primary study, along with one of each child's parents who provided informed consent. Primary study exclusion criteria included any opioid use within the last six months, neurological deficits, and congenital or acquired facial deformities (because the original study evaluated facial expressions during pain and facial deformities would interfere with coding of facial activity).

## Procedure

**Primary study—**The primary study examined the validity of automated assessment of youth's post-operative pain using computer vision and machine learning methods (see (Sikka et al., 2015)). IRB review was sought and both the primary study and this secondary analysis were approved. Youth and their parents were approached for research participation after undergoing surgery and provided written assent and informed consent, respectively, for study participation. The consent process advised that research participants would not personally or directly benefit from participation in the research and fully disclosed the study protocol, including a description of the pressure pain induction procedure. One hundred dollars was given to the parent for the youth and parent's participation in the primary study upon completion and/or withdrawal (proportional to participation). The level of compensation was based on prior work in this setting and had approval of the local IRB in the context of compensation rates provided in other studies. Ninety-eight percent of parents and youth in the primary study had not previously participated in a research study.

Participants underwent three study visits (within 24 hours following surgery, approximately 24 hours later (inpatient), and following discharge up to 42 days later (outpatient)) wherein they were assessed for pain across the recovery period following laparoscopic appendectomy. Study visits required approximately 30 minutes to prepare participants for procedures and record activity during spontaneous and induced pain. An additional 30-60 minutes was required to administer questionnaires. In this postoperative setting, spontaneous pain was defined as pain occurring without any manipulation, presumably from pathology (residual appendiceal and/or post-surgical inflammation). Induced pain was performed per research protocol and involved manual pressure adjacent to the surgical site for a period of 10 seconds (heretofore referred to as the pain pressure task and was repeated twice) for a total of 30 seconds; participants were asked to provide pain scores (on a numeric scale of 0 to 10) before and after each pain pressure task. The pain pressure task evaluations were also performed on the day of performance of acceptability questionnaires.

**Current acceptability study—**For the acceptability study reported here, all participating youth (N=54) and their parents (N=54) attending the final study visit of the primary study were given the opportunity to provide data appraising their participation in the primary

study. Questionnaires assessing acceptability were administered separately to the youth and their parent at the third and final study visit to measure quantitative and qualitative aspects of the study experience. These were based on questionnaires developed by Birnie et al (Birnie et al., 2011) to study experimental pain in healthy youth. The full questionnaire is available upon request to the senior author of this referenced paper. Participants and parents were given the opportunity to read questions, but if they appeared to have difficulty reading or understanding the questions, the experimenter read the items and answered questions to ensure comprehension and understanding. Responses to questions were self-recorded by participants in writing.

**Acceptability questionnaires—**The questionnaires were relatively brief (seven questions asked of the youth; 13 of the parent), with the parent questionnaire mirroring some of the questions asked of the youth. Both quantitative and qualitative questions were asked. The qualitative data was sought through open-ended questions.

**Quantitative questions:** Youth were asked “Overall, how would you rate this experience?” and parents were asked “Overall, how would you rate your participation experience,” each on an 11-point numerical scale, ranging between 0, labeled “Very Negative,” and 10, labeled “Very Positive,” with 5 labeled “Neutral.” A positive or favorable experience response to those questions with response formats on a scale of 0 (very negative or unfavorable) to 10 (very positive or favorable) was defined as a score of 6 or greater.

Youth were asked to rate “Who decided you would take part in this study?” on an 11-point numerical scale, ranging between 0, labeled “Parent Only,” and 10, labeled “Child Only,” with 5 labeled “Both Equally.”

Parents were given an opportunity to endorse reasons for allowing their child to participate. They were asked to “rate on a scale of 0 (not important at all) to 5 (extremely important) how important the following reasons were in your decision to participate in this study.” The several possible reasons listed appear in Table 1.

Using a yes/no format, youth were asked to agree or disagree with a series of statements concerning their beliefs and motives for participation. Their answers were not shared with their parents. The statements are shown in Table 2. Parents were also asked several yes/no format questions: “Would you take part in another research study in the future?”; “Would you recommend this experience to a friend?”; “Did you feel that the study was explained well enough to you and your child?”; “Were you given the opportunity to ask the researcher questions?”; and “Do you feel that the compensation that you and your child received was reasonable for the amount of time and effort that you contributed?” Finally, youth were asked “Do you feel that your experience of pain was worth participating because you contributed to science (our understanding and ability to control children’s pain)?”, with an equivalent question asked of the parents by inserting the words “your child’s” before the word “experience”.

