Milking of the Cut Cord During Stabilization of Infants Born Very Premature: A Randomized Controlled Trial

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Objective To investigate the feasibility of cut-umbilical cord milking (C-UCM) during stabilization of preterm infants after birth.

Study design This was a pilot randomized controlled trial of initial resuscitation. Infants born to eligible, consenting women presenting in preterm labor at <32 weeks' gestation were randomized to receive either the standard practice of deferred cord clamping (DCC) for 30-60 seconds at birth or C-UCM while supporting breathing and following 30 seconds of DCC. The primary outcome was feasibility in terms of percentage recruitment, intervention compliance, safety, and study completion. Short-term clinical outcomes were collected. Analysis was by intention to treat.

Results Of the 133 pregnant women approached, 93 consented to participate (70%). Fifty infants delivered <32 weeks' gestation were randomized to either C-UCM (25) or DCC (25). Baseline characteristics of infants were similar. All participants completed the study. One infant in the C-UCM group and 5 infants in the DCC group did not receive the allocated intervention. Median (IQR) time to cord milking was 62 (54, 99) seconds and median (IQR) length of the cut-cord milked was 20 (14, 29) cm. C-UCM was not associated with increased adverse effects compared with DCC.

Conclusion Milking of the long-cut cord after 30 seconds of DCC while supporting breathing was feasible and not associated with significant adverse effects. A larger randomized controlled trial is required to assess the efficacy and safety of this approach on clinical outcomes. C-UCM may be especially useful in situations when DCC is not feasible.

Trial registration ClinicalTrials.gov: NCT03852134. *(J Pediatr 2025;278:114444)*.

Deferred cord clamping (DCC) for at least 30-60 seconds after birth has been recommended as the standard of care for most infants born preterm.[1-3] Placental transfusion through DCC increases hematocrit levels, reduces the need for blood transfusion and, most importantly, decreases mortality in infants born preterm.[4,5] However, DCC may not always be feasible or optimal; the practice is contraindicated in cases of interrupted placental circulation (placental abruption, bleeding placenta previa, or cord avulsion).[1-3] Concerns over delaying resuscitation when DCC is practiced can lead to noncompliance.[6] In addition, whether DCC is the best umbilical cord management practice for infants born preterm who are not vigorous or depressed at birth remains unclear.[1-3] In such cases, the Neonatal Resuscitation Program (NRP) recommends a brief period of DCC whilst undertaking initial resuscitation steps: stimulation, providing warmth, and suction by the obstetric provider before clamping the cord.[3] Establishing breathing and pulmonary circulation during blood transfusion by DCC is a key determinant for effective placental transfusion and for a smooth physiological transition from fetal to postnatal circulation.[7-11]

Intact-umbilical cord milking is a potential substitute to DCC and a quicker method of placental transfusion. Its implementation has been limited by physiological concerns derived from animal studies showing fluctuations in the carotid blood flow and pressure, and clinical human data noting increased

DCC	Deferred cord clamping
C-UCM	Cut-umbilical cord milking
NICU	Neonatal Intensive Care Unit
PDA	Patent Ductus Arteriosus
IVH	Intraventricular hemorrhage
BPD	Bronchopulmonary dysplasia
NEC	Necrotizing enterocolitis
ROP	Retinopathy of prematurity

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rates of severe intracranial hemorrhage in infants born extremely preterm.[12-14] Cut-umbilical cord milking (C-UCM), on the other hand, has been proposed as an alternative when DCC is not feasible. A potential advantage of C-UCM is the ability to coordinate the blood transfusion to the infant with the establishment of breathing and pulmonary circulation in order to achieve a smooth physiological cardiovascular and respiratory transition.[15-17] Hosono et al estimated the amount of blood transfused to the infant born extremely preterm from one time milking of the long cut-cord segment (around 20 cm) to be 18 mL/kg.[18] Studies in infants born at term and those born moderately preterm reported improved hemoglobin and iron stores at 6 weeks of age after receiving C-UCM compared with early cord clamping (ECC).[19,20] Potential concerns with C-UCM include insufficient volumes of placental transfusion, and hemodynamic instability if cord milking is performed at a fast pace. Nevertheless, there is paucity of literature about the role of C-UCM as a possible alternative to DCC during stabilization of infants born very preterm when DCC is not feasible. This lower gestational age group is potentially the most likely group to benefit from C-UCM as these infants are often non-vigorous at birth and frequently need blood transfusions postnatally. The need for further research on C-UCM was identified among the gaps in knowledge in cord management practices of infants born preterm by the International Liaison Committee on Resuscitation (ILCOR).[21]

