SUPPORTING JUSTIFICATION – Part B

Child Strength Study Funded by CPSC

1. BACKGROUND

The methodology and test fixtures for the proposed study are informed by those used in previous studies of the strength capabilities of children, described below.

Exertions with Hands and Feet

Brown, Buchanan, and Mandel (1973, 1974) conducted a study of strength capabilities of children ages 2 through 6 years. The intent was to develop standards for toys and products. Two custom devices were developed: a push-pull and pull-apart tester to quantify hand and grip strength for a range of postures. The push-pull tester included several attachments: small diameter knob, narrow lever covered with a rubber sleeve, pull chain connected to a lever, twister (small diameter knob) mounted on the top and front of a testing device, and a hand dynamometer. The pull-apart tester included two cylindrical, T-shaped handles. No adaptations were made in the test rig to account for child anthropometry. For the push-pull measures, the tester was secured to a table, approximately 20 inches from the floor, and child participants were encouraged to use innovation, creativity, and volition to achieve maximum performance, approximating a more normal play condition. For the pull-apart measures, the child participant held the instrumented cylinder parallel and approximately perpendicular to the shoulders at chest height, and pulled the handles apart, bilaterally, and with the left or right hand extended forward. In addition to verbal encouragement, the testers included several colored lights that illuminated proportional to force exerted to motivate the children. Sample size for this study was 50 children per age group.

Owings et al. (1977) conducted a study of the strength of U.S. children, ages 2 to 10 years, with the intention of informing product safety design. The study included 33 isometric exertion measures conducted on an instrumented reclining chair. Isolated joint strength was measured at wrist, elbow, shoulder, ankle, knee, hip, and trunk. Torque was quantified about the available degrees of freedom (*e.g.*, shoulder flexion, extension, adduction, abduction, medial and lateral rotation). The customized chair included a series of cantilevered beams to form an adjustable exoskeleton that articulated in at least one plane and aligned to the center of rotation for each joint. Anthropometric measures were taken to scale the chair to fit each child. Friction contact surfaces and Velcro straps were used to standardize body posture without causing discomfort. To elicit maximal voluntary effort, caregivers and research staff provided verbal encouragement and visual feedback via a graphical display. Criterion for an acceptable measurement was defined as an exertion sustained for 4-6 seconds that was reasonably repeatable in a test-re-test, and representative of real-world observations in child strength. Force values were extracted using a

moving average over 1 second during the 3 seconds of the exertion. Sample size for this study was approximately 20-30 children per age group.

Grip strength measurements and upper extremity joint strength of children ages 2 to 10 years were collected as part of a larger study (Owings et al., 1977). Isolated joint strength about the elbow joint was quantified through a range of angles from flexion through to full extension. These measures were conducted using the instrumented reclining chair and protocol described for the whole-body joint torques. Grip strength measures included: 2-pt, 3-pt, 5-pt pinch grips, lateral grip, and squeeze with different degrees of hand closure. Grip strength measures were scaled to hand dimensions and performed at a range of one-centimeter increments between 2 and 9 cm. A customized grip transducer with varying handle sets was developed for this study. Force exertions were quantified as a 2D vector, defined the direction, magnitude, location of the resultant force in terms of normal and shear components.

Norris and Wilson (1995) compiled CHILDATA, a design resource that accumulated available references on children to provide guidance to product design. Data on body dimensions, strength, motor abilities, skills related to specific products, and psychological data were compiled from the United States, United Kingdom, and the Netherlands. Strength measures included pushing forward, pushing downwards, pushing sideways, pulling, and lifting up against a range of handle configurations, in both vertical and horizontal orientations, and in standing and seated postures. Hand grip strength measures included hitting force with a fist, wrist twist, opening strength, squeeze grip, and varying pinches. Sample sizes were relatively small for all of the measures, typically fewer than 20 per age group.

