MOBILITY AND SOCIALIZATION OF TYPICALLY DEVELOPING TODDLERS IN VARIOUS CHILDCARE ENVIRONMENTS

by

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ABSTRACT

One major goal of the lab's clinical research program is to quantify the daily lives of young children who are typically developing and those with special needs. Development in young children is embodied. Typically developing children benefit from the ability to explore their environment and socialize. Not surprisingly, young children with mobility impairments have difficulty keeping up with peers, which results in difficulties in exploration and socialization. The dosage of mobility (exploration) and socialization is unknown in typically developing toddlers. This limited information reduces the ability of clinicians and educators to assess and assist in the progression of mobility and socialization in children with and without disabilities. The specific goal of this thesis proposal is to quantify the types of mobility and socialization of typically developing children between 18-30 months. Specifically, Aim 1 will quantify the Types of Mobility and Levels of Exertion. Aim 2 will quantify the Types of Socialization. Aim 3 focuses on the co-occurrence of mobility and socialization categories.

Chapter 1

SPECIFIC AIMS

The overall goal of this thesis is to quantify the types of mobility, levels of exertion and types of socialization occurring within the daily lives of young typically developing children. This proposal will extend previous work by broadening measures to types of mobility and socialization. This thesis will present the types of mobility, socialization and their co-occurrence within the classroom, playground and gym of the Early Learning Center, a university based children care research center. **Specific Aim 1:** Quantify the types of mobility and levels of exertion. **Specific Aim 2:** Quantify socialization behaviors.

Specific Aim 3: Quantify the co-occurrence of mobility and socialization.

Significance: 1) Addresses the need for benchmark information on the mobility and socialization of young children. 2) Offers insight to the effects that mobility and socialization have on one another. 3) Results have implications for the assessment and interventions with developmentally delayed children. **Innovation:** This is the first study that observed 1) typical mobility and socialization behaviors, 2) the co-occurrence of mobility and socialization and 3) how these behaviors changed across contexts (classroom, playground and gym).

Chapter 2

BACKGROUND AND SIGNIFICANCE

2.1 Embodied Development: The Relationship between Mobility and Development

Physical activity is a hallmark of human life –especially of the life of a young child. Children and adults move one or more body parts both when in one location and when moving between locations ('mobility'). Interestingly, movement and mobility are simultaneously the result of optimal body function and a major cause of optimal body function (Campos et al., 2000). Movement and mobility are required for optimal *physiological* development of many body systems including the nervous (Damiano, 2009), muscular, cardiovascular (Reilly et al., 2003) and skeletal systems. Interaction with the physical environment for information pickup ('exploration') through movement and mobility is also a major factor in a child's *psychological and behavioral* development including cognitive, social and language development (Smith, 2005)(Bushnell & Boudreau, 1993)(Kermoian & Campos, 1988). This relationship between physical and psychological development is formally known as the *embodiment hypothesis* (Smith, 2005). This lab is specifically interested in the general relationships between the development of movement-mobility and socialization.

This lab has increasingly focused on providing young children with mobility impairments with the technology and training to more optimally explore, learn and socialize. The gold standard for the lab's interventions are to meet and then exceed the levels of mobility and socialization enjoyed by their typically developing peers. Unfortunately and surprisingly, there is a significant lack of quantitative data on the daily mobility and socialization levels displayed by typically developing children in natural environments outside labs and clinics. In this thesis a compendium is presented to address the current lack of information on these typical levels of mobility and socialization. Specifically, this proposal focuses on quantifying the level of physical and social activity in typically developing 2-3 year old children ('toddlers').

Over the first 3-4 years of life, a child's daily behaviors increasingly involve physical activity co-occurring with interaction with other people ('socialization')(Uchiyama et al., 2008)(Kopp, 2011). For example, the socialization of young children increased as their mobility increased (Adolph et al., 2012) (Clearfield, Osborne, & Mullen, 2008)(Clearfield, 2011)(Karasik, Tamis-LeMonda, & Adolph, 2011). In contrast, reduced physical activity has been proposed to be a serious risk factor for impairments in socialization (Hay, Payne, & Chadwick, 2004).

Children with chronic movement and mobility impairments such as Cerebral Palsy (Baxter et al., n.d.), Spina Bifida (Kelly, Altiok, Gorzkowski, Abrams, & Vogel, 2011) and/or Down syndrome (Missiuna & Pollock, 1991) are at risk for secondary impairments in socialization. For example, reduced motor activity is associated with reduced social activity in toddlers with various degrees of gross motor function (Whittingham, Fahey, Rawicki, & Boyd, 2010). The lab focuses on enhancing the mobility and socialization of young children through the daily use of technology such as exoskeletons, body weight support systems and high and low tech power mobility devices, within natural environments such as schools, homes and community spaces. The focus of this thesis is to quantify mobility and socialization of typically developing toddlers. This thesis originated from issues noted during the lab's ongoing research and prototype development especially the lab's work with power mobility devices (PMDs).

2.2 Technology to Advance Mobility and Socialization

The use of power mobility devices (PMDs) (Hansen, 2008), such as pediatric power chairs (Bottos, Bolcati, Sciuto, Ruggeri, & Feliciangeli, 2001), experimental mobile robots (Deitz, Swinth, & White, 2002) and modified ride on toy cars (Lynch, Ryu, Agrawal, & Galloway, 2009) have the potential to positively impact mobility and development of young children with and without mobility impairments (Nilsson & Nyberg, 2003) (Livingstone, 2011). For example, use of PMDs advanced basic driving skill and development in typically developing infants (Galloway, Ryu, & Agrawal, 2008)(Chen, Ragonesi, Galloway, & Agrawal, 2011) and advanced driving skill in typically developing toddlers. PMD use is also feasible for increasing the mobility in young children with special needs (C Butler, Okamoto, & McKay, 1983)(Lynch, Ryu, Agrawal, & Galloway, 2009)(C Butler, 1986)(M. a Jones, McEwen, & Neas, 2012) including those with Spina Bifida, cerebral palsy (Ragonesi & Galloway, 2012)(Ragonesi, Chen, Agrawal, & Galloway, 2010a)(Huang et al in press) and Down syndrome (Logan et al under review). Increased socialization is often associated with use of PMDs compared to periods without the use of a PMD. (M. A Jones, McEwen, & Hansen, 2003)(M. a Jones et al., 2012).

