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Data Article

Dataset used to refine a treatment protocol of a biofeedback-based virtual reality intervention for pain and anxiety in children and adolescents undergoing surgery

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ABSTRACT

There is a great need for nonpharmacologic pain management strategies, given the catastrophic effects of the opioid epidemic and the role of opioid prescription in precipitating addiction [1], particularly in children and adolescents at risk of chronic pain and opioid use after surgery [2–4]. Biofeedback-based virtual reality (VR-BF) is an innovative approach to managing pain that compliments and may even increase accessibility [5] and acceptability [6] of existing mind-body therapies for pain management, like biofeedback (BF). BF teaches patients behavioral modification techniques that impact involuntary processes [7,8]. For example, slow breathing increases heart rate variability (HRV) [9] to reduce pain through the downregulation of the sympathetic nervous system [10,11]. However, barriers to widespread use, such as

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(HRV), Heart rate variability
Acute postoperative pain
(VR), Virtual reality

the need for trained personnel and high costs of direct intervention, have hindered its widespread clinical use and access to this therapy [5,12]. VR-BF has not yet been integrated into perioperative care, and as such, no defined treatment protocols for preoperative training and postoperative application of VR-BF exist, particularly in children. The dataset presented in this article may help fill the unmet, critical need for accessible, effective, alternative therapeutic options for reducing postoperative pain and opioid exposure in children. This investigation aimed to establish measurable outcomes impacting a perioperative treatment protocol of VR-BF, a novel VR-based therapy that teaches patients relaxation techniques and monitors the sensitivity of heart rate variability (HRV) to different frequencies and durations of VR-BF sessions. Achievement of target physiological parameters, including HRV, was measured in children and adolescents undergoing surgery anticipated to cause moderate to severe pain (e.g., orthopedic, chest) requiring postoperative pain management by the Acute Pain Services at Nationwide Children's Hospital (NCH).

This dataset included 23 surgical patients evaluated quantitatively and qualitatively to refine a treatment protocol for the feasibility and acceptability of (a) preoperative education and training in relaxation, and (b) postoperative application of a VR-BF intervention for pain management [13]. Qualitative data was collected using an investigator-derived questionnaire to obtain feedback and understand the patient and family experience using VR-BF. Descriptive statistics (mean±SD or median with interquartile range [IQR] for continuous variables; frequencies and percentages for categorical variables) and exploratory spline regression analyses were generated to define measurable outcomes for a future pilot, randomized clinical trial protocol.

Specifications table

Subject:	Anesthesiology and Pain Medicine
Specific subject area:	Feasibility and acceptability of a biofeedback-based virtual reality intervention for postoperative pain and anxiety management in children and adolescents
Type of data:	Table, Figure
How the data were acquired:	The HeartMath program (https://www.heartmath.com/) consists of the Inner Balance device and mobile app to monitor and record patient physiological data, including session usage and heartrate variability (HRV) during sessions. Feedback on patient and parent experiences were obtained via investigator-derived questionnaires (Figs. 4-7). All data were transferred and stored in REDCap (https://www.project-redcap.org) for data management and analysis.
Data format:	Raw, Analyzed
Description of data collection:	Participants (12–18 years of age, inclusive) undergoing procedures known to cause moderate to severe pain with ≥ 1-night of postoperative hospital admission were instructed to complete daily, 10-minute VR-BF sessions for 7 days prior to surgery until up to 14 days after hospital discharge. Achievement of target HRV based on the frequency and duration of each VR-BF session was collected.

(*continued on next page*)

Data source location:	Nationwide Children's Hospital, Columbus, OH, United States
Data accessibility:	Repository name: Mendeley Data identification number: 10.17632/k7khzz7jr6.1 Direct URL to data: Dataset used to refine a treatment protocol of a biofeedback-based virtual reality intervention for pain and anxiety in children and adolescents undergoing surgery - Mendeley Data

Value of the data

- This data assesses a technique (VR-BF) that has the potential to reduce pain, anxiety, and opioid consumption in children after surgery.
- This data may support a technique that could benefit children and adolescents experiencing pain and/or anxiety associated with surgery or other contexts.
- This data provides the basis for investigating a technology that may benefit patients at higher risk of chronic pain and opioid use due to persistent postoperative pain and exposure in the perioperative period.
- This data could lead to further investigation of the effects of VR-BF on the reduction of postoperative pain, anxiety, and opioid consumption in other patient populations.
- This data could allow for future efficacy trials beyond the perioperative setting.