**Qualitative questions:** Open-ended response questions asked of youth were: “What was the best thing about your experience with us?” and “What did you like the least?” Open-ended

response requests asked of parents were: “What was the most positive aspect of your participation?”; “What was the most difficult part of your participation?”; and “Is there anything that would have made it easier for you to participate?”.

**Analyses—**In reported analyses, child indicates a young person aged 5 to 12 years, while adolescent indicates a young person aged 13 to 17 years. Yes/no answers were categorized accordingly and percentage responses reported. Fisher’s exact test (2-tailed) was used to compare agreement responses by age grouping. Open-ended questions were analyzed for common themes and then thematically coded according to the Birnie et al (Birnie et al., 2011) classification categories (e.g., classification categories in response to best- and least-liked aspects of study participation: pain induction method, compensation, learning, and research contribution; see Tables 3 and 4). For the best- and least-liked aspects of study participation, the category “other aspects of the study’s protocol” included reference to their experience of features of participation other than the focus upon pain, including the video recording and interaction with experimenters. Multiple theme codes were allowed for single responses when multiple themes were present in answers. Inter-rater coding reliability was established for 20% of parent and child open-ended questions, randomly selected. Second coders yielded inter-rater reliabilities of 95.8% on average.

Distribution analyses were performed for reporting results. Chi-squared analyses were used to analyze categorical responses based on age in youth (child v. adolescent). Correlation analysis was performed for the comparison between pain scores and child study experience ratings.

## Results

### Participants

The median age of the 54 youth participants in our acceptability study was 13 years (mean 12, range 5-17, standard deviation 3 years). The cohort was equally divided between children and adolescents (27 children; 27 adolescents). Youth participants self-identified as 52% males and 48% females. Ethnicity of the participants was 89% Caucasian, 7% Asian American, 2% American Native/Alaskan Native, and 2% Pacific Islander; 74% of participants were Hispanic. The 54 parents (46 mothers and 8 fathers) of participating youth were aged 23-60 years with a median age of 39 years (8 years standard deviation) (9 parents did not answer the age question), and primarily Hispanic (74%).

In regard to participation in our acceptability study of those eligible in the primary study, two youth discontinued participation (due to parental report of child not feeling well in the hospital) prior to the last study visit and five youth were lost to follow-up. Demographics of youth who dropped-out and/or were lost to follow up did not statistically significantly differ from the primary study cohort ($p \geq 0.20$ for age, sex, and ethnicity comparisons). Similarly, mean pain ratings of the 54 participants in our acceptability study did not differ from those who dropped out and/or were lost to follow-up for both spontaneous pain (Pain scores (on a scale of 0 (no pain) to 10 (most severe pain)): 4.1 (SD=2.5) v. 4.6 (SD=3.2), participants v. drop out or lost to follow-up, p=0.67) and pain reported during the pain pressure task (4.6 (SD=2.7) v. 3.8 (SD=3.1), participants v. drop out or lost to follow-up, p=0.47).

## Quantitative Measure Outcomes

Both youth [mean(SD): 7.9(2.4)] and parents [9.4(1.3)] independently rated their overall research experience as positive. Children (7.3(3.1) rated their research experience significantly (p=0.04) but only slightly less than adolescents (8.6(1.2)). Both groups rated their overall research experience as positive. Overall, child research experience ratings did not significantly vary with pain score severity ($r$=0.14, p=0.33). Youth reported that, in general, they were the main decision makers to participate in the study (with youth's scores slightly favoring the youth participants' contribution to the decision [6.1(2.2)]) and this finding did not vary significantly by child's age (r=0.03, p=0.83) or by child v. adolescent (p=0.95). The top three reasons for parental participation in the study were altruistic in nature: the belief that research is important, desire to contribute to medical knowledge, and desire to help others (Table 1).

## Qualitative Measure Outcomes

All youth reported that they were happy to have participated in the research. Their top three reasons for participation were that research is important, that they helped others, and that they helped increase knowledge (Table 2).

The majority (98%) of parents responded positively (yes) to the queries regarding participation in research in the future, recommending the experience to a friend, and whether the study was well explained during the consent process. Further, 100% of participants agreed that they were given the opportunity to ask the researcher questions. Ninety-eight percent of parent participants reported appropriate compensation for their contributions of time and effort. In fact, no parent suggested an alternative dollar amount when asked, and three parents indicated they would have done it for free.