The objective of this study was to investigate the feasibility of C-UCM during resuscitation/stabilization of infants born very preterm following 30 seconds of DCC (to allow the obstetric provider to administer the initial resuscitation steps with the cord intact) compared with the standard practice of DCC at birth. Feasibility included recruitment percentage, intervention compliance, and study completion. We hypothesized that C-UCM during resuscitation/stabilization of infants born very preterm would be feasible and safe compared with DCC.

Methods

This pilot parallel group randomized controlled trial was conducted in Halifax, Canada, at IWK Health, a tertiary care perinatal center with approximately 5000 births per year. The neonatal intensive care unit (NICU) is a tertiary care unit with around 900 annual admissions. The study was approved by the IWK Health Research Ethics Board. Written informed consent was obtained antenatally from all women participating. The trial was registered at ClinicalTrials.gov (NCT03852134).

Eligible women, presenting in preterm labor between 23^{+0} and 32^{+0} weeks of gestation, were approached to participate in the study. Infants born very preterm were randomized to receive either C-UCM (intervention group) or DCC (control group). Exclusion criteria included clinical evidence of interrupted placental circulation (placental abruption, avulsed cord, or bleeding placenta previa), monochorionic twins or higher order multiple pregnancy, major fetal congenital or chromosomal anomalies, fetal anemia, and intent to withhold active treatment of the infant.

Consenting eligible mothers were randomized prior to delivery once preterm labor was considered inevitable. Randomization was done in variable block sizes, concealed by opaque envelopes, prepared in advance using R statistical software (*blockrand* package, R Foundation for Statistical Computing). Envelopes were opened just before delivery by the neonatal resuscitation nurse who informed the obstetric provider about the study intervention. Each enrolled infant was assigned to the next sealed opaque envelope from the study kit. Dichorionic twins had the same assignment. Stratification was used for gestational age (23^{+0} to 27^{+6} and 28^{+0} to 31^{+6} weeks). A log was maintained to ensure commitment to randomized allocation.

Study Procedures

All neonatal and obstetrical care providers were oriented before the study began to achieve consistency in study procedures.

C-UCM (Intervention) Group. Infants were positioned at or below the level of the placenta, placed in a plastic bag for warmth, and stimulated to breathe by the obstetric provider for the first 30 seconds while the cord was still attached to placenta. The mouth and nose were suctioned if needed as per standard NRP practice. The obstetrician then clamped and cut the cord about 5 cm from the introitus (in vaginal deliveries) or from the abdominal incision (in cesarean deliveries) before handing the infant with the long-cut cord segment over to the neonatal team to continue resuscitation and stabilization of the infant. The neonatal team provided stabilization as per standard NRP practice. While the infant was breathing, either spontaneously or with positive pressure ventilation, one member of the neonatal team untwisted the long-cut cord and milked it slowly one time from the clamped end toward the infant over 10 seconds before clamping and cutting the cord 1-2 cm from the umbilicus.

DCC (Control) Group. Infants were treated the same as the C-UCM group in the first 30 seconds. If the infant was breathing after these initial 30 seconds, the obstetrician waited for 30 more seconds before clamping and cutting the cord close to the umbilicus. If the infant was not breathing after the initial 30 seconds of DCC, the obstetrician clamped and cut the cord close to the umbilicus. After the cord was cut, infants were handed over to the neonatal team to continue resuscitation as per standard NRP practice.

Maternal and perinatal data, as well as neonatal clinical information, were prospectively collected during infant's hospital stay. All study infants received bedside echocardiography at 12-24 hours of age as part of hemodynamic assessment to ensure safety of study interventions (results for these outcomes will be reported separately).