1. Objective

This dataset was generated to establish measurable outcomes for VR-BF, a novel pain management therapy, impacting a treatment protocol for preoperative education and training and postoperative application of VR-BF in the pediatric population. Additionally, this dataset includes responses to standardized questionnaires to obtain feedback and understand the patient's and family's experiences using VR-BF perioperatively for pain and anxiety reduction.

2. Data description

2.1. Patients

Table 1 describes the demographic and medical information, including the age, sex, race, ethnicity, length of hospital stay, surgery type, and American Society of Anesthesiologists (ASA) status of the 23 patients enrolled in this study. All patients received pain medications throughout their study participation. Any missing data resulting from challenges in patient adherence, including compliance to study protocol, experiencing pain and other negative symptoms due to the operation, and failure to reach patients, were accounted for in the analysis of this dataset.

2.2. VR-BF sessions

Table 2 illustrates the session usage and achievement of target HRV parameters during VR-BF sessions, separated by each (preoperative, postoperative, and home) and the combined (overall) perioperative periods. Descriptive statistics (mean±SD or median and min/IQR/max values for continuous variables; frequencies and percentages for categorical variables) were used for this dataset.

Figs. 1 and 2 depict the spline regression model on the effect of average session duration and the number of sessions, respectively, on the percentage of sessions achieving target parameters for 50% or more of session time.

Table 1
Participant demographic and medical data.

Variable	Value
Total number of participants, n	23
Age, years (SD)	15.5 (1.8)
Length of hospital stay, nights, median (IQR)	2 (1, 3)
Sex, n (%)	
Male	7 (30)
Female	16 (70)
Race, n (%)	
African American/Black	3 (13)
Caucasian/White	19 (83)
Asian	1 (4)
Ethnicity, n (%)	
Hispanic	1 (4)
Non-Hispanic	22 (96)
Surgery type, n (%)	
Abdominal	3 (13)
Bariatric	2 (9)
Chest	2 (9)
Colorectal	3 (13)
Orthopedic	12 (52)
Urology	1 (4)
ASA Status, n (%)	
I/II (healthy, mild systemic disease)	14 (61)
III/IV (severe or life-threatening disease)	9 (39)

ASA: American Society of Anesthesiologists; SD: standard deviation; IQR: interquartile range.

Table 2
Descriptive data on patient participation and achievement of target parameters using the Mindfulness Aurora VR application and the HeartMath Inner Balance device during the preoperative, postoperative, and at-home periods (total enrolled patients, $n = 23$).

Characteristic	Preop	Postop	Home	Overall
Number of patients completing ≥1 session(s), n (%)	20 (87)	16 (70)	10 (43)	21 (91)
Number of sessions, median (IQR)	6 (4, 7)	2 (1, 2.5)	2.5 (2, 4)	9 (6, 10)
Average session duration, minutes, mean (SD)	9.6 (2.3)	9.5 (2.3)	9.2 (1.9)	9.5 (1.9)
Percentage of sessions maintaining target parameters for ≥50% of session time,%, median (IQR)	100 (86, 100)	83 (42, 100)	92 (50, 100)	89 (67, 100)
Number of patients achieving target parameters for ≥50% of session time for >1 session(s), n (%)	19 (95)	13 (81)	8 (80)	20 (95)
Session number when target parameters were first achieved by patient for ≥50% of session time, median (IQR) / (min, max)	1 (1, 1) (1, 4)	1 (1, 1) (1, 3)	1 (1, 1.5) (1, 2)	1 (1, 1) (1, 4)

SD: standard deviation; IQR: interquartile range.

2.3. Patient experience

Figs. 3-8 visually describe the questionnaire items and responses related to the acceptability of the VR-BF intervention. A total of 20 (87%) patients and 19 (83%) family members completed the survey.

