Pediatric Pain Assessment in the Emergency Department

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Purpose:

To examine how pediatric pain scales are used in clinical practice in a pediatric emergency department (ED). Specifically we will examine the use of Wong-Baker FACES ® Pain Rating Scale (WBF) and Faces Pain Scale – Revised (FPS-R) by ED nurses, as well as the correlation of results with the children's subjective descriptions of pain before and after an analgesic intervention as well as parental estimates of their children's pain. We will determine if a child's successful use of these scales can be predicted by evaluating his/her neurocognitive development.

Background:

"Most children five years and older can provide meaningful self-reports of pain if they are provided with age appropriate tools and training."[1] Self-report is the desired method of data collection.[2,3] Face scales provide an ordinal self-report of pain, and the literature suggests that they are the preferred method of pain reporting by children.[2]

Both the WBF and the FPS-R have been studied extensively in children with chronic pain, post-operatively, and those experiencing procedural pain; however, data for their use in assessing acute pain while in the ED is limited. It is imperative that pain be assessed accurately, as it is the most common reason for presentation to the ED. However, it is also important because often we draw conclusions about the efficacy of an intervention based on the results of these pain scales.

Both the WBF and FPS-R are designed to be delivered with a specific script. However, in practice these scripts are rarely used as intended, and caregivers' perception of the child's pain is often used as a surrogate for self-report. There have been no studies determining whether a caregiver's rating of his/her child's pain using the WBF or FPS-R accurately reflects the child's self-report; however, the practice of relying on the parents' assessment of their child's pain has been demonstrated in some studies to poorly correlate with the patient's own perceived pain intensity.[4]

The WBF has an intended age range of 3-18 years, while the FPS-R is intended for 4-12 year olds.[5] There are a limited number of studies that have examined whether children can be screened to predict their ability to use these scales, but none have used validated developmental screening tools. There are cognitive and social abilities that are necessary to self-report pain.[6] However, evidence is limited as to whether screening for these skills can accurately predict children that will successfully use self-report pain scales.

Phase 1 – Primary Aim:

To examine how pain scales are administered by clinicians at the bedside in a pediatric ED and how it impacts the recorded pain score.

Hypothesis: There will be significant variability in how the WBF and FPS-R are administered in actual practice, including inconsistency in taking into consideration the caregiver's perception of the child's pain.

Rationale: Both the WBF and FPS-R were validated with specific scripts; however, it is unknown if the normal variation in application of the scales diminishes their validity. To

determine the magnitude of this problem, we will complete an initial survey of patients with painful conditions and observe how the WBF is used in actual practice. Specifically, we will determine how often the recommended script is followed, but we will also determine if there are common variations from the recommended script. We will also evaluate how often a caregiver's perception of the child's pain is considered when completing the self-report scales.

Methods Summary: Prospective, observational, qualitative examination of bedside pain assessment in the pediatric ED.

The frequency and nature of deviations from the pain scale script at the initial pain assessment in triage will be directly observed by the PI and audio recorded for future word-for- word analysis of deviations from the script. The audio recordings will be used to make transcripts devoid of PHI for this purpose. Field notes will be taken by the PI in order to provide context and other key observations not captured by the audio recordings. Variations from the transcript will be identified and quantified. Field notes, coupled with quantitative data of the frequency of deviations from the pain scale script and their location within the script will be analyzed by qualitative methods of interview analysis described in the Qualitative Analysis Guide of Leuven, modified to analyze our observations.[7] Briefly, the data of the script deviations and field notes will be conceptualized, whereby the data will be filtered and the most important data clustered into concepts to prepare for analysis. The transcripts and field notes will be re-read with the concepts in mind and refined. The individual transcripts will be assessed by the constant comparative method with review of common themes and the identification of new themes. Concepts will be integrated into a conceptual framework relating to the hypothesis and discussed with the research team to obtain consensus prior to generating a final summary of concepts.

Phase 2 – Primary Aim #1:

To determine if level of neurocognitive development impacts responsivity of the WBF and FPS-R (whether the measure is able to identify changes in pain over time that are clinically important to patients) when used in the pediatric ED with children presenting with acute pain.