Study Outcomes

The primary outcomes related to the feasibility of the new approach of C-UCM were percentage recruitment and

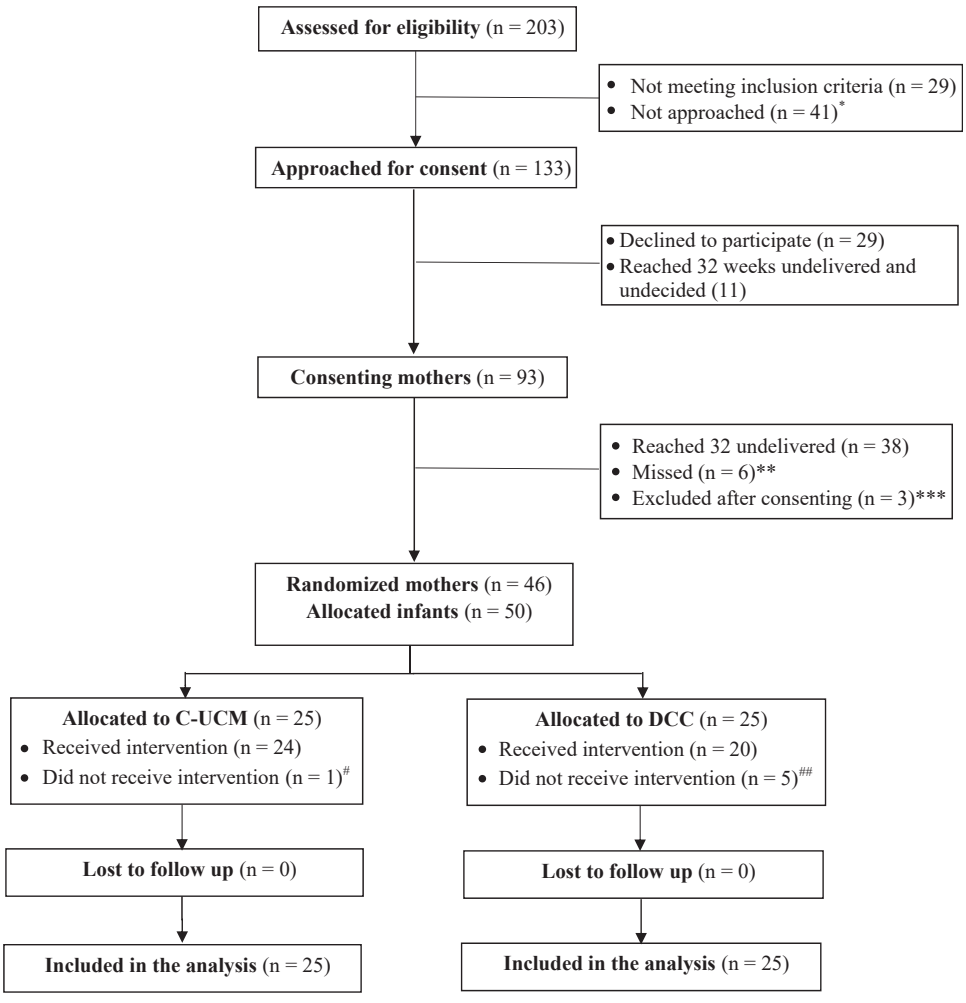
intervention compliance. Secondary outcomes included intervention's safety (rates of potential adverse events as hyperbilirubinemia, hyperkalemia, polycythemia, and intraventricular hemorrhage (IVH)) and study completion. Hemoglobin concentration on NICU admission and short-term clinical outcomes were also collected.

All infants were carefully monitored as part of the routine NICU care. Hemodynamic stability was assessed clinically and with bedside echocardiography in the first 24 hours after birth. Adverse effects that could relate to placental transfusion such as polycythemia, hyperbilirubinemia, and hyperkalemia were also monitored. To assess for IVH, head ultrasounds were conducted at 3, 14, and 42 postnatal days and at term-equivalent postmenstrual age. Additional studies were conducted if there was a need for more frequent monitoring.

Sample Size and Statistical Analysis

As this was a pilot study to assess the feasibility of C-UCM, the sample size was either 98 infants or the number that could be recruited in a 2 year-period (based on our unit's expected annual rate of admission), whichever came first. This would allow us to estimate the important elements of feasibility (ie, recruitment, intervention compliance, safety, study completion), and the parameters needed to perform an accurate sample size calculation for a future large-scale multicenter trial.