3. Experimental design, materials, and methods

This prospective, single-center study aimed to refine a treatment protocol for preoperative education and training and postoperative application of VR-BF for a future efficacy trial assessing the use of VR-BF to reduce pain, anxiety, and opioid consumption in children and adolescents

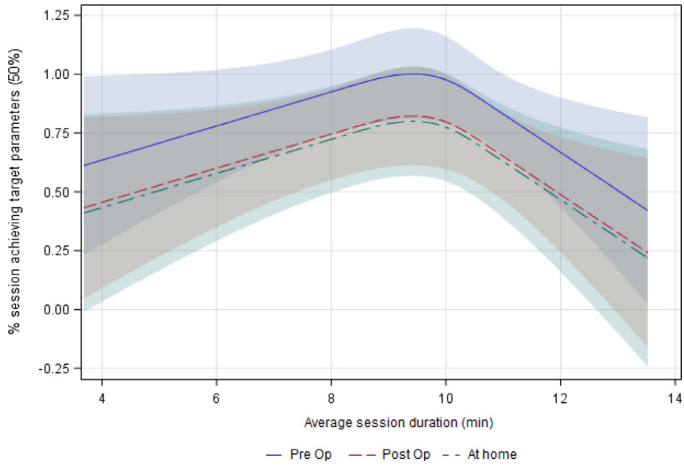

Fig. 1. Spline fit of average session duration and% sessions achieving target parameters (with 95% confidence limits). Nonlinear regression was used to examine the impact of average session duration (modeled using restricted cubic splines with 3 knots placed at equally spaced percentiles) on% sessions achieving target parameters while adjusting for preoperative, postoperative, or home use. Random participant effect was inlcuded in the models when significant.

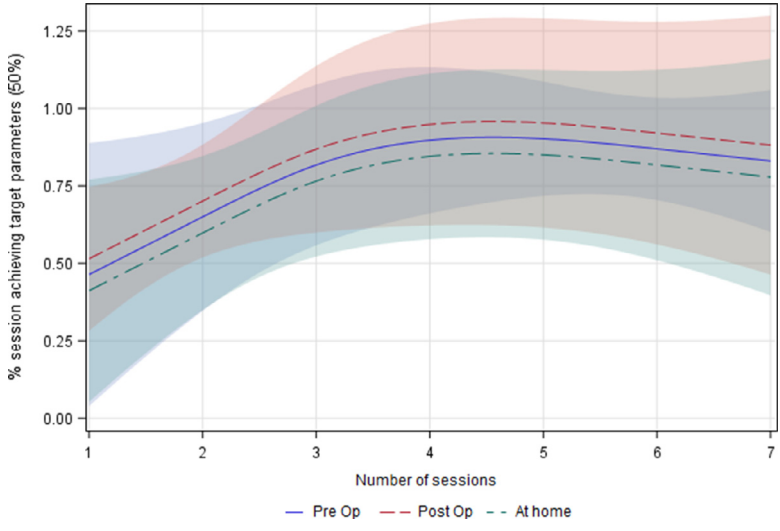

Fig. 2. Spline fit of the number of sessions and% sessions achieving target parameters (with 95% confidence limits). Nonlinear regression was used to examine the impact of average session duration (modeled using restricted cubic splines with 3 knots placed at equally spaced percentiles) on% sessions achieving target parameters while adjusting for preoperative, postoperative, or home use. Random participant effect was inlcuded in the models when significant.

after surgery. The secondary aim was to obtain qualitative feedback to better understand the patient and family experience with VR-BF therapy.

Preoperative education and training. Participants received a scripted tutorial given virtually or in person by research staff on the study procedures, materials, and benefits of BF up to 2 weeks before surgery. They were instructed to practice using VR-BF prior to surgery by undergoing a daily, 10-minute session for 7 days prior to surgery (a total of 7 sessions).

Postoperative application. Participants were asked to complete, at minimum, one daily, 10-minute session(s) during their inpatient admission after surgery. During the postoperative pe-