PMD's are universally promoted to increase both mobility and participation in activities of daily living including socialization. While the literature supports that

PMD use typically leads to increases in mobility. That is, children placed in a PMD often consistently activate the switch or joystick and move from one location to another. The lab's recent work however suggests that this increase in mobility does not guarantee the use of that new found mobility for socialization (Chen et al., 2011)(Lynch et al., 2009)(Ragonesi & Galloway, 2012)(Damiano, 2006). For example, in a case report of a child with cerebral palsy, PMD training using the typical model of adult training a child to drive in clinic environments without peer socialization led to increased driving skill but not use of that mobility for socialization (Ragonesi et al., 2010a). In the follow-up case report with the same child, socialization training provided using the common model of adult organizing socialization events between peers and the focal child but without PMD use or involving mobility. Interestingly, the child increased his socialization during these organized events but did not increase his socialization using his PMD outside of the organized events when mobility was required to socialize (Chen et al., 2011). Taken together, the above literature suggests that mobility and socialization not only co-emerge in typical development but this co-emergence should be tested as a novel developmentally based model of PMD training. Although innovative, this model requires that we know the typical mobility and socialization displayed by young children in their various natural environments. This is important not only to set the levels ('dosage') but also to begin to understand the potentially complex co-emergence of mobility and socialization. That is, to understand the dynamic interplay between a child's changing mobility and a child's changing social interactions.

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The development of mobility (Horovitz & Matson, 2011), socialization (Horovitz & Matson, 2011)(Hay et al., 2004) and mobility for socialization (Pellegrini & Smith, 1998) have long been areas of interest in childhood development especially for school age children. Surprisingly, there are relatively few studies quantifying the basic types of mobility, socialization and mobility for socialization of younger children such as those between 1.5 and 3 years of age ('toddlers') (Cardon, Van Cauwenberghe, & De Bourdeaudhuij, 2011).

2.3 Mobility and Socialization in Typically Developing Toddlers: Concepts

Mobility of typically developing children is often studied within the field of 'physical activity'. Studies of the toddler physical activity have focused on four main topics: obesity, biomechanics, increasing activity and ethnological studies (Timmons et al., 2012)(Tremblay et al., 2012)(Leblanc et al., 2012). In this thesis, <u>types of mobility</u> and <u>levels of exertion</u> will be quantified.

<u>Types of Mobility</u>: The types of mobility, such as standing, sitting, walking and running, are often the focus of ethnological studies. These studies aim to record fine details of behavior in either a) diary based case study (Shatz, 1994) or b) broad observational studies (Cohen, 1983)(Buhler, 1974). Ethnological studies of childhood mobility have a long history of use and have resulted in the various 'motor milestones' of baby books and pediatric textbooks (McGraw, 1935)(McGrew, 1972). Instead of focusing on a rigid set of standard milestones to be followed by pediatric rehabilitation and early education, this study aims to quantify the amount of the various types of mobility as a guide to gold standard dosage in rehabilitation and education. Levels of Exertion: Studies in levels of exertion have largely focused on tracking the amount of sedentary behavior in young children given the current obesity epidemic in the US and abroad (Timmons et al., 2012)(Tremblay et al., 2012)(Leblanc et al., 2012). Pedometers and other accelerometers (Cliff, Reilly, & Okely, 2009)(Hnatiuk et al., 2012), questionnaires (Manios, 2006) and direct observation are used to measure levels of exertion (Cardon et al., 2011). In this thesis, the literature will focus on the categorization of levels of exertion by direct observation (Van Cauwenberghe, Gubbels, De Bourdeaudhuij, & Cardon, 2011)(Brown et al., 2006).

<u>Types of Socialization</u>: Capturing toddlers' daily behavior requires, at minimum, quantifying mobility and socialization (Dwyer, Baur, & Hardy, 2009)(Welk, Corbin, & Dale, 2000)(Buhler, 1974)(Pellegrini & Smith, 1998). Studies in toddler socialization focus on three main categories: caregiver dyad, social play stages and peer relationship (Hay et al., 2004). In this thesis, the types of socialization as reported by Howes will be recorded (Howes & Matheson, 1992).

<u>Co-occurrence of Mobility and Socialization</u>: This proposal will quantify the typical co-emergence of mobility and socialization given its importance to our intervention model. There are few studies in this area (Eckerman & Whatley, 1977)(Eckerman, Whitehead, & Eckerman, 1999). In particular, the idea of co-occurring physical activity and socialization (B. Jones, 1972) will be refined by assuring that the co-occurrences are happening during the same time. Another important factor to consider is the context of these behaviors.

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2.4 Mobility and Socialization in Typically Developing Toddlers: Measures

The general methodology of this thesis involves videotaping toddlers in the classroom, gym and playground of the UD Early Learning Center; a university based early education and research center. There were no experimental manipulations of the physical or social environment, ELC scheduling or activities.

Mobility Measures. Mobility, both the Types of Mobility and Levels of Exertion, will be quantified using a modified version of the Observational System for Recording Activity in Children – Preschool Version (OSRAC-P). The OSRAC-P is a reliable coding protocol for physical activity in young children (Brown et al., 2006). It was constructed to encompass the most common types of mobility and levels of exertion in young children as well as incorporating information from the most commonly used observational tools in young children. OSRAC-P was created by combining three observational systems, Children's Activity Rating Scale (CARS), Code for Active Student Engagement – Revised (CASPER II) and Observational System for the Environmental Determinants of Physical Activity in Preschool Children (Ii, 2012). Testing with accelerometers has shown that this protocol is a reliable in toddlers (Van Cauwenberghe et al., 2011). Additionally it has been used in large investigations of preschool children (Pate, McIver, Dowda, Brown, & Addy, 2008). Types of mobility codes toddler behavior into the following comprehensive and mutually exclusive categories: lying down, sitting (kneeling), squatting, crawling, standing, walking, running and cycling. Levels of exertion codes of toddler behavior are the following comprehensive and mutually exclusive categories. *Stationary and motionless*: child is not taking more than three steps in any direction and not performing gross motor actions. Stationary with and trunk and limb movements: child

is not taking more than three steps in any direction and but is performing gross motor actions. *Slow and Easy Movements:* child is walking at a normal pace with no objects. *Moderate movements*: child walking briskly or carrying a large object during slow and easy walking. *Fast Movement:* child is moving at their highest level of exertion such as running. See Methods section for coding inter-rater and intra-rater reliability.

Socialization: *Types of socialization* will be measured by using a modified version of Howes' Peer Play Scale (Howes & Matheson, 1992) used previously within the lab (Ragonesi, Chen, Agrawal, & Galloway, 2010b). This scale was constructed similar to the previous peer play scales (Bledsoe & Shepherd, 1982)(Bakeman & Brownlee, 1980). Similar peer play scales have also been used to validate other scales (Dougan & Kaszuba, 1999). This scale codes toddler behavior into the following comprehensive and mutually exclusive categories: *Solitary Play:* child is greater than three feet from another peer or adult and no physical or verbal interaction. *Parallel Play:* child is within three feet of a peer or adult but with no physical or verbal interaction. *Peer interaction:* child is within three feet of peer and having physical and/or verbal interaction with peer. *Teacher interaction:* child is within three feet of adult and having physical and/or verbal interaction with adult. See Methods section for coding inter-rater and intra-rater reliability.