The majority of youth (91%) and their parents (89%) endorsed that the pain experienced during the study was "worth participating." As found previously, categorization of the youth into child v. adolescent did not demonstrate significant differences in endorsement (p=0.11).

For youth, social factors dominated among the most liked features of research participation, i.e., "friendly people" and "research contribution/helping others" (Table 3). The pain pressure task was identified as the best liked feature by two youth (3.7%) and a minority of the youth indicated that the pain pressure task was their least liked task (13%). Most described some other features of the study as liked least (57.4%).

For parents, "contribution to research/science" was the most positive aspect of research participation (Table 4), and the majority (56.9%) reported that there was not a most difficult aspect of participation (none|nothing). Notably, the pain pressure feature of the tasks was not singled out as a difficult event, although 21.6% of parents indicated that it was difficult to see their child in pain. When asked, 90% of parents stated that they would not change any aspects of the study's methodology. In contrast only a minority (8%) of parents suggested logistical changes (timing, scheduling, parking, improved description of methodology, and follow up).

For both youth and parents, responses did not differ by the age of the youth participant.

## Discussion

This report addresses a need for additional information concerning youths' and their parents' experiences during research participation to better inform the public, clinicians, research ethics committees, and researchers on the ethical conduct of research with this vulnerable population (Crane & Broome, 2017). Understanding the perspectives of youth and their parents could contribute to a more informed balance between undue apprehension about the impact of participation on youth and failure to exercise caution concerning their potential for harm.

The current study found that youth and their parents consistently reported positive experiences during participation in our investigation of spontaneous and induced clinical pain following laparoscopic appendectomy. Although seven of the 54 youth participants indicated that the pain pressure task was their least liked part of the experience, the pain pressure task was **not** among the top two least-liked or most difficult activities of the study as ranked by both parents and youth. In contrast, two participants stated that the pain pressure task was the best part of their experience with the study. The majority of youth and their parents stated they were happy they participated in the study and that they would recommend participation to a friend.

Not all youth expressed a favorable attitude toward the study; 5.5% (n=3) reported a negative impression of the study as defined by an overall score of less than 5 on the 0-to-10 scale with 0, labeled "Very Negative,"10, labeled "Very Positive," and 5 labeled "Neutral." While naturalistic observation of pain that is spontaneous must remain a preferred methodology, our results suggest that observation of induced pain for research or nontherapeutic purposes can be acceptable to youth and their parents. Our evaluation of the acceptability of a pain research protocol involving a pain pressure task (induced pain) offers evidence that pediatric pain research can be acceptable to children and their parents.

Although clinical pain and laboratory pain differ substantially in predictability and controllability, and in the populations studied, among other possibilities, it is noteworthy that the findings of this clinical study were generally consistent with the acceptability to youth and their parents of the cold pressor task in the laboratory setting, as described empirically by Birnie et al (Birnie et al., 2011) and anecdotally by LeBaron et al (LeBaron et al., 1989). Nevertheless, there were differences worth noting that have implications in particular for the type of pain induction task used. Birnie et al. (2011) found that 7.2% of parents reported watching the child in pain as the most difficult aspect, whereas in the current study, 21.6% found this to be the worst part. Similarly, in the Birnie investigation, the cold pressor task was the best thing experienced by 20.0% of the children, whereas in the current study, the pain task was the best thing for only 3.7% of children.

Currently, empirical information regarding the acceptability of other methods of pain induction is lacking. There are research precedents for inducing pain in clinically ill youth for therapeutic and nontherapeutic purposes. In our literature search, and consistent with a prior literature review by Birnie et al (Birnie et al., 2014), we did not find appraisals of the acceptability of induced pain using a variety of protocols in youth with the following