Differences between groups in maternal and infant characteristics were tested using the Wilcoxon rank sum test for



*Missed: Consented but not randomized; 5 precipitous deliveries plus 1 missed by staff.
**Not approached because of precipitous deliveries, parental stress, or staff too busy.
*** excluded after consenting because of placental abruption at delivery.
#Cord was cut short for lack of communication.
4 Early cord clamping for being non-vigorous and 1 received milking of the attached cord for being non-vigorous at birth.

Figure. CONSORT flow diagram.

Table I. Maternal and infant baseline characteristics

Characteristic	C-UCM (n = 25)	DCC (n = 25)
Maternal age in ys, mean (SD)	30.4 (5.3)	32.7 (5.7)
Diabetes, n (%)	4 (16)	6 (24)
Hypertension, n (%)	12 (48)	8 (32)
Pre-eclampsia, n (%)	11 (44)	6 (24)
Multiple pregnancies, n (%)	4 (16)	4 (16)
Antenatal steroids, n (%)	24 (96)	25 (100)
Magnesium sulfate, n (%)	25 (100)	23 (92)
Rupture of membranes >18 hrs, n (%)	6 (24)	6 (24)
Clinical chorioamnionitis, n (%)	3 (12)	7 (28)
Vaginal deliveries, n (%)	9 (36)	10 (40)
Gestational age in wks, mean (SD)	28.7 (2.7)	28.9 (2.5)
Males, n (%)	10 (40)	17 (68)
Small for gestational age, n (%)	1 (4)	3 (12)
Birth weight in grams, mean (SD)	1222 (508)	1258 (466)
Arterial cord pH, median (IQR)	7.26 (7.23, 7.27)	7.26 (7.22, 7.28)
Arterial cord HCO_3, median (IQR)	23.1 (22.0, 25.6)	24.4 (21.2, 25.3)
Apgar score at 1 min, median (IQR)	5 (3, 8)	5 (3, 7)
Time to first breath, n (%)		
<30 s	13 (52)	15 (60)
30-60 s	3 (12)	4 (16)
>60 s	9 (36)	6 (24)

continuous variables, Pearson's Chi-squared test for categorical variables with all expected counts greater than or equal to 5, and Fisher's exact test for categorical variables with any expected cell counts less than 5. Clustering was not accounted for in tests of differences in maternal or infant characteristics. Continuous outcomes were analyzed using ordinary least squares, binary outcomes with logistic regression, and categorical outcomes with a multinomial logistic regression. In the primary analysis, treatment effects were conditional on gestational age which was entered as a linear main effect (on the linear predictor scale) to allow for increased precision. Unadjusted models were provided for context. No analyses were conducted when one or both groups either all had an event or no event for binary outcomes. All models accounted for the potential effects of clustering within twins by using a clustered Bayesian bootstrap estimate of the variance-covariance matrix. Marginal risk differences and their CIs from logistic/multinomial models were estimated by standardization as implemented in the marginal effects package. All analyses were conducted using R software.[22] Analysis was by intention to treat.

Results

We assessed 203 mothers for eligibility during the 2-year study period (February 2019 to August 2021). The study was suspended due to the COVID-19 pandemic for about 6 months and the rate of admission of infants born very preterm dropped during the whole study period. In total, 93 out of 133 approached eligible mothers consented to participate (70%). Fifty fetuses (46 women) were enrolled and randomized: 25 to the C-UCM group and 25 to the DCC group (**Figure**). Maternal and perinatal baseline characteristics were similar (**Table I**). All infants completed the study. One infant in the C-UCM group did not receive the allocated intervention after the cord was cut short due to miscommunication (96% compliance rate). Due to being nonvigorous at birth, 5 infants in the DCC group did not receive the allocated intervention; 4 received ECC, and one received milking of the attached cord (80% compliance rate). All study infants were analyzed within the group to which they were randomized.

The mean (SD) time to cord clamping was 33 (9) and 39 (20) seconds in C-UCM and DCC groups respectively. For the C-UCM group, the median (IQR) time to cord milking was 62 (54, 99) seconds and median (IQR) length of the milked cut-cord was 20 (14, 29) cm.

Outcomes at birth and during hospital stay were generally similar between both groups (**Tables II** and **III**). Milking of the cut cord during stabilization of infants after birth was not associated with adverse effects compared with DCC. Infants in the C-UCM group had lower admission mean blood pressure but a similar proportion was diagnosed with hypotension within the first 72 hours (4.0% vs 8.3% in the DCC group; *P*-value .20).