Co-occurrence Terms: co-occurrence will be measured for both mobility and socialization. Mobility codes toddler behavior by extrapolating mobility behaviors into movement, and mobility. Movement is considered as any level of exertion other than motionless. Mobility is considered as any level of exertion other than motionless and trunk and limb movements. That is, mobility is defined as translocation from one place to another. Additionally, socialization will be coded as any type of social behavior other than solitary play.

2.5 Significance and Innovation

Significance: This study using benchmark information on the mobility and socialization of young children. The information is useful for children with disabilities, developmentally delayed and typically developing children. Clinicians can use this information to guide interventions for those with disabilities. Researchers can also use this information to assess the effectiveness of different types of treatments that try to increase mobility and socialization in the developmentally delayed. Developmentalists can use this information to determine the effect that mobility has on the development of socialization in the typically developing.

Innovation: This is the first study that has observed types of mobility and socialization in the same time frame. This approach allows researchers to observe mobility and socialization in its basic form. Additionally, the co-occurrence of mobility and socialization within the same time frame has not (to the best of my knowledge) been investigated. Also, each of these measures was observed in the classroom, playground and gym. This would be one of the few studies that have looked at any behavior and its changes with respect to the classroom, playground and gym.

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Chapter 3

METHODS

3.1 Facilities

All data was collected at the Early Learning Center (ELC), a research oriented childcare center at the University of a Delaware. Children of various social, cultural and economic backgrounds from birth to kindergarten attend the ELC with the majority spending 6-8 hours in the classrooms, playground and gym. Each classroom includes two accessible cameras and microphones. One-way glass in booths outside of each classroom and the gym allow undetected observation.

3.2 Participants

Twenty-one typically developing toddlers were observed between 08/13/2012 and 11/25/2012. Toddlers were between 16 and 31 months of age at the beginning of collection and 20 and 35 months of age at the end of collection. Data collection of each child was at the IRB approved ELC. Parental consent to observe and noninvasively videotape the children was received upon matriculation into the ELC.

3.3 Data Collection

The goal was to use valid and reliable protocols to videotape toddlers in a naturalistic setting. Each toddler was taped for 20 minutes in each context, classroom, playground and gym. On average each toddler was videotaped for at least one hour.

All data collections were obtained during the typical activities and within the typical contexts without structure or interference by researchers. All data was collected by the PI, Schreiber. That is, the behaviors and contexts recorded with the normal daily activities of each toddler subject, teacher and toddler peers. Data was collected through videotape in the morning after breakfast (8:30 EST) and before lunch (11:30 EST), which is primarily unstructured or lightly structured 'free play'. Data was collected from four toddler classes; Toddler Room 1: Crawford and Kuczmarski, Toddler Room 3: Jackson and Brellahan, Toddler Room 4: Walls and Lewis and Toddler Room 6: Clayton and Hays.

One toddler classroom was recorded each collection. Each child was recorded with their class in a predetermined order alternating between boys and girls. This is a common practice when observing physical activity in young children. The first child was recorded for four minutes, and then the next child (of another gender) was recorded (See figure 2). If the focal child went out of view, the next child would be recorded until the four-minute observation of the previous child has ended. When all children within a class were recorded, the cycle continued until each child was observed for 20 minutes per context (classroom, playground and gym). The videographer identified children by zooming into the child's body and kept the focal child, caregivers and peer in view. During collection in the gym and playground, the videographer stayed between 5 and 10 feet from the child to record clear audio yet avoid being a distraction.

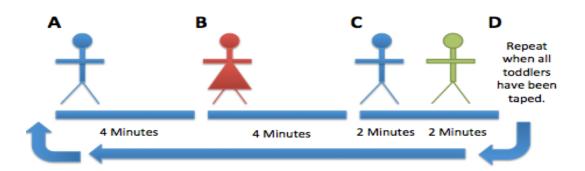


Figure 1: Video Coding Example: This figure illustrates the videotaping protocol within this study. At point A, the first toddler, in this case a male is recorded for four minutes. At point B, the second toddler, opposite gender, is then recorded for four minutes. At point C, the third toddler, opposite gender, is recorded. In the special case that a toddler becomes out of view, another toddler of the same gender will be videotaped until the four minutes bout is over. At point D, when all toddlers within one class have been videotaped, repeat the cycle until 20 minutes of video per toddler per context is recorded.

3.4 Data Processing

All data was processed by the PI, Schreiber. Future coding of the OSRAC-P required identification of 5-sec interval/15-sec epochs. An interval is a portion of the video that is observed and coded. An epoch is a portion of the video that includes both the observed and "not coded" section. This coding scheme is implemented in order to gain a general understanding of the activities of toddlers without having to code for the entire video. For this reason, videos were processed to include interval identification numbers and alternating red/green border. Explicitly, an alternating red/green border overlaid the collected data using iMovie (Apple, California). A red border appears for ten seconds during the "not coded" section then a green border for five seconds during each coded interval. A ten second red border indicates the coder

should not code that section. A 5-sec green border indicates the coder should code for mobility or socialization within that interval. This interval length of five seconds allows for one behavior to be recorded during five seconds. Additionally, recording 5-sec interval/15-sec epoch will allow researchers to obtain a sample of activity that can be extrapolated over time without coding for every five seconds. Previous researchers have used a five second coding and ten second of "not coding" methodology for the OSRAC-P protocol (Brown et al., 2006). Social play stages have similar coding schemes in that the most dominant play stage that occurs during a 15-sec interval would be coded for that interval (Bakeman & Brownlee, 1980). Therefore, it is reasonable to code mobility and socialization in a 5-sec interval/15-sec epoch.

An interval was not coded in instances where a (1) child's full body could not be seen for more than half the interval (2) if the child had noticed that they are being observed and (3) if the film contains excessive shakiness preventing the ability to code reliably. One variable in each category of mobility and socialization will be coded. A variable gets coded for a category when that variable occurs for the majority of the interval. In the event that no variable occurs for the majority of the interval, the variable that occurs first will be coded. All the coded variables will be recorded on an excel sheet for each video with the interval numbers.

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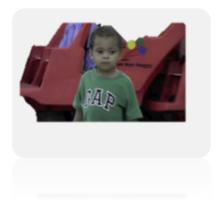


Figure 2: Coding Example: This intervals number and the red/green border mentioned earlier. The child's body is identified by zooming function and then the videographer views the child's entire body.