conditions: chronic pain in general (Evans, Tsao, & Zeltzer, 2008; Tsao, Evans, Seidman, & Zeltzer, 2012; Zeltzer et al., 2002); sickle cell disease (Gil et al., 2001; Gil et al., 1997; O'Leary, Crawford, Odame, Shorten, & McGrath, 2014); myofascial pain (Tsao et al., 2012; Zeltzer et al., 2002); fibromyalgia (Reid, McGrath, & Lang, 2005); complex regional pain syndrome (Tsao et al., 2012; Zeltzer et al., 2002); extracephalic tenderness (Metsahonkala et al., 2006); headache (tension) (Birnie et al., 2011; Ciabchett, Celeste Serci, Madeddu, Cossu, & Giuseppina Ledda, 2011; de Oliveira & Valenca, 2012; Evans et al., 2008; Fernandez-de-Las-Penas et al., 2010; Metsahonkala et al., 2006; Smith, Martin-Herz, Womack, & McMahon, 1999; Tsao et al., 2012); migraine (Ciabchett et al., 2011; de Oliveira & Valenca, 2012; Smith et al., 1999; Tsao et al., 2012; Zeltzer et al., 2002); arthritis (Gualano et al., 2010; Reid et al., 2005; Thastum, Zachariae, Scholer, Bjerring, & Herlin, 1997; Zeltzer et al., 2002); joint pain (Tsao et al., 2012); limb pain (Evans et al., 2008); back pain (Evans et al., 2008; Zeltzer et al., 2002); neck pain (Evans et al., 2008); chest pain (Zeltzer et al., 2002); neurovisceral pain (Tsao et al., 2012); recurrent and functional abdominal pain (Apley, Haslam, & Tulloh, 1971; Birnie et al., 2011; Dufton, Dunn, Slosky, & Compas, 2011; Dufton et al., 2008; Evans et al., 2008; Feuerstein, Barr, Francoeur, Houle, & Rafman, 1982; Tsao et al., 2012; Walker, Williams, Smith, Garber, Van Slyke, & Lipani, 2006; Walker, Williams, Smith, Garber, Van Slyke, Lipani, et al., 2006; Williams, Blount, & Walker, 2011; Zeltzer et al., 2002; Zohsel, Hohmeister, Flor, & Hermann, 2008); and surgical pain (Srikandarajah & Gilron, 2011). The perspectives of youth and their families concerning instigation of pain in these settings would be of interest. To better understand and inform standards regarding pain instigation in pediatric pain research, investigators using pain instigation strategies for either clinical or purely investigatory purposes should include assessment of acceptability.

Our findings contribute to the empirical body of knowledge available to IRBs applying ethical standards to proposed pediatric research studies (Shah, Whittle, Wilfond, Gensler, & Wendler, 2004; Whittle, Shah, Wilfond, Gensler, & Wendler, 2004). If research studies inducing medically unnecessary pain are to be undertaken with pediatric patients, data regarding acceptability would be appropriate to determine initial or continuing approval. In our study, both parents and youth reported that instigation of pain for research purposes with no direct benefit to youth to be a positive experience for a variety of reasons and provide data supporting continuation of this line of research. The ethical justification for inducing medically unnecessary pain in patients will also depend upon the contribution of the investigation to improving care for youth. Participating youth and their parents must have a reasonable expectation that the science being undertaken will improve quality of care.

Research ethic boards may raise concerns about the induction of pain in youth even though the research may involve only minimal risk (Whittle et al., 2004). According to Edwards (Edwards, 2012), minimal risk is commonly described as brief pain from a small abrasion or wound, injections, or from common medical procedures where the probability of harm is no more than one would encounter in daily life. Some researchers have concluded that the definition of low risk differs between a healthy population of study and a clinical population of study (Wendler, 2009). We note that the pressure pain youth experienced in our study was no more severe than that commonly induced during routine clinical examination, physiotherapy, and routine motions/tasks following surgery (i.e., moving from bed to toilet

or bath). It would seem desirable for clinicians and researchers to collect and report acceptability data as a customary practice. Accumulation of this information from children and their parents concerning perception of participation in pain research would assist research ethics boards who are fulfilling responsibilities to protect children.

### Study limitations and opportunities for future research

We recognize several study limitations. First, evaluation of the acceptability of participating in this pain study took place at least 12 days after the most severe pain was reported (immediately following surgery). This could have led to diminished recall of distress and possibly more favorable attitudes. However, there is evidence that memory decay for pain experience is minimal even after one year and, while youth and parent memory for pain is complex, reported memories of pain generally are accurate (Badali et al., 2000; Noel et al., 2010). Secondly, seven of the 61 youth originally recruited for study did not complete the acceptability questionnaire and it was not possible to determine why this happened. It is noteworthy that 54 youth persisted through the 3 study sessions, although this remains a small sample size overall.

Investigation of the acceptability of exposure to painful procedures for research and clinical purposes is a developing field. The current findings may not be generalizable to youth and parents in other pain research settings or using other methods. The following considerations might be worthwhile addressing in future investigations. Although allowing youth to respond to the questions privately was designed to minimize audience bias (we would have expected youth to attempt to please their parents), even asking questions could have a biasing impact. Face-to-face interviews could add clarity, particularly when questions are left unanswered or responses are unclear. Other features of research participation not fully investigated here also deserve study, including the role of youths' perception of control over the situation, their ability to withdraw, and the relationship between cognitive capacity and the ability to understand the assent they were providing. As well, we did not examine participants' experiences with the informed consent and assent procedures used here. It would have been useful to know whether there were discrepancies between expectations formed during the consent process and the realities of their experiences. Discordancies between expectations and experiences are likely to lead to less favorable appraisals. Finally, acceptability was queried during the final session, following resolution of pain. It would be of interest to assess acceptability earlier in the study, particularly at all study visits during which pain was induced.