Discussion

In this feasibility study of infants born very preterm, slow milking of the long-cut umbilical cord while supporting breathing after 30 seconds of DCC was found to be feasible and not associated with significant adverse effects compared with the standard practice of DCC. The parental consent rate for the study was 70% and the compliance of maternity and neonatal

Table II. Outcomes at birth

Outcome	C-UCM (n = 25)	DCC (n = 25)	*Mean/risk difference (95% CI)
Apgar score at 5 min, median (IQR)	8 (6, 8)	8 (6, 9)	−0.2 (−1.2 to 0.8)
Positive pressure ventilation, n (%)	15 (60)	15 (60)	0.0 (−0.2 to 0.2)
N-CPAP in delivery room, n (%)	21 (84)	23 (92)	−0.1 (−0.2 to 0.1)
Intubation at birth, n (%)	6 (24)	5 (20)	0.02 (−0.2 to 0.2)
Chest compression, n (%)	3 (12)	2 (8)	0.02 (−0.2 to 0.2)
Epinephrine, n (%)	2 (8)	2 (8)	−0.02 (−0.2 to 0.1)
Volume expander, n (%)	0 (0)	0 (0)	0.0 (–)

IQR, interquartile range; *N-CPAP*, nasal continuous positive airway pressure.
*Adjusted models include linear term for gestational age.

Table III. Clinical outcomes during hospital stay

Outcome	C-UCM (n = 25)	DCC (n = 25)	*Mean/Risk difference (95% CI)
Admission temperature in Celsius, median (IQR)	37.0 (36.7, 37.3)	37.0 (36.7, 37.2)	0.1 (−0.2 to 0.4)
Admission mean blood pressure in mmHg, mean (SD)	40 (8)	46 (10)	−6.2 (−11.2 to −1.2)
Admission hemoglobin in g/dL, mean (SD)	168 (26)	167 (25)	3.7 (−8.3 to 15.6)
CRIB II score, median (IQR)	6 (4, 10)	5 (3, 9)	0.8 (−0.5 to 2.0)
Hypotension in first 72 hrs, n/N (%)	1/25 (4.0)	2/24 (8.3)	−0.1 (−0.3 to 0.1)
Peak serum bilirubin in mmol/L, median (IQR)	154 (130, 171)	155 (126, 173)	−3.1 (−18 to 12)
Phototherapy, n/N (%)	25/25 (100)	24/25 (96)	4.0 (−3.7 to 11.7)
Duration of phototherapy in hrs, median (IQR)	69 (39, 101)	87 (51, 115)	−15.5 (−47 to 16)
Polycythemia (hematocrit>0.65), n/N (%)	2/25 (8.0)	1/24 (4.2)	0.04 (−0.11 to 0.2)
Hyperkalemia (K > 7 mmol/L), n (%)	4/25 (16)	3/24 (12)	0.01 (−0.2 to 0.2)
Blood transfusion during hospital stay, n/N (%)	4/25 (16)	5/25 (20)	−0.1 (−0.2 to 0.1)
Necrotizing enterocolitis (confirmed), n/N (%)	1/23 (4.3)	0/24 (0)	4.3 (−4.0 to 12.7)
BPD (02 at 36 wks' gestational age), n/N (%)	3/19 (16)	4/19 (21)	17.9 (−160 to 195)
IVH, n/N (%)	8/25 (32)	5/24 (21)	0.11 (−0.1 to 0.4)
Grade III and IV IVH or PVL, n/N (%)	1/25 (4.0)	1/24 (4.2)	0 (−0.1 to 0.1)
Late-onset sepsis, n/N (%)	2/23 (8.7)	2/21 (9.5)	−0.02 (−0.2 to 0.2)
ROP, stage 3 or treated, n/N (%)	0/21 (0)	0/21 (0)	0.0 (−)
Patent ductus arteriosus (medically treated), n/N (%)	6/25 (24)	3/25 (12)	0.1 (−0.1 to 0.3)
Mortality, n/N (%)	2/25 (8.0)	2/25 (8.0)	0.0 (−0.1 to 0.1)

BPD, bronchopulmonary dysplasia; *CRIB*, clinical risk index for babies; *IQR*, interquartile range; *IVH*, intraventricular hemorrhage; *PVL*, periventricular leukomalacia; *ROP*, retinopathy of prematurity.
*Adjusted models include linear term for gestational age.

providers to C-UCM was 96% compared with 80% in the DCC group. Only one infant in the C-UCM group (4%) missed the intervention because of miscommunication. This supports the feasibility and easy applicability of C-UCM by both obstetric and neonatal care providers and presents it as a practical alternative for cord management in infants born very preterm.