Appropriate video coding reliability protocol was followed before coding the entire data set. Ten percent of the video was evenly spread across each context and across 75% of the children that were coded. Coding became reliable by point-to-point inter-rater reliability and intra-rater reliability. Inter-rater reliability is the reliability between the main coder and other coders of the same data set. The goal was to achieve 85% reliability between the main coder and other coders. Inter-rater reliability is reliability across all contexts combined was achieved for each investigative categories, types of mobility at 88%, levels of exertion at 86% and types of socialization 89%. Some individual contexts and investigative categories included reliability below 85%. The following percentages is the reliability according to categories and context; types of mobility in the classroom 82%, playground 90% and gym 75%; levels of exertion in the classroom 77%, playground 89% and gym 88%.

Once inter-rater reliability was achieved intra-rater reliability was determined. Intra-rater reliability or the reliability of the main coder to code the same variables was also determined. Some individual contexts and investigative categories included reliability below 85%. The following percentages is the reliability according to categories and context; types of mobility in the classroom 82%, playground 88%, gym 88% and total 90%; levels of exertion in the classroom 82%, playground 93%, gym 87% and total 91%; types of socialization in the classroom 82%, playground 88%, gym 88% and total 91%.

3.5 Coding Measures

All intervals that did not fall under the previous exclusion criteria were coded with video title, recording date, subject identification, interval number, context, type of mobility, level of exertion, type of socialization, mobile/not mobile, movement/no movement and lastly socialization/no socialization. Each video was recorded in three, separate passes, (1) administrative set up for excel coding sheet (2) coding for mobility measures and (3) coding for social measures. Administrative set up for excel coding sheet encompassed writing down the video title, recording date, subject identification, interval number, context and setup for the variables that can be coded for within an interval for types of mobility, levels of exertion and types of socialization.

DATA ANALYSIS

Graphs and tables were created to summarize the mobility and socialization measures. Specifically, pivot tables were used to summarize data. Occurrence of any activity in a toddler was determined by the "occurrence of activity"/ "total time videotaped". Determining co-occurrence utilized the pivot table to organize data by main categories and sub-categories. The sub-categories were used to determine cooccurrence of activity. Preliminary data section shows these graphs/tables with means standard deviations. See Preliminary Data Section.

3.6 Data Validation

3.6.1 Time Sampling

Time sampling has been investigated in observational studies (Bakemen & Quera, 2011). Time sampling within this study is defined, as is the number of intervals needed per epoch to fully quantify the mobile and social behaviors of typically developing toddlers. Determining time sampling in behavioral studies is key to recording high quality data with high efficiency. Observational data is at its highest quality when it is behavior dependent (Bakemen & Quera, 2011). Certain behaviors can require high or low time sampling. For example, sitting which occurs very frequently only requires a low time sampling. However, running which occurs less

frequently requires a high time sampling. Observational studies need to determine the appropriate time sampling that neither over-samples or under-samples any of the behaviors recorded in the study(Kahan, Nicaise, & Reuben, 2013). Further, changes in the time sampling can create high/low quality data sets (Bakemen & Ouera, 2011). For example, over-sampling a behavior that occurs frequently has no effect on the outcome of that behavior. However, under-sampling a behavior that does not occur frequently can be the cause of error through underrepresentation of that behavior. Therefore, over-sampling may be the best method to record all behaviors with little error. However, over-sampling observational data comes with a cost. In order to be the most efficient, cost-benefit analysis needs to be considered when determining the most appropriate time sampling (Hands & Parker, 2006). During over-sampling, researchers must weigh the cost of time spent coding the video with the quality of data received. Most behavioral studies observing children have used a time sampling of 5-sec interval/15-sec epoch (Ii, 2012)(Brown et al., 2006). Although epoch lengths vary between the studies, most studies agree that the interval of an observation of physical activity in young children should be 5-sec (Oliver, Schofield, & Kolt, 2007)(Kahan et al., 2013)(Larson, Normand, & Hustyi, 2011).

It is unclear whether 5-sec interval/15-sec epochs are sufficient enough to determine all mobile and social behaviors investigated within this study. To determine this, a one-hour videotape was used for behavior coding for every five seconds of the video. Each interval within the video was labeled. Three coding schemes of 5-sec

interval/epoch combinations were analyzed, (1) 5-sec interval/10-sec epoch, (2) 5-sec interval/15-sec epoch and (3) 5-sec interval/20-sec epoch. The percentage of each type of mobility was averaged across each interval/epoch combination. The means and standard deviations of each type of mobility were calculated. That is, the mean of each group was determined along with the standard deviation. The process was repeated for levels of exertion and types of socialization.

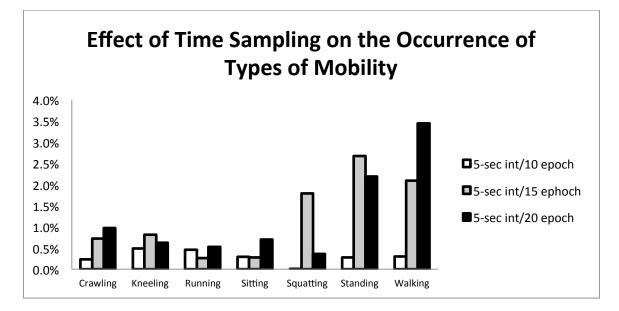


Figure 3: Effect of Time Sampling on the Occurrence of Types of Mobility: On the x-axis are the types of mobility that occurred in the one-hour video. There are three interval/epoch combinations, represented in the bar graph. On the y-axis is the standard deviation between the types of mobility and the interval/epoch combinations. All the standard deviations between groups are less than 4%. The smallest standard deviations occur during the 5-sec interval/10-sec epoch combination. The largest standard deviations occur during the 5-sec interval/20-sec epoch.

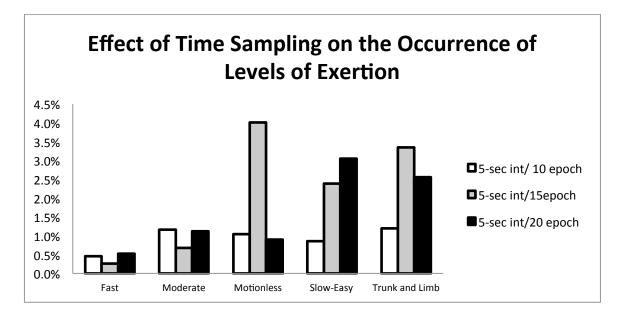


Figure 4: Effect of Time Sampling on the Occurrence of Levels of Exertion: On the x-axis are the levels of exertion that occurred in the one-hour video. There are three interval/epoch combinations, represented in the bar graph. On the y-axis is the standard deviation between the levels of exertion and the interval/epoch combinations. All standard deviations between groups are less than 5%. The smallest standard deviations occur during the 5-sec interval/10-sec epoch. The largest standard deviations occur during the 5-sec interval/15-sec epoch.