The United Kingdom Department of Trade & Industry, Government Consumer Safety Research (2000) conducted a strength study for design safety. Anthropometric and strength measurements were recorded for 150 participants, ranging from 2 to 90 years of age (n=17 for children ages 2-5). Hand strength measures included finger push, pinch-pull, hand grip, wrist-twisting, opening strength, push and pull strength. Additional measures of whole-body strength were also captured (DTI, 2002). Measures included maximal push and pull strength, push with thumb or 2-or-more fingers, push with shoulder, maximal pull with different grips, wrist twisting and push-and-turn strength, pull on a can ring-pull, and press and lift with foot. Force targets were presented in a range of size configurations, orientations and locations, defined by participant anthropometry. Participants used their dominant hand and self-selected posture during exertions. Visual feedback was provided throughout the protocol.

Few studies have measured strength in children younger than 24 months. Reus et al. (2013) presented a pull-strength test based on a simulated play scenario for children 6 months to 36 months of age. Children were positioned in a chair with an Infant Muscle Strength (IMS) meter attached to a metal platform with a strength sensor. The chair was adjusted based on the children's anthropometric characteristics, so that their trunk, shoulders, and hips were fixed, and

their feet could not touch the floor. Children pulled on a stiff toy held by the researcher, who provided counter strength to evoke maximum pulling strength. In the context of that work, the team noted that no standardized strength-testing methods were available for younger children.

Because the literature review uncovered no systematic studies of exertions with hands and feet for children less than 24 months old, the methodology and test fixtures for the youngest children in the proposed study will be adapted from those used for older children, with consideration for child development patterns and capabilities.

Bite Strength

Within the CHILDATA resource, Norris & Wilson (1995) cite four studies that quantify maximum bite force. The studies differed in the size, shape, position and material of the device used to record maximum force. Krogman (1971) recorded bite force at the anterior (incisal) and posterior (molar) sites within the dental arch for children ages 3-6 years. Garner and Hotwal (1973) quantified incisive biting force (front teeth) for children ages 10-14 years. Vertical bite force was measured by Wu (1978) for children who ranged from 18 months to 36 months and 3-8 years. Bite force was also measured on an instrumented test of a feeding bottle for children ages 2-3 years (CEN 1992).

Lemos et al. (2006) investigated the correlation between chewing performance and maximal bite force in children ages 7-12 years. Bite force was measured with a pressurized rubber tube connected to a sensor element. The tube was placed bilaterally between the posterior maxillary and mandibular teeth. Child participants were instructed to bite the tube with maximum force for 3 repetitions, holding each exertion for 5 seconds.

Mountain et al. (2011) measured bite force in children ages 3-6 years to address a gap in the literature on primary dentition of young children. A total of 205 child participants were asked to bite down for 2-3 seconds on a single tooth force gauge placed between the 1st and 2nd primary molars and at the central incisors. A customized device was designed to accommodate a single-use parallel bite sensor prong. Results showed substantial variability both between and within participants, with an overall range of 12 to 350 N.

Maximal occlusal bite force for children in different dentition stages were recorded in a large-scale study (Owais et al. 2013). Children were stratified across the range of dentition stages and ages 3 to 18 years. Two hundred children were measured within each dentition stage. Bite force was quantified alternatively on the right and left side, positioned at the second primary or the first permanent molars region. A portable occlusal force gauge was used, consisting of a hydraulic pressure gauge and bite element encased in a vinyl material. Maximal bite forces differed significantly across the dentition stages, increasing with age. Age, gender and height were found to be significant predictors of bite force at the later stages of dentition.

Conflicting evidence persists in defining the relationship between bite force and sex, age, size and physical characteristics of children. The variability of bite force data is considerable, with numerous factors influencing these results. To address this debate, Singh, Sandhu, and Kashyap (2012) investigated the relationship between bite force and facial morphology, classified by malocclusion groups, for children ages 12 to 16 years. Bite force was measured at intercuspal position and anterior bite position. No significant differences were observed between the classes of malocclusion.