Hypothesis: Patients with at or above expected cognitive development will exhibit improved responsivity when using the WBF and FPS-R compared to children with lower than expected cognitive development. Those who can successfully complete behavioral tasks such as matching and grouping will exhibit improved responsivity when using the WBF and FPS-R compared to children who cannot complete such tasks successfully.

Phase 2 – Primary Aim #2:

To determine the cognitive age equivalent at which children presenting to the emergency department with acute pain can use the WBF and FPS-R accurately to self-report their level of pain at two separate time points during their ED evaluation.

Hypothesis: Children with a cognitive age equivalent of at least five years old will more reliably use the WBF and FPS-R to self-report acute pain when presenting to the emergency department

Rationale: Multiple studies have compared children's ability to use pain scales based on age, and both the WBF and FPS-R are conventionally believed to be appropriate for children once they are four years old. However, age is used as a proxy for developmental level; not all four year old children have the developmental and cognitive skills to quantify and report their pain. Whether children have the skill set to complete a self-report of pain is variable until approximately the age of five years. This study would serve to more clearly classify the level of cognitive development needed to use the pain scales effectively.

Methods Summary: Prospective, observational study to determine if there is correlation between neurocognitive development and responsivity when using the WBF and FPS-R as well as the minimum cognitive age equivalent needed to effectively use the WBF and FPS-R. Initial and repeat WBF and FPS-R self-report scores will be compared at two points during the ED evaluation of patients presenting with acute pain. The change in the WBF and FPS-R pain scores will be compared to the subjective self-reports of change in pain. Children will complete the BRIGANCE ® Early Childhood Screens III to determine whether they are at, above, or below the expected cognitive development for their age. Children with at or above expected cognitive development for their age will be compared to those with lower than expected cognitive development. Children will also complete a series of tasks aimed to assess ability to successfully use the WBF and FPS-R (Appendix 2). Children that complete all tasks successfully will be compared to those who do not. The BRIGANCE will also be used to determine the cognitive age equivalent for each subject. We will determine the minimum cognitive age equivalent associated with accurate use of the WBF and FPS-R, defined as a self-report that matches the subjective report of change in pain.

Phase 2 – Secondary Aim #1:

To determine whether the WBF and FPS-R exhibit convergent validity (degree to which they produce similar results) when used with children presenting to the emergency department with acute pain

Hypothesis: The WBF and FPS-R will demonstrate convergent validity when used to measure acute pain in children presenting to the emergency department

Rationale: Both the WBF and FPS-R have been studied for their use in obtaining self-reports of pain in children, and overall have been determined to be two of the preferred methods of pain assessment in pediatric patients. Although each has been compared to other methods of pain measurement, the two have not been compared to each other. If the two studies were proven to have convergent validity, it would strengthen the evidence that these methods should be the preferred tools for assessing pain in children.

Methods Summary: Prospective, observational study to determine the convergent validity of the WBF and FPS-R for children presenting to the ED with acute pain. The initial and repeat WBF and FPS-R self-report scores will be compared in patients presenting to the ED with acute pain.

Phase 2 – Secondary Aim #2

To determine if there is inter-rater reliability between patients presenting to the pediatric ED with acute pain and their caregivers when using the WBF and FPS-R at two separate time points during their ED evaluation

Hypothesis: There will be low inter-rater reliability between patients and their caregivers using the WBF and FPS-R.

Rationale: Caregiver perception of a pediatric patient's pain is often used as a substitute for the patient's self report of pain; however, studies are limited to show that caregivers are able to predict children's pain level accurately when in the acute care setting.

Methods Summary: Prospective, observational study to determine the inter-rater reliability between patients and their caregivers when using the WBF and FPS-R. The initial and repeat WBF and FPS-R self-report scores will be compared to caregivers' initial and repeat WBF and FPS-R ratings in patients presenting to the pediatric ED with acute pain.

Identification of Subjects

Participants will come from a convenience sample of children presenting to the ED. Triage nurses and ED providers will be aware of the study and notify the PI or designee by phone if patients may qualify for the study. The PI and designees will also have access to the ED track-board and can screen for possible participants.