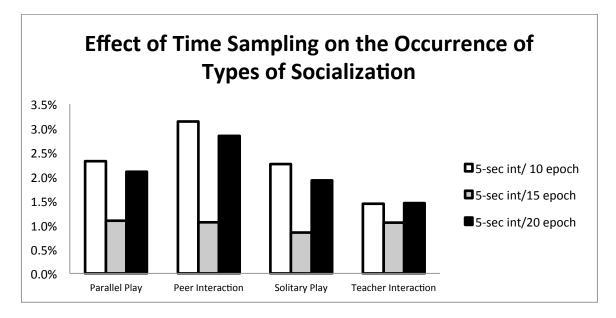


Figure 5: Effect of Time Sampling on the Occurrence of Types of Socialization: On the x-axis are the types of socialization that occurred in the one-hour video. There are three interval/epoch combinations, represented in the bar graph. On the y-axis is the standard deviation between the types of socialization and the interval/epoch combinations. All standard deviations are less than 4%. The smallest standard deviations occur during the 5-sec interval/15-sec epoch. The largest standard deviations occur during the 5-sec interval/10-sec epoch.

There was little difference between interval/epoch combinations, which have led to no additional re-coding. For all main categories there is less than 5% difference between coding time sampling. Standard deviations are small and therefore within an acceptable range. Errors increased with a decrease in sample rate. For mobility categories, 5-sec interval/20-sec epoch offers the least error for the least time consumption. For socialization categories, 5-sec interval/15-sec epoch offers the least error. However, 5-sec interval/15 sec epoch will be used in this study because of small standard deviations, low researcher cost and consistency with literature.

3.6.2 Majority Rules Versus Frequency

Majority rules (Single code event) and frequency (multi-code events) schemes are two behavioral coding systems (Bakemen & Quera, 2011). Frequency (Multi-code events) behavioral coding observes and records the occurrence of multiple behaviors within the same category over an interval. For example, the occurrence of walking and running within types of mobility during an interval. Majority rules (Single code event) behavioral coding observes and records only the behavior that occurs the most during an interval. Majority rules (Single code event) and frequency (Multi-code events) coding is investigated in observational studies (Bakemen & Quera, 2011). Majority rules coding scheme has been suggested and may be a possible source of error in that it may under-represent the occurrences of shorter duration activities. Frequency coding scheme has been suggested to have less error and may not represent the activities that occur for longer duration.

A two-hour video of 5-sec interval/15-sec epoch was coded. Majority rules events were coded during the original data set. Frequency events were coded for each interval of the same video. The percent occurrences of majority rules and frequency were compared.

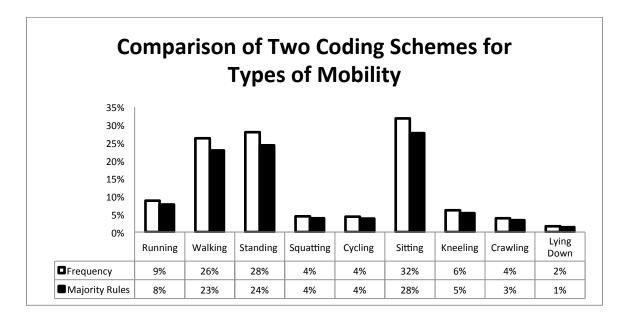


Figure 6: Comparison of Two Coding Schemes for Types of Mobility: On the xaxis are the types of mobility that occurred during the two-hour video. The bar graph represents the frequency and majority rules coding schemes. On the y-axis is the percent occurrence of types of mobility for each coding scheme. For example, running occurs 9% of the time in the frequency-coding scheme. There is small difference between the two coding methods (at most 4% difference).

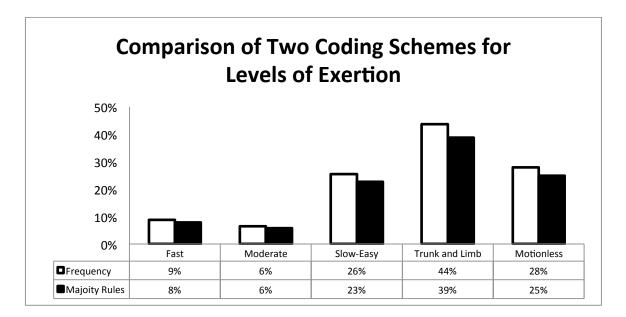


Figure 7: Comparison of Two Coding Schemes for Levels of Exertion: On the xaxis are the levels of exertion that occurred during the two-hour video. The bar graph represents the frequency and majority rules coding schemes. On the y-axis is the percent occurrence of levels of exertion for each coding scheme. For example, fast activity occurs 9% percent of the time in frequency-coding scheme. There is small difference between the two coding methods (at most 5% difference).

Small differences between the coding systems show that both coding systems are reliable. Majority rules (Single code event) coding is less costly for the coder and has been used in the remainder of the thesis for the categories of types of mobility and levels of exertion.

3.6.3 Social Frequency Versus Hierarchy

Social Frequency is a behavioral coding system that observes the occurrence of

any types of socialization during an interval. Social Hierarchy is a behavioral coding

system that observes all social activity and uses a hierarchy to determine one social behavior to be coded per interval. The hierarchy codes are in order of solitary play, parallel play, peer interaction and finally teacher interaction. For example, in the case that teacher interaction occurs within the same interval as peer interaction, peer interaction will be coded. Coding for types of socialization with a hierarchy scheme may not code for all of peer interaction since teacher interaction is coded over peer interaction.

A two-hour, 5-sec interval/15-sec epoch was coded with the frequency and hierarchy coding system. The percent occurrence of each method was compared to one another. The means and standard deviations were calculated. There is little difference between all types of socialization except for parallel play. Parallel play can co-occur with Peer and Teacher Interaction. Therefore, it is acceptable to observe more parallel play in the frequency-coding scheme. Hierarchy system of coding is acceptable due to the small differences between the coding systems.

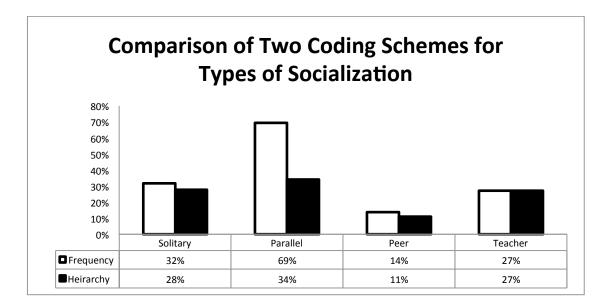


Figure 8: Comparison of Two Coding Schemes for Types of Socialization: On the x-axis are the types of socialization that occurred during the two-hour video. The bar graph represents the frequency and hierarchy-coding scheme. On the y-axis is the percent occurrence of types of socialization for each coding scheme. For example, solitary play occurred 32% of the time during the frequency-coding scheme.