Recently, Verma et al. (2017) published a comprehensive overview of bite force transducers, covering both custom devices used in research and commercially available systems. Many of the systems have limited applicability to child bite force measurement, due to the relatively large sizes (many more than 10 mm thick).

With guidance from the literature, the research team for the proposed study plans to fabricate a bite dynamometer suitable for measurements with young children. The dynamometer should enable measurement of maximum and sustained incisal and buccal bite strength, will be capable of being sterilized, and will be covered with sterile, disposable, non-allergenic material before measurement of each participant.

2. DESCRIPTION OF SAMPLING METHOD TO BE USED

The research team at UMTRI will collect data from approximately 800 children for the study.

A convenience sampling method will be used. The population of interest is children ranging in age from 3 months (bite strength) or 6 months (exertions with hands and feet) through 5 years. Participants for older age group ranges will be recruited first, followed by younger participants later in the study. They will be recruited via their caregivers through the University of Michigan Engage site, Craigslist, and flyers placed at UMTRI. The participants will be screened via a phone conversation with the caregiver. Inclusion criteria will include: the targeted age group; lack of current illness or injury; age appropriate cognitive and motor development, as reported by the caregiver; and the caregiver's ability to understand written and spoken English (older children should also understand spoken English).

3. DESCRIPTION OF PROCEDURES FOR INFORMATION COLLECTION, INCLUDING STATISTICAL METHODOLOGY FOR STRATIFICATION AND SAMPLE SELECTION

The target number of participants per age group in the proposed study (50 children) is the same as that used in Brown, Buchanan, and Mandel (1973, 1974), and it is larger than the number used in Owings et al. (1977), U.K. Department of Trade & Industry, Government Consumer Safety Research (2000), Reus et al. (2013), and studies referenced in Norris and Wilson (1995). In

addition, the proposed study has narrow age bands, to allow more precision in assessing child strength by age.

The data gathered in this study will be used for a wide range of purposes, some foreseen and others that will arise in the future. Thus, as an exploratory research study, it is not possible, or sensible, to specify a necessary level of precision for any estimates of population distribution parameters. A calculation of sample size, using data from a previous strength study and a potential confidence bound, is shown below, assuming the sample size criteria were met.

Gajdosik (2005) published data on isometric elbow flexions and extensions, shoulder flexion, and knee flexion and extension from a sample of 45 children ages 2 through 4 years. In this dataset, the coefficient of variation (COV) within 1-year age bins averaged 0.42. The mean strength for the exercise with the largest mean (knee extension) was about 40 N. Using a COV of 0.4, the estimated standard deviation within an age cohort is 16 N. Estimation of mean strength with 95% confidence and ± 2 N precision would require a minimum sample size of 246 children.

When the anticipated COV is high, large sample sizes are needed to obtain high-precision mean estimates. For the current work, this suggests sample sizes as large as is practicable. Because the existing data are so sparse, even samples of 25 or more per age cohort will represent a substantial improvement. However, larger samples will improve precision of population parameter estimates.

This study is not designed to be powered adequately for hypothesis testing. However, this is a controlled, randomized, well-designed study with pre-specified criteria of interest, to explore. The results and information gathered in this study, ideally, will provide a framework that future hypothesis-testing studies can follow.

4. PROCEDURES

UMTRI will begin the initial data collection starting with older children, which is why the IRB-approved materials and instruments provided currently focus on the older age range. The full age range of the study is children 3 months to 5 years of age.

Appendix A provides an example of how the OMB Control Number will be displayed on materials provided to participants. All time calculations have been included in the burden estimates provided in Supporting Statement A.

1. At UMTRI, a research assistant will explain and demonstrate the procedures to the caregiver and child. Written consent will be obtained from the caregivers, who will remain with the children at all times. Researchers will obtain verbal assent from the children who are old enough to provide it. An example of the written consent is provided,

called Research Study Consent. This consent form references the age range 18 to 71 months, and after the initial data collection, the form will be amended to include children who are 3 months and older.