Inclusion Criteria

Patients $\geq$ 3 years and $\leq$7 years six months old
Chief complaint of pain or painful condition (Phase 1 only)
Pain score $\geq$ 4/10 (Phase 2 only)
Caregiver speaks English or Spanish

Exclusion criteria

Altered mental status
History of traumatic brain injury (TBI)
History of developmental delay
History of Autism
History of chronic pain, defined as persistent or recurrent pain in children with chronic health conditions[8]
Non-verbal patients

Outcome Measures:

Phase 1 - Primary Aim
Rate of intended script use in pain scale delivery
Review of themes during nursing pain assessment
Consistency in delivery of WBF by nursing

Phase 2 - Primary
Neurocognitive development score
BRIGANCE ® score
Initial WBF score
Repeat WBF score
Initial FPS-R score
Repeat FPS-R score
Anchor report of pain (a lot better, a little better, the same, a little worse, a lot worse)

Phase 2 - Secondary
Initial WBF score (patient and caregiver)
Repeat WBF score (patient and caregiver)
Initial FPS-R score (patient and caregiver)
Repeat FPS-R score (patient and caregiver)

Study Definitions:

"Caregiver" will refer to an adult who is able to provide consent for treatment and provides regular care for the child.

"Chronic pain" includes persistent (ongoing) and recurrent (episodic) pain in children with chronic health conditions.

Convergent validity evaluates the degree to which two different scales that are supposed to measure the same thing produce similar results.

"Repeat pain score" will be completed approximately 20 minutes after the initial pain score, or if administered, approximately 20 minutes after analgesic intervention.

Responsivity is the degree to which a test behaves in a manner that is consistent with what the test is purported to measure. It determines whether the measure is able to identify changes in pain over time that are clinically important to patients.

Phase 1 Study Protocol:

1. Once the subject is identified, the caregiver will provide verbal consent for participation in the study.
2. After verbal consent is obtained, the primary investigator will observe and audio record nursing's assessment of the patient's pain and complete the observation checklist (Appendix 1).

Phase 2 Study Protocol:

1. Once the subject is identified, the caregiver will provide written consent for participation in the study (if a self-report pain score was not collected in the triage process, patients with pain or a potentially painful condition will have their pain assessed using an age appropriate self-report pain scale by the PI or designee).
2. Early in the ED visit, the investigator or designee will help the patient complete Part One of the Patient Survey (Appendix 3), which includes the WBF, and the FPS-R.
3. The caregiver will also complete Part One of the Caregiver Survey (Appendix 4).
4. Subjects will be treated per usual care by an MD/ACP.
5. The investigator or designee will help the patient complete Part Two of the Patient Survey (Appendix 3), which includes the WBF and the FPS-R. This will occur approximately 20 minutes after analgesic administration, if it was ordered.
6. The caregiver will also complete Parts Two and Three of the Caregiver Survey (Appendix 4).
7. If the patient indicates in Part Two of the Patient Survey that he/she feels better, the investigator or designee will complete a brief neurocognitive skills assessment (Appendix 2) as well as the BRIGANCE ® Early Childhood Screens III with the patient.
8. If the patient indicates that he/she feels the same or worse on Part Two of the Patient Survey the treating MD/ACP will be notified.
9. The patient will be reassessed by the PI or designee at least 20 minutes after analgesic administration, if it was ordered, or after a reasonable time period if no analgesic medication was ordered.
10. On reassessment, if the patient says that he/she is willing to participate, the PI or designee will complete a brief neurocognitive skills assessment (Appendix 2) as well as the BRIGANCE ® Early Childhood Screens III with the patient. If the patient is not willing to participate, study assessments will cease.

Statistical Analysis:

Phase 1

Sample size: 30

Rate of compliance with intended script and rate of consideration of caregiver perception will be reported as percentages. Qualitative data will also be reviewed by the PI for the emergence of themes.