3.7 Timeline

All data has been collected and processed. The following timeline outlines the recruitment, data collection, reliability and data analysis for a master's thesis project of two years. Recruitment of 20 children was minimal given that all children attended the ELC daily. Data collection of 20 toddlers x 20 video minutes x 3 contexts (classroom: everyday, playground: at least 3 hours in morning per week, gym: at least 1 hour in morning per week) for 2 hours of videotaping per day took approximately six weeks. Obtaining reliability of 85% took three weeks. Data processing took 2 x length of video to create coding video, 4 passes x length of video for coding and 40

hours to create appropriate graphs for analysis. Thus 20 hours of data collection required approximately 100 hours or about three weeks of data processing. In total, the entire project took approximately four months from recruitment to initial preliminary data graphs.

Chapter 4

RESULTS

The literature is clear but limited on the occurrences of different types of mobility (Van Cauwenberghe et al., 2011). Sitting, Standing and Walking are the most frequent types of mobility (Brown et al., 2006). Running occurs the least frequent of all activities. The conclusions made from this study agree with what the literature has conveyed about types of mobility. The majority of activity or 1/3 of activity occurs in the Standing position whereas the least of the activity (<2%) occurs in the Lying Down position. Standard deviation of sitting and standing were the largest of each type of mobility but remained in an acceptable tolerance. The distribution of types of mobility is variable. Additionally, there is no preference between types of mobility that are lower to the ground (prone) or upright.

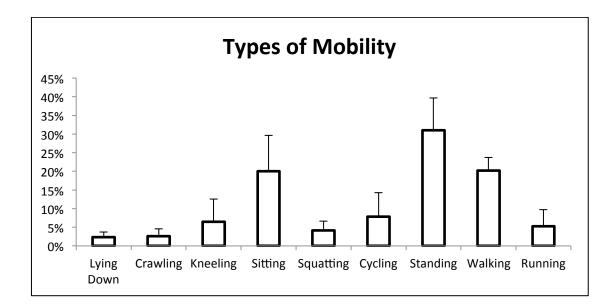


Figure 9: Types of Mobility: On the x-axis are the types of mobility from left to right in order of those low to the ground and low exertion to upright and high exertion. On the y-axis is the percent occurrence of types of mobility. For example running activity occurred about 5% of the time.

Overall, there are three conclusions that can be made about types of mobility in toddlers. Out of all types of mobility, sitting, standing and walking occur the most at 70% of the time. The two peaks occur in the Sitting and Standing positions or upright and stationary. Types of mobility are not equally distributed and are variable by the toddlers in this study. Other activities besides sitting, standing and walking occur less than 10% of the time each spread across 30% of all activity. Types of mobility alone cannot be used as a way to observe physical activity, levels of exertion must also be observed.

Physical activity literature has studied levels of exertion in detail (Oliver et al., 2007)(Cliff et al., 2009). Physical activity literature states that most of toddler activity occurs in motionless and trunk and limb activities (Van Cauwenberghe et al., 2011)(Pate, O'Neill, & Mitchell, 2010)(Pate et al., 2008). Moderate and Fast activity occurs the least. Slow-Easy activity occurs between the other two groups. This data set confirms the literature and other observations. Trunk and limb activity occurs the most at 47% of the time. Moderate and Fast movements occur the least at 5 and 6% respectively. The standard deviations are within an acceptable range. The distribution is skewed to the right where the majority of behavior occurs at low levels of exertion.

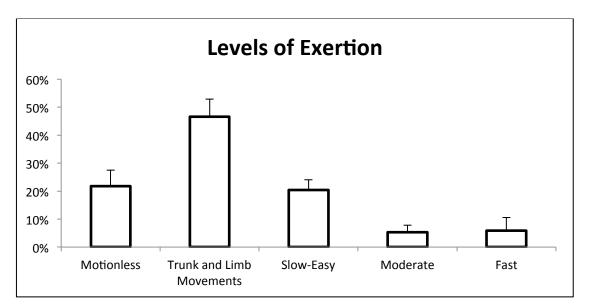


Figure 10: Levels of Exertion: On the x-axis are the five types of mobility. Motionless and trunk and limb movements are considered stationary. Slow-Easy, moderate and fast movements are considered mobile. On the y-axis is the percentage occurrence of these levels of exertion. For example, slow-easy movements occurred 20% of the time. Overall three major observations can be made. Trunk and limb movements occur just under half of all activity. Motionless and slow-easy movements occur the same amount of time at about 20% of the time. High exertion movements occur the least amount of time at about 5%. Physical activity literature has investigated types of mobility and levels of exertion, however few studies have investigated socialization.

Socialization in toddlers has been well investigated (Parten, 1933). There are four or five main types of socialization in toddlers, solitary play, parallel play, peer interaction and teacher interaction(Howes & Matheson, 1992)(Hay et al., 2004). Other types of socialization do not occur often in toddlers(Barbu, Cabanes, & Le Maner-Idrissi, 2011). Toddlers transition from solitary play into parallel play(Kopp, 2011)(Bakeman & Brownlee, 1980). Parallel play aids in the less frequent peer interaction. Teacher interaction occurs at all ages. This study confirms the major point of socialization studies in toddlers. Parallel play occurs the most or at least 35% and peer interaction occurs 10% of the time. However, there are close similarities in percent occurrence for every type of socialization other than peer interaction.

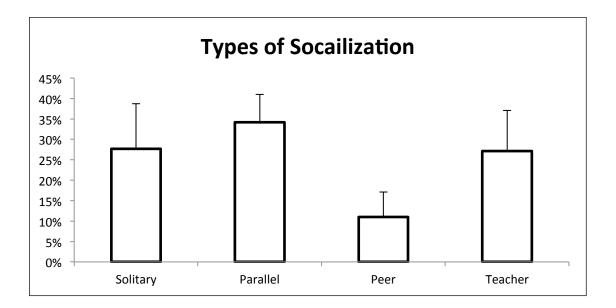
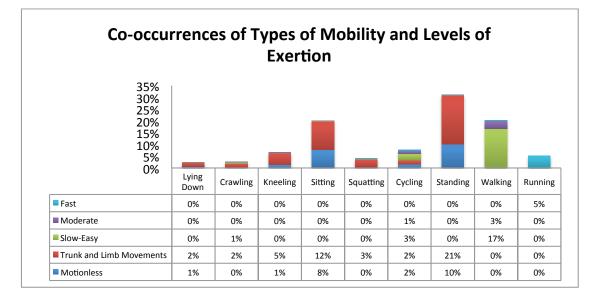


Figure 11: Types of Socialization: On the x-axis are the four different types of socialization as previously described. Socialization is label from least social to most social. Hierarchy code events present one type of socialization per interval with a preference for teacher interaction over peer interaction, a preference for peer interaction over parallel play and finally a preference for parallel play over solitary play. On the y-axis is the percent occurrence of these activities. For example, parallel play occurs about 35% in the hierarchy-coding scheme.