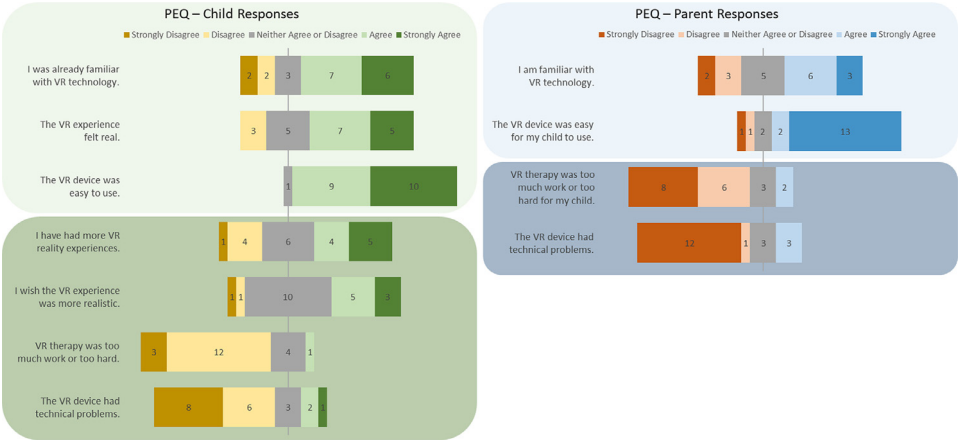

Fig. 3. Stacked bar plot of patient and parent responses to VR content and usability questionnaire items. PEQ, Patient Experience Questionnaire; VR, virtual reality. The vertical reference line indicates the response of 'Neither Agree or Disagree'. The overall length of the bar corresponds to the number of patients completing each question. The length of the sub-bars corresponds to the frequency of each response.

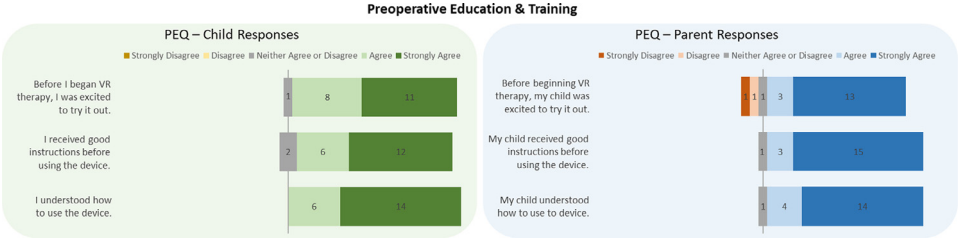

Fig. 4. Stacked bar plot of patient and parent responses to preoperative education and training questionnaire items. The vertical reference line indicates the response of 'Neither Agree or Disagree'. The overall length of the bar corresponds to the number of patients completing each question. The length of the sub-bars corresponds to the frequency of each response.

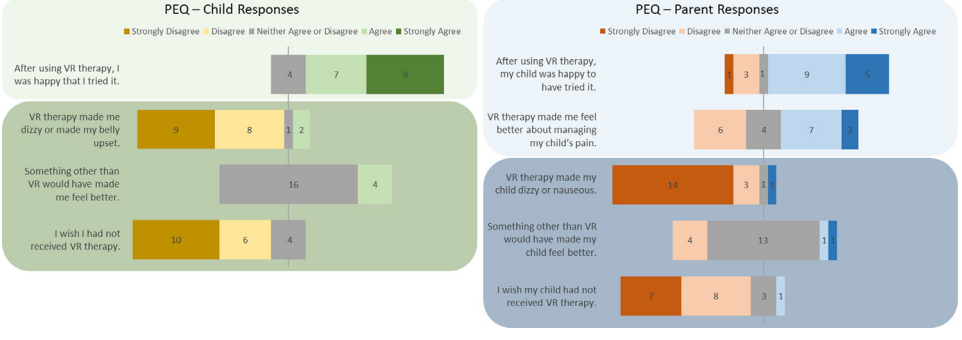

Fig. 5. Stacked bar plot of patient and parent responses to postoperative application questionnaire items. The vertical reference line indicates the response of 'Neither Agree or Disagree'. The overall length of the bar corresponds to the number of patients completing each question. The length of the sub-bars corresponds to the frequency of each response.