Phase 2

Sample size: approximately 250

Responsivity will be measured by correlating the change in the WBF and FPS-R scores before and after analgesic intervention with the anchor change in pain score (a lot better, a little better, the same, a little worse, a lot worse). Pearson correlations will be estimated between each change score and the anchor score. In addition, we will use ANOVA to test the difference in mean pain change among the children reporting “a lot better”, “a little better”, and “the same”. For the scales to be considered responsive, we would need to see significant reductions for the

children reporting “a lot better”, minimal to no reduction for those reporting “the same”, and increase in pain for those reporting “worse”. We will need a relatively large number of children in each category (a lot better, a little better, the same) to be able to test for differences (at least 30 per group). We will use Fisher’s z-transformation to test if level of neurocognitive development impacts responsivity. Levels of neurocognitive development will be defined as at or above expected or lower than expected. The Fisher’s z-transformation formally tests if the correlations between two measures (change in pain and anchor rating) differ between two groups. Here we assume we will have significant variability in change scores and in the anchor ratings to conduct these correlations and the formal test. We would need at least 56 children in each neurogcognitive development group (expected or above versus below). If the variability is limited in that most children report improvement and few report same or worsening, we will test for responsivity differences using a two-way ANOVA where the two factors are self reported anchor response (“better”, “same” or “worse) and neurocognitive level (expected or above expected vs below expected). The outcomes are the change in the WBF and the change in the FPS-R. The test of interest will be the two way interaction between the anchor and the neurocognitive development level. The BRIGANCE also provides the developmental age for each child which can be compared to their actual age. We will test if this difference is significant using a paired t-test. We will also explore the age where responsivity worsens by conducting similar analyses but stratified by actual age (each year) and developmental age. Given the proposed analysis, we will need at least 50 children for each cognitive age (3, 4, 5, 6, and 7 years) assuming at least 10 fall into the “a lot better”, “a little better”, “the same” categories for the anchor pain question.

Convergent validity will be assessed by determining both Pearson’s correlation and agreement using the Bland-Altman method between the WBF and FPS-R scores before and after analgesic intervention. We will compare Pearson correlations using Fisher r-to-Z transformation.

Inter-rater reliability will be determined by calculating intra-class correlation coefficients (ICCs) between the parent and the child reports at the same time points.

This analysis will be completed with the biostatistics team under the direction of CORE (Center for Outcomes of Research and Excellence).

Appendix 1 – Qualitative Assessment (Phase 1 Primary Aim)

Subject # _____

Observed Pain Assessment

Start Time: _____ End Time: _____ RN: _____

Initial pain scale used

Wong Baker FACES Numerical Other

Initial phrasing of question

_____

How is the question framed?

Zero	Ten
No pain	Worst pain experienced
No hurt	Worst pain possible
Other _____	Other _____

Example given for 10/10? Yes No

Patient's initial response _____

Time to give answer _____

Is the question rephrased? Yes No

Final scale used

Wong Baker FACES Numerical Other

Is parent asked for confirmation? Yes No

Does the parent rate the child's pain? Yes ___/10 No

Is parent asked for their perception? Yes No

Other tasks completed during assessment? Yes No

Vitals *Medication*

Is "happy because there is no pain/hurt" mentioned? Yes No

Is "you do not have to be crying" mentioned? Yes No

Final score documented _____

Does the RN believe the child understands the scale? Yes No

Does the caregiver believe the child understands the scale? Yes No

Investigator Initials: _____ Date: _____

Appendix 2 – Neurocognitive Assessment (Phase 2 Primary Aims #1 and #2)

Part I: Neurocognitive Skills Assessment

Classification

Children will be asked to "put together things that are alike" to determine their ability to classify objects. First they will be presented with a total of nine squares of paper of equal size (three red, three blue, and three yellow) and will be expected to group them by color. They will then be presented with nine faces from the WBF (three of 0/10, three of 4/10, and three of 10/10) and asked to group similar faces. Finally, they will be presented with nine faces from the FPS-R (three of 0/10, three of 4/10, and three of 10/10) and asked to group similar faces. Final score will be 0-3 points, with one point assigned for each group properly classified.

Seriation

Participants will be asked to put a series of six squares with increasing size in order from smallest to largest. They will then be asked to put the six individual faces from WBF in order from least pain to most pain. They will repeat the task with the six individual faces from FPS-R. Final score will be 0-3, with one point assigned for each group properly ordered.

Magnitude of Pain

Using pictures and scenarios from the Charleston Pediatric Pain Pictures (CPPP),[9] participants will be asked whether the pictures show "no hurt," "a little hurt," or "a lot of hurt" and will be assigned one point for each scenario properly classified for a total of 0-3 points.