Overall, there are three main points to know about socialization. Socialization occurs at least 70% of the time. Peer interaction occurred 10% of the time with the remaining types of socialization each occurring 30% of the time. Physical and social activity has been observed in the literature, however the co-occurrences of physical and social activity has not been observed in great detail (Pellegrini & Smith, 1998).

Literature has been able to determine the types of mobility and levels of exertion exclusive from one another in young children(Van Cauwenberghe et al., 2011) but has not been able to determine the co-occurrences of these activities as shown in this study. For most types of mobility there are only two levels of exertion. Running only contains one level of exertion whereas cycling contains all levels of exertion. Types of mobility other cycling and running are comprised mostly of two levels of exertion. Types of mobility other than cycling and running and those that are under 5% occurrence are more than 75% comprised of trunk and limb movements. Trunk and limb movements and motionless occurs in every type of mobility other than the types of mobility that are only classified as moving (i.e. Walking and running). Trunk and limb movements are distributed throughout each type of mobility. Physical activity can also be observed as co-occurring with socialization.



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Figure 12: Co-occurrences of Types of Mobility and Levels of Exertion: On the xaxis are the types of mobility. Each color in the bar chart represents the levels of exertion. Levels of exertion represented in the bar graph increases from low to high exertion moving from the base of the bar to the top of the bar. For example, running encompassed of only fast activity. Another example shows that the sitting position is comprised of mainly motionless and trunk and limb movements. Trunk and limb movements are displayed on top of motionless movement.

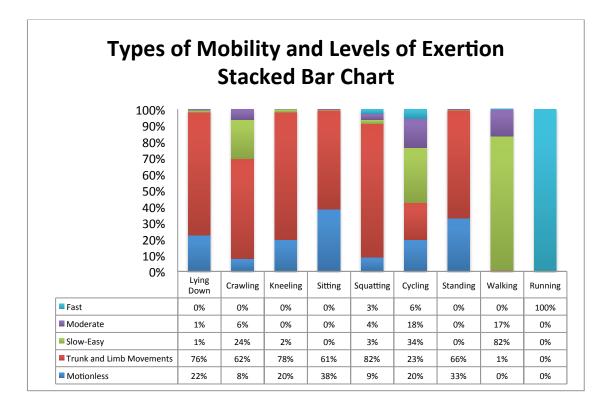


Figure 13: Types of Mobility and Levels of Exertion Stacked Bar Chart: On the xaxis are the types of mobility. Each color in the bar chart represents the levels of exertion. Levels of exertion represented in the bar graph increases from low to high exertion moving from the base of the bar to the top of the bar. Each type of mobility is broken up into the percentage of time it occurs with each level of exertion. For example, running encompassed of only fast activity at 100%. Another example shows that the sitting position is comprised of mainly motionless and trunk and limb movements. Trunk and limb movements are displayed on top of motionless movement. Each type of mobility should add up to 100%.

Although one study has attempted to observed movement, socialization and other basic categories such as object use. That study has only been able to determine percent occurrences of mobility and socialization (B. Jones, 1972) but not cooccurrences of movement and socialization or mobility and socialization. Movement and socialization occur the most at 55% of the time, whereas no movement and no socialization occured the least at 5% of the time. The standard deviations are small and acceptable for this data set.

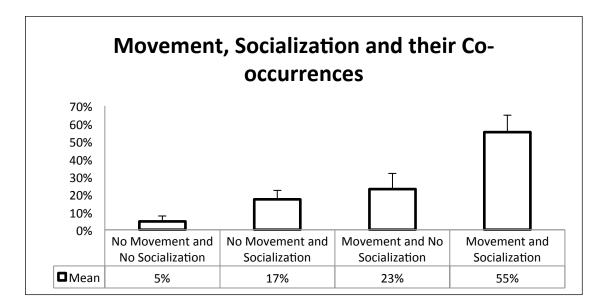


Figure 14: Movement, Socialization and their Co-occurrences: On the x-axis are movement, socialization and their co-occurrences. Movement is considered as any level of exertion other than motionless activity. Socialization is considered as any types of socialization other than solitary play. On the y-axis is the percent occurrence of these activities. For example, motionless activity (no movement) and socialization occurs 17% of the time.

There are three essentials points that can be observed from this graph.

Movement or socialization occurred occurred 95% of the time. Movement and

socializtion occur more than half of the time. Movement with no socialization and

Socialization with no movement occurred about 20% of the time equally. No

movement and no socialization occur about 5% of the time. More importantly,

socialization changes with different types of mobility.

The literature has not been able to quantify the co-occurrences of socialization and types of mobility (Pellegrini & Smith, 1998)(B. Jones, 1972). Additionally, it is unclear in one study of mobility and socialization whether mobility was studied with socialization within the same time frame (B. Jones, 1972). Similar studies such as these one need to be replicated with the a protocol for young children on mobility (Brown et al., 2006) and socialization (Parten, 1933). This study will bridge that gap in the literature. Socialization varies within each type of mobility. Socialization occurs the majority of the time in each type of mobility. Types of mobility that are lower to the ground contain higher amounts of social activity. Socialization is prevalent in all types of mobility. How does socialization co-occur with levels of exertion?

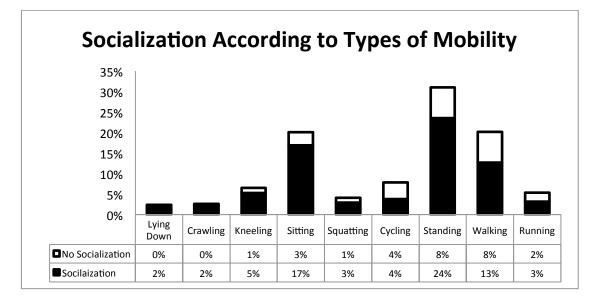


Figure 15: Socialization According to Types of Mobility: On the x-axis are the types of mobility. The bar chart represents socialization as any other type of socialization other than solitary play. On the y-axis are the percent occurrences of these activities. The attached table gives the percent co-occurrences of types of mobility and socialization. For example, socialization during sitting occurred 17% of total time. The percent occurrences in this graph are of the total time.