The higher noncompliance to the standard DCC (20%) was mainly related to birth depression and the concern of delaying resuscitation. This perception has been the main reason for nonadherence to DCC in literature. A noncompliance rate of 27% for DCC for 60 seconds was reported in the largest study in the literature in infants born very preterm.[6]

In our study, 48% of infants in the C-UCM group and 40% of infants in the DCC group were nonvigorous at birth and received respiratory support after 30 seconds of DCC. There are few options for cord management of infants born preterm who require resuscitation at birth. Although resuscitation with the intact cord is gaining interest as a promising physiologically-sound alternative, the practice needs additional training and resources. In addition, it does not address situations when DCC is contraindicated (as in interrupted placental circulation).[2,23-26] Although animal data are encouraging, clinical benefits in human infants born preterm are still to be demonstrated.[7,21,27,28] The other alternative, intact umbilical cord milking that was favored to ECC in nonvigorous infants >35 weeks' gestation,[29] is not recommended in infants born extremely preterm after animal studies raised concerns about its physiological appropriateness and clinical trials in humans showing increased rate of severe IVH in infants born extremely preterm.[12-14]

Two recent small randomized controlled trials from India compared C-UCM with ECC in infants born preterm who required resuscitation at birth and found increased hemoglobin and ferritin levels in the C-UCM group with no adverse effects related to C-UCM. However, their technique of providing C-UCM was different from our study as they milked the cut-cord 3 times over about 6 seconds regardless of the establishment of breathing and their study samples were of higher gestational age (>30 weeks).[20,30] In our study, we tried to avoid the physiological concerns related to the fast delivery of a large volume of blood to the circulation of infants born preterm (as in intact umbilical cord milking), especially when breathing and pulmonary circulation are not yet established. Our study intervention allowed for brief DCC while providing initial resuscitation steps by the obstetric provider (warming, stimulating to breathe), giving the infant an opportunity to start breathing. If not, the blood was squeezed from the long cut-cord segment slowly to the infant after supporting breathing to facilitate a normal transition physiology.

We acknowledge that C-UCM may not be as physiologically equivalent to DCC, but the intervention we propose might be superior to ECC and I-UCM when DCC cannot be practiced.

To our knowledge, our study is the first to address the feasibility of slow C-UCM during stabilization of infants born very preterm after brief DCC in comparison with standard DCC practice. The technique used was found to be feasible, practical, and, without increased adverse events (although a larger study is required to confirm safety). The study was not designed to compare the effectiveness of C-UCM to DCC and it does not address the long-term safety or benefits of the intervention. The generalizability of the findings may be limited by the tertiary care setting and the sample studied. The antenatal consenting in our study was convenient for the parents though it could have affected the representativeness of the study sample (emergency/sicker patients may not have time for consenting). An alternative approach for such resuscitation trials would be waiving or delaying the consent as used by others.[29] Despite being a simple intervention, C-UCM still requires some training of both obstetric and neonatal teams.

Milking of the long-cut cord for one time after 30 seconds of DCC whilst supporting breathing was feasible and was not associated with significant adverse effects in infants born very

preterm. A large randomized controlled trial is required to assess the efficacy and safety of this approach on clinical outcomes. C-UCM may be especially useful in situations when DCC is not feasible and/or when immediate clamping is indicated. ■

CRediT authorship contribution statement

Walid El-Naggar: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Souvik Mitra:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition. **Jayani Abeysekera:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation. **Tim Disher:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Christy Woolcott:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Conceptualization. **Tara Hatfield:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Formal analysis, Data curation. **Douglas McMillan:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Conceptualization. **Jon Dorling:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of Competing Interest

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Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

The authors did not use AI during the preparation of this work. They take full responsibility for the content of the publication.

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Data Statement

Data sharing statement available at www.jpeds.com.

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