Matching

Using pictures from the CPPP, participants will assign face scale levels of pain to a no-pain, a medium-pain, and a severe-pain picture using the WBF (0/10, 4/10, and 10/10) and the FPS-R (0/10, 4/10, and 10/10). They will receive one point for each scenario correctly matched for a total of 0-6 points.

Reverse Matching

Participants will be shown faces from the WBF and FPS-R (0/10, 4/10, and 10/10) and asked to select a pain scenario from the CPPP to match. They will receive one point for each scenario properly matched for a total of 0-6 points.

Part 2: BRIGANCE ® Early Childhood Screens III

Appendix 3 – Patient Survey (Phase 2 Primary and Secondary Aims)

Part One

Time: _____

1. Does anything hurt on you right now?

2. Faces Pain Scale-Revised reported score:

3. Wong-Baker FACES ® reported score:

Medication: _____

Time administered: _____

Investigator Initials: _____ Date: _____

Part Two

Time: _____

1. Do you feel better, worse, or the same?

Better (go to Section A) Worse (go to Section B) Same (go to Section C)

Section A

Do you feel a little bit better or a lot better?

A little bit A lot

Does anything hurt on you right now?

Yes No

What hurts on you right now? _____

Section B

Do you feel a little bit worse or a lot worse?

A little bit A lot

What hurts on you right now? _____

☐ **MD notified**

Section C

Does anything hurt on you right now?

Yes No

What hurts on you right now? _____

☐ **MD notified**

2. Faces Pain Scale-Revised reported score:

3. Wong-Baker FACES ® reported score:

Investigator Initials: _____ Date: _____

Appendix 4 – Caregiver Survey (Phase 2 Secondary Aim #2)

Part One

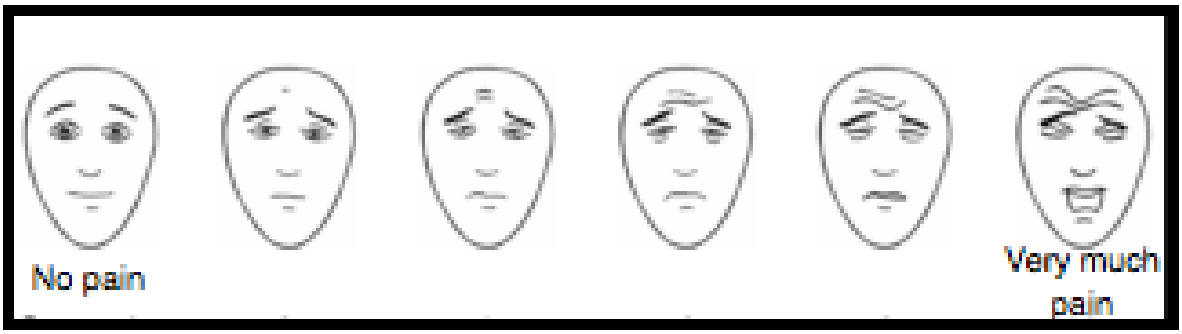
Thank you for agreeing to participate in this study of pain scales used in children. Your responses will help us make sure we are doing the best job we can to address your child's pain. Please do not ask your child about his/her pain while you answer these questions.

What do you believe is hurting on your child?

_____

These faces show how much something can hurt. The face on the far-left shows no pain. The faces show more and more pain up to the far-right. It shows very much pain.

Please circle the face that shows how much you think your child hurts right now.



Each face below is for a person who has no pain, or some, or a lot of pain. Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurts a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Please circle the face that represents your child's pain right now.