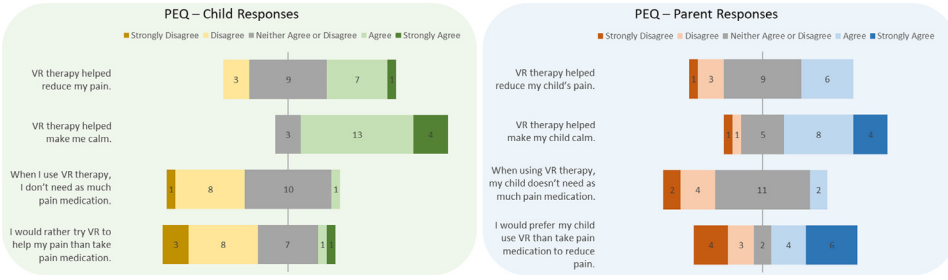

Fig. 6. Stacked bar plot of patient and parent responses to perceived benefits of VR-BF questionnaire items. The vertical reference line indicates the response of 'Neither Agree or Disagree'. The overall length of the bar corresponds to the number of patients completing each question. The length of the sub-bars corresponds to the frequency of each response.

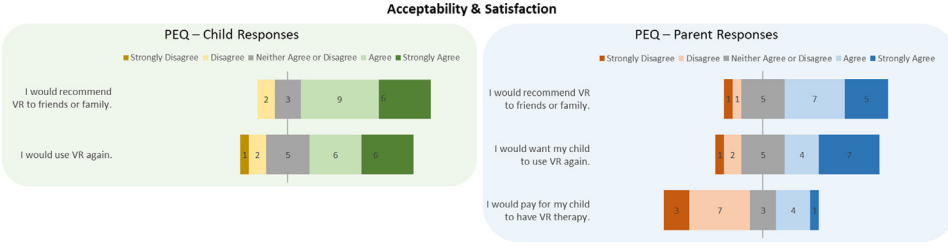

Fig. 7. Stacked bar plot of patient and parent responses to acceptability and satisfaction of VR-BF questionnaire items. The vertical reference line indicates the response of 'Neither Agree or Disagree'. The overall length of the bar corresponds to the number of patients completing each question. The length of the sub-bars corresponds to the frequency of each response.

Fig. 8. Stacked bar plot of patient and parent responses to other questionnaire items. The vertical reference line indicates the response of 'Neither Agree or Disagree'. The overall length of the bar corresponds to the number of patients completing each question. The length of the sub-bars corresponds to the frequency of each response.

riod, they were instructed to freely use VR-BF, particularly when in pain, with the option to continue VR-BF therapy at home for up to 14 days following hospital discharge. While admitted to the hospital, participants were visited by a study coordinator as needed to assist with any technology or use issues.

3.1. Patients

A total of 23 patients were recruited between March 2022 and September 2022 using purposive sampling to establish a representative patient group according to age, sex, and race. A written informed consent (and assent for patients under age 18) was obtained from all patients prior to study participation. Each participant was compensated up to $100 for study completion and return of the equipment.

Patients were screened for eligibility through patient lists provided by surgical schedulers and identified for recruitment when scheduled for surgeries that required postoperative pain management by the Acute Pain Service. Eligibility criteria were as follows:

Inclusion criteria. (a) 12–18 years-old, inclusive; (b) able to read, understand, and speak English; (c) scheduled to undergo surgery at NCH anticipated to cause moderate to severe pain that required $\geq$1 night in the hospital post-op; (d) required postoperative pain management by the Acute Pain Service; (e) own or have access to a mobile device or computer.

Exclusion criteria. (a) $<$12 or $>$18 years old; (b) non-English speaking; (c) history of significant developmental delay, psychiatric conditions associated with hallucinations or delusions, or significant neurological disease including epilepsy or seizure disorders; (d) history of significant motion sickness; (e) history of chronic pain; (f) chronic opioid or benzodiazepine use for the management of pain; (g) actively experiencing nausea or vomiting; (h) any conditions that preclude their ability to use the virtual reality (VR) headset, such as craniofacial abnormalities or surgeries of the head and neck; (i) previous participation in this study.

3.2. Measures

HRV. HRV was measured using the HeartMath biofeedback system. HRV, typically depicted as a sine wave on a graph, is the cyclic acceleration of heart rate during periods of inhalation and the subsequent deacceleration during exhalation [14]. The HeartMath system developed a model for analyzing the strength of how sine-wave-like a patient's HRV pattern is into low (poor), medium, and high (good) levels of coherence during a session. HeartMath defines high coherence as an ordered and stable pattern of the heart's input to the brain that facilitates cognitive function and reinforces positive feelings and emotional stability, which is associated with parasympathetic nervous system activity or a rest and digest state. Within a single session, the proportion of session time a patient spends performing under one of the 3 coherence levels is described as a coherence ratio.