2. Researchers will obtain several standard anthropometric measurements from each child, including body weight and erect standing height. For bite strength participants, researchers will record mouth breadth and maximum mandibular opening. Anthropometric measures will allow the data to be normed to the U.S. population using anthropometric data from NHANES (CDC).

3. Researchers will record the participant's body shape using a whole-body laser scanner (VITUS XXL) and a Microsoft Kinect sensor. The research team has used both of these systems in several previous child studies. The laser scanner captures a high-resolution image of the subject's body shape in about 12 seconds. The Kinect will be used to capture the force-exertion postures. The laser-scan data will be used to create a subject-specific avatar that is used to aid posture tracking with the Kinect. The posture data are valuable to characterize the tactics that the children use for each exertion.

4. In the laboratory, the children will perform a sequence of tasks to test maximal exertions with their hands and feet. For standing tasks, they will grip a padded handle with one or both hands, as instructed, and push or pull as hard as they can. Each exertion will be targeted for approximately 5 seconds, including the ramp-up and release. Feedback will be provided to the participants via a graphic display that shows their maximum level achieved, so that they can be encouraged to go beyond that level, if possible. For bite strength, children will bite on a bite dynamometer that is fabricated to suit the age cohort.

5. For some trials, the participant will be seated in a specially constructed laboratory chair. Seated exertions will include pushes and pulls with the hands and pushes with one and both feet. Conditions will be varied to avoid loading up one part of the body consecutively. For example, a hand pull might be followed by a hand or foot push. Researchers will determine the trials to be performed, based on the result of previous pilot testing and the ability of the child. For example, if researchers have already established that children 36 months and up can reliably perform standing two-hand pushes, they will choose different types of exertions with subsequent subjects.

6. Researchers will record video and still images of the trials. The video and images will be used by the research team to assess the children's performance, particularly their tactics for achieving the requested exertions. This information will be valuable for developing the measurement protocols.

7. Trials will be separated by a minimum of 15 seconds to allow time for recovery. Longer recovery time is anticipated to be impractical, due to a loss of attention from the child;

but switching between limbs and exertion directions will reduce fatigue. The caregivers will be engaged in every step of the process, including directing and encouraging the children.

8. The number of trials to be performed will depend on the capability and attention of the child, but the maximum duration of a child's participation in a single session will be 2 hours. A 5-minute break will be taken at least every 20 minutes, to allow the child to relax and play. The caregiver and child can take a break, or discontinue participation, at any time.

9. The caregiver will be paid an incentive of $40 for up to 2 hours of participation.

10. Photos and video of the participants will be taken in some conditions to document their exertion postures. The researchers will de-identify the photos by blurring or obscuring the faces.

5. DESCRIPTION OF METHODS TO MAXIMIZE RESPONSE RATE AND TO DEAL WITH NON-RESPONSE ISSUES

To reduce the number of no-shows, researchers will send scheduled participants a reminder letter and/or call them on the telephone, giving the time of the session and directions to the location.

Researchers will provide $40-$50 compensation for up to 2 hours of participation, as an incentive to participate in the experiment. Additional detail on the importance of compensation is provided in Supporting Statement A.

6. DESCRIBE ANY TESTS FOR PROCEDURES OR METHODS TO BE UNDERTAKEN

The Child Strength Study will be based on convenience sampling and is not intended to be a representative sample to accurately reflect the characteristics of the children living in the United States. The sampling technique and sample size for the proposed study is consistent with previous child strength studies. These data have been used to draw inferences about the strength capabilities of children in the United States. To address the limitations of convenience sampling and ensure the representativeness of the study, UMTRI will use statistical methods to relate the measures strength to child age, as well as anthropometric factors that vary with age, such as body weight and standing height. This will allow the data to be normed to the U.S. population using anthropometric data from NHANES (CDC).