Investigator Initials: _____ Date: _____

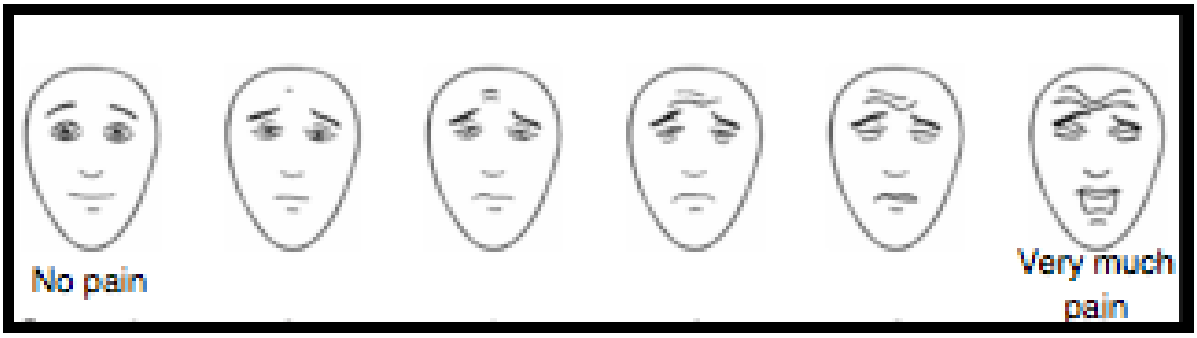
Part Two

Your child has received medications to help lessen his/her pain. Please answer the following questions about your child and his/her level of pain right now.

Please do not ask your child about his/her pain while you answer these questions.

These faces show how much something can hurt. The face on the far-left shows no pain. The faces show more and more pain up to the far-right. It shows very much pain.

Please circle the face that shows how much you think your child hurts right now.



Each face below is for a person who has no pain, or some, or a lot of pain. Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurts a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Please circle the face that represents your child's pain right now.

Investigator Initials: _____ Date: _____

Do you think your child is in less pain than when you last rated his/her pain in Part One?
(Circle your answer)

Yes No

If yes, what makes you believe his/her pain is less`?

_____

_____

If no, what makes you think his/her pain is not less?

_____

_____

Investigator Initials: _____ Date: _____

Part Three

If you do not feel that your child's pain has improved, please notify a provider at this time.

Please answer the following questions about your child's ability to report his/her pain.

Do you think that your child would understand the pain scales you used to rate his/her pain?

(Circle your answer)

Yes No

Do you think your child can accurately rate the level of his/her pain?

(Circle your answer)

Yes No

What do you think is the most painful experience your child has had up to this point?

_____

Has your child ever had surgery?

_____

Has your child ever had stiches?

_____

Has your child ever had a broken bone/fracture?

_____

References

1. von Baeyer C. Children's Self-Reports of Pain Intensity: Scale Selection, Limitations and Interpretation. Pain Research and Management. 2006;11(3):157-162. doi:10.1155/2006/197616.

2. Garra G, Singer A, Taira B et al. Validation of the Wong-Baker FACES Pain Rating Scale in Pediatric Emergency Department Patients. Academic Emergency Medicine. 2010;17(1):50-54. doi:10.1111/j.1553-2712.2009.00620.x.

3. Tomlinson D, von Baeyer C, Stinson J, Sung L. A Systematic Review of Faces Scales for the Self-report of Pain Intensity in Children. PEDIATRICS. 2010;126(5):e1168-e1198. doi:10.1542/peds.2010-1609.

4. Belville R, Seupaul R. Pain Measurement in Pediatric Emergency Care. Pediatric Emergency Care. 2005;21(2):90-93. doi:10.1097/01.pec.0000159051.26812.8b.

5. Stinson J, Kavanagh T, Yamada J, Gill N, Stevens B. Systematic review of the psychometric properties, interpretability and feasibility of self-report pain intensity measures for use in clinical trials in children and adolescents. Pain. 2006;125(1):143-157. doi:10.1016/j.pain.2006.05.006.

6. Besenski L, Forsyth S, von Baeyer C. Screening young children for their ability to use self-report pain scales. Pediatric Pain Letter. 2007;9(1):1-7.

7. Dierckx de Casterlé B, Gastmans C, Bryon E, Denier Y. QUAGOL: A guide for qualitative data analysis. International Journal of Nursing Studies. 2012;49(3):360-371. doi:10.1016/j.ijnurstu.2011.09.012.

8. American Pain Society. "Assessment and Management of Children with Chronic Pain: A Position Statement from the American Pain Society" 2012.

9. Belter R, McIntosh J, Finch Jr. A, Saylor C. Preschoolers' Ability to Differentiate Levels of Pain: Relative Efficacy of Three Self-Report Measures. Journal of Clinical Child Psychology. 1988;17(4):329-335. doi:10.1207/s15374424jccp1704.