In this study, a high coherence ratio of 50% of session time was set as the target parameter. The frequency and duration of sessions needed for patients to achieve target HRV parameters were assessed to define a treatment protocol for perioperative VR-BF use.

Patient experience. At the final study visit, participants completed an investigator-derived survey inquiring the extent to which they agreed or disagreed with a series of statements, each pertaining to one of 5 domains of the VR-BF experience: (a) VR content and usability; (b) preoperative education and training; (c) postoperative utilization; (d) perceived efficacy on pain reduction; and (e) acceptability and satisfaction. Responses to each questionnaire item were rated on a 5-point Likert scale of "strongly agree," "agree," "neither agree nor disagree," "disagree," or "strongly disagree." Primary caregivers were also asked to complete a similar survey about their perception and satisfaction with their child's use and experience with VR-BF.

This qualitative information, along with quantitative data on patient sensitivity to changes in HRV, allowed us to refine VR-BF dosing (e.g., frequency and duration of the VR experience) for each perioperative phase and better understand the feasibility and acceptability of VR-BF therapy in children and adolescents undergoing surgery.

3.3. Study materials

Research Electronic Data Capture (REDCap) database. A meta-driven electronic data capture software (UL1TR001425) for designing and managing research databases was used to distribute patient surveys and logs, including obtaining e-consent approved by the IRB. After each session, patients completed daily logs recording their VR-BF usage (date, time, duration).

VR headset. All participants were given the commercially available Meta Quest 2 VR headset, a non-invasive device widely used for entertainment, to deliver the untethered VR content described below. The FDA does not regulate this VR headset, as it is considered a gaming device

and poses minimal risk to users. Audio capabilities are built into the headset to deliver instructions and application sounds to enhance the sense of presence during VR-BF sessions. Before and after participant use, each device was thoroughly cleaned per infection control standards and underwent further cleaning under ultraviolet light.

VR content. Participants were instructed to use *Mindfulness Aurora* (Stanford Chariot Program, Stanford, CA), an application that transports patients to an alpine meadow as it transitions from day to night. This application provides participants with a 10-minute immersive experience in a 3D natural environment and a tool to learn relaxation techniques with the help of visual and audio instructions to mimic their rate of breathing with slow, paced changes in the virtual world around them as the scene shifts from day to night (e.g., floating butterflies, northern lights).

HeartMath. Participants used the HeartMath Inner Balance device to measure and record HRV coherence during sessions. This device uses Bluetooth capabilities or plugs directly into participants' smartphones and then operates from a corresponding app. The program stores patient use and performance information for each session into HeartCloud, a data storage platform easily accessible by the research team using the emWave Pro-software. This heart-rate monitoring system, along with other HeartMath programs, is commercially available and widely used to teach BF to patients. HeartMath products are well validated and have been used in over 400 peer-reviewed publications.

Ethics statements

This research was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving human subjects and adhered to the CONSORT (Consolidated Standards of Reporting Trials) guidelines. The protocol was approved by the Institutional Review Board (IRB #STUDY00002080) at NCH and was registered on ClinicalTrials.gov on 17 May 2021 (NCT04943874). This study was no more than minimal risk, and a HIPAA-compliant informed consent (and assent for patients $<$18 years) was obtained from each participant.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Dataset used to refine a treatment protocol of a biofeedback-based virtual reality intervention for pain and anxiety in children and adolescents undergoing surgery (Original data) (Mendeley Data)

CRediT Author Statement

Zandantsetseg Orgil: Writing – original draft, Investigation, Resources, Data curation, Visualization, Project administration; **Anitra Karthic:** Data curation, Writing – review & editing; **Nora Bell:** Writing – review & editing; **Sara E Williams:** Conceptualization, Methodology, Writing – review & editing; **Lili Ding:** Formal analysis, Writing – review & editing; **Susmita Kashikar-Zuck:** Conceptualization, Methodology, Writing – review & editing; **Christopher D. King:** Conceptualization, Methodology, Writing – review & editing; **Vanessa A. Olbrecht:** Funding acquisition, Conceptualization, Methodology, Resources, Supervision, Project administration, Writing – review & editing.

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