Initial pilot testing has been conducted, and an additional pilot study will be conducted to refine the data collection procedures and instruments, followed by the full study. Because this pilot is

designed solely to test the study methods and not for analysis of the data, researchers will select the pilot participants.

COVID-19 Mitigation

UMTRI researcher have developed a safety protocol to include COVID-related precautions. UMTRI researchers are required to adhere to guidance from the University of Michigan Office of Research concerning human subject testing. The Office of Research has issued guidance for human research during the pandemic, which is available on their website (https://research.umich.edu/covid-19/human-research-during-covid-19/); this guidance is updated regularly to address changing health and safety measures. As of December 2021, the University of Michigan requires research team members to wear a face covering when conducting face-to-face interactions with human research participants; University of Michigan faculty, staff, and students are required to receive the COVID-19 vaccination. The ability to conduct human subjects testing will be based on local conditions and applicable mandates. CPSC has reviewed the risk-mitigation protocols recommended by the Office of Research and implemented by UMTRI, and the Child Strength Study will proceed only on the basis that these mitigation protocols will be adhered to.

One purpose of the Child Strength Study is to update and expand child strength data with a focus on real-world scenarios. Researchers at UMTRI are hopeful that they can conduct the Child Strength Study without any COVID-related restrictions on how the child participant interacts with the test fixture or the investigators (masks for the investigators and caregivers would be fine). There are some measures in the study, for example bite strength, for which it would be very difficult or impossible to collect meaningful data with the restrictions currently in place. If restrictions are still in place when it is time to collect data, researchers and CPSC staff will make decisions on what measures can be collected without compromising the real-world applicability of the data, and will modify the list of measures as needed. This is because it would not be worthwhile to gather this important data, which is intended to have long-term archival value, with the condition of it being collected during a pandemic. Data that are compromised by the COVID pandemic or protocols are not worth collecting at this time.

7. PROVIDE NAME AND PHONE NUMBER OF INDIVIDUALS CONSULTED ON STATISTICAL ASPECTS OF STUDY DESIGN AND OTHER PERSONS WHO WILL COLLECT/ANALYZE INFORMATION FOR AGENCY

Matthew P. Reed, Ph.D. (734) 936-1111. Research Professor and Head Biosciences Group, University of Michigan Transportation Research Institute (Collect and Analyze)

8. REFERENCES

Brown W.C., Buchanan, C.J. and Mandel, J. (1973). A Study of the Strength Capabilities of Children Ages Two Through Six. Washington, DC: U.S. Department of Commerce, National Bureau of Standards. NBSIR 73-156.

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Reus, L., van Vlimmeren, L.A., Staal, J.B., Janssen, A.J.W.M., Otten, B.J., Pelzer, B.J. and Nijhuis-van der Sanden, M.W.G. (2013). Objective Evaluation of Muscle Strength in Infants with Hypotonia and Muscle Weakness. *Research in Developmental Disabilities*, 34: 1160-1169.

Appendix A.

The OMB Control Number and Expiration date will be displayed in the following format on participant documents:

OMB Control Number: XXXX-XXXX

Expiration Date: XX/XX/XXXX

Example of how OMB Control Number could be displayed in the consent form:

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Child Strength Measurement

Principal Investigator: Matthew P. Reed, PhD, University of Michigan Transportation Research Institute
Co-Investigator: Monica L.H. Jones, PhD, University of Michigan Transportation Research Institute
Co-Investigator: Prachi Shah, MD, Michigan Medicine
Co-Investigator: Darya Dabiri, DMD, MS, Michigan Medicines

Study Sponsor: U.S. Consumer Product Safety Commission.

Your child is invited to take part in a research study. This form contains information that will help you decide whether your child will join the study. Taking part in this research project is voluntary. Your child does not have to participate, and your child can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

OMB Control Number: XXXX-XXXX, **Expiration Date:** XX/XX/XX