## Conclusion

We demonstrate positive experiences reported by parents and youth participating in a pediatric pain research protocol including pain instigation. Our data suggest that inclusion of youth into research involving pain that is induced for investigation is acceptable to youth and families. We recognize that our findings may be limited to the current research protocol investigated and we recommend that other researchers of pediatric pain include acceptability ratings in their study designs to better understand acceptability in pediatric pain research as a whole.

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## Abbreviations:

| | |
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| **IRB** | institutional review board |
| **SD** | standard deviation |

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**Table 1.**

Rank Ordered Parent Ratings of Reasons for Decision to Participate (scale 0 (not important at all) to 5 (extremely important))

| Reason for Participating | Mean (SD) |
|---|---|
| Belief that research is important | 4.85(.36) |
| Desire to contribute to medical knowledge | 4.81(.44) |
| Desire to help others | 4.77(.61) |
| Educational for child * | 4.52(.92) |
| Child wanted to participate * | 4.37(1.17) |
| Want to learn more about health research * | 4.06(1.16) |
| May benefit my child | 3.87(1.41) |
| Reimbursement/incentive offered * | 3.38(1.78) |

Fifty-three parents participated. Asterisked (*) reasons for participating were ranked by 52 of the 53 participating parents.

**Table 2.**

Youth's Agreement with Statements

| Statements | Group Agreement (%) | Child 5-12 y) agreement (%) | Adolescent (13-17 y) agreement (%) |
|---|---|---|---|
| I am happy that I took part | 100 | 100 | 100 |
| I believe that research is important | 98 | 96 | 100 |
| I feel like I helped others * | 94 | 92 | 96 |
| Through my participation, I helped other people learn something new * | 91 | 87 | 96 |
| I feel like I learned something new | 83 | 82 | 85 |
| I would tell a friend to participate | 83 | 81 | 89 |

Fifty-four youth participated. Asterisked (*) reasons for participating were ranked by 53 of the 54 participating youth. There were no statistical differences between agreements by group ($p>0.05$).

**Table 3.**

Youth's Coded and Categorized Responses to Queries about Best and Least Liked Aspects of Study (n=54).

| **Best things about the experience:** | |
|---|---|
| **Coded category** | **(%)** |
| Research contribution/helping others | 31.5 |
| Aspect of the study other than being exposed to pain, e.g., being video recorded, wearing the sensors, how easy it was to participate, the questionnaires, and answering the pain ratings | 24.1 |
| Friendly people (i.e. researchers/researchers assistants) | 20.4 |
| Compensation | 9.3 |
| Having fun/learning | 9.3 |
| Other | 7.4 |
| Pain pressure task | 3.7 |
| **Least liked things about the experience:** | |
| **Coded category** | **(%)** |
| Aspect of the study other than pain, e.g., answering the questionnaires, wearing the sensors, staring at the camera, length of time | 57.4 |
| Nothing | 20.4 |
| Pain pressure task | 13.0 |
| Other | 9.3 |

Response categories were not mutually exclusive and thus totals exceeded 100%.

**Table 4.**

Parents' Coded Responses as Most Positive and Most Difficult Aspects of Study.

| **Most positive aspect of participation (52 respondents)** | |
|---|---|
| **Response category** | **(%)** |
| Contribution to research/science | 59.6 |
| Other, e.g., being helpful, learning opportunities | 28.8 |
| Child's enjoyment/participation | 11.5 |
| Researchers | 7.7 |
| Participating with child | 5.8 |
| Compensation | 3.8 |
| **Most difficult aspect of participation (51 respondents)** | |
| **Response category** | **(%)** |
| None/nothing | 56.9 |
| Procedure/watching my child in pain/discomfort | 21.6 |
| Logistics (e.g. timing, parking, scheduling) | 9.8 |
| Other, e.g., the behavior of my child, getting my child to behave, initial study visit, and delay in scheduling final visit | 9.8 |
| Answering questions/questionnaires | 7.8 |

Totals exceed 100% as parents sometimes identified more than one theme.