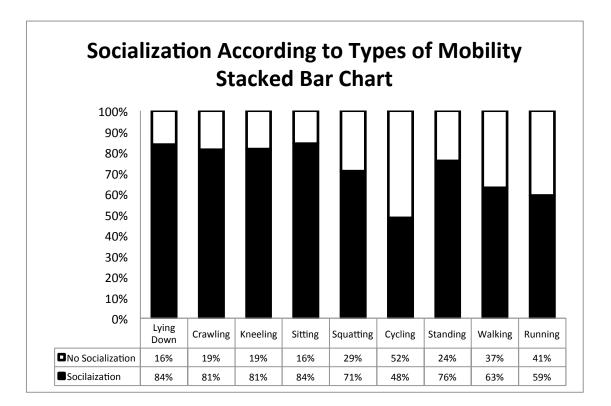


Figure 16: Socialization According to Types of Mobility Stacked Bar Chart: On the x-axis are the types of mobility. The bar chart represents socialization as any other type of socialization other than solitary play. On the y-axis are the percent occurrences of these activities normalized to 100% of time within each type of mobility. The attached table gives the percent co-occurrences of types of mobility and socialization. For example, socialization during sitting occurred 84% of sitting time.

The literature has not been able to quantify the co-occurrences of socialization and levels of exertion (Pellegrini & Smith, 1998). This study will bridge that gap in the literature. Socialization varies within each level of exertion. Socialization occurs at least half of the time in each level of exertion. Half of all high exertion activities (moderate and fast movements) occur with socialization. This study concludes that socialization occurs most of the time.

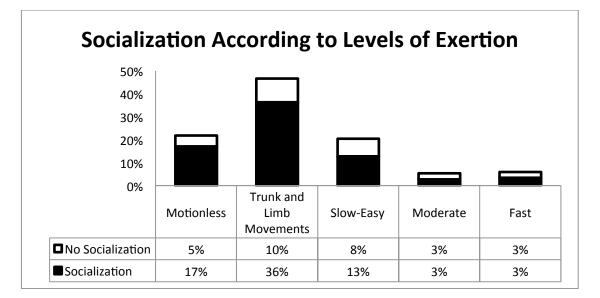


Figure 17: Socialization According to Levels of Exertion: On the x-axis are the levels of exertion with increasing exertion from left to right. The bar chart represents socialization as any other type of socialization other than solitary play. On the y-axis are the percent occurrences of these activities. For example, socialization while motionless occurs 17% of the total time.

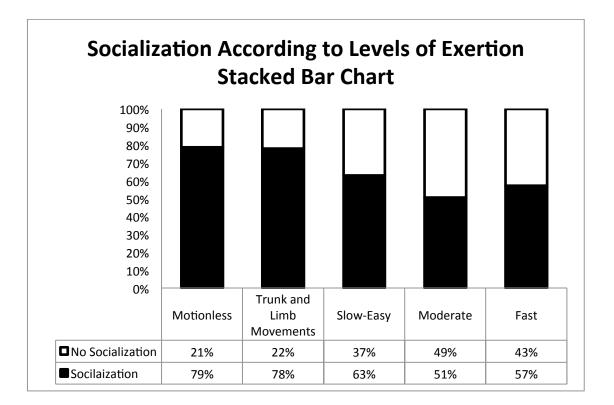


Figure 18: Socialization According to Levels of Exertion Stacked Bar Chart: On the x-axis are the levels of exertion with increasing exertion from left to right. The bar chart represents socialization as any other type of socialization other than solitary play. On the y-axis are the percent occurrences of these activities normalized to 100% of time within each level of exertion. For example, socialization while motionless occurs 79% of the time spent in motionless activity.

Chapter 5

DISCUSSION

5.1 Limitations

The results appear reliable and valid within the scope of the study, and add important information to the limited data on toddler mobility and socialization. Every study, however, has important limitations to the generalizability of results which require consideration and combination with previous findings. The study used a version of the OSRAC-P for preschoolers. Certain OSRAC-P activities did not occur in toddlers and/or could not occur at the ELC. Thus, the OSRAC-P was modified. For example, sitting and squatting counted separately instead of together as in the original protocol. Other activities such as swinging could not occur as there are no swings at the ELC. OSRAC-P also includes social behaviors however they were too specific for the focus of this study. In addition to the modified measures, this study observed a relatively small group of child within one type of setting: a childcare center. Different environments, such as the home, would be expected to impact the distribution of mobility, exertion and socialization (McIver, Brown, Pfeiffer, Dowda, & Pate, 2009) (Hart & Sheehan, 1986). Moreover, the one hour per day per child was also during 'free play'. Follow up studies are now required to test further hypotheses and to generate descriptive databases in the range of contexts over different period of

time in which young children are mobile and social. Future work in this lab in this area is focused on a) generating database of mobility and socialization in infants and preschoolers within the ELC to complement the current results in toddlers, and b) expanding our infant-toddler-preschooler database to other contexts (ex. Home and out of home community locations) and activities (ex. Feeding/eating and bath/dressing).

The following sections of the Discussion will provide a brief summary of the major findings of the current study. Following the Discussion section is an Implications section in which more details are provided on the scientific and clinical implications of results.

5.2 Mobility

Valid and reliable data on the mobility of typically developing children is critical for the design and testing of interventions (ex. technology and training) improve the mobility of children with special needs. The cost/benefit (i.e.worth) of technology and training can be tested only if there is a quantitative understanding of typical mobility. For example, assume treatment A leads to 50% more mobility than treatment B, which in absolute terms hypothetically translates to 1 hour of total mobility. Although treatment A is an improvement over B, the value of treatment A would likely be judged to be different if the 'goal' standards for daily mobility set by typically developing children are 1, 4, or 8 hours per day. Therefore, understanding typical mobility is not only scientifically important but also clinically imperative to the proper design and testing of technology and training such as mobility devices.

The current study found that toddlers were almost constantly moving their bodies in time and space. Relatively little data is available on the mobility of typically developing toddlers. There is general information about physical activity such as types of mobility and levels of exertion in preschoolers (Pate et al., 2010), however less in toddlers (Tremblay et al., 2012) (Cardon et al., 2011). Few studies track types of mobility and levels of exertion together(Van Cauwenberghe et al., 2011). Similar to Van Cauwenberghe, the current study found that sitting, standing and walking occurred 70% of the time with the remaining 30% of activities individually occurring less than 10% each. Therefore, types of mobility varied in percent occurrence. The current study also found that 'movement' (i.e. a combination of all levels of exertion other than motionless activity) occurred 80% of the time. Therefore, no movement or motionless activity was observed for only 20% of all activity. The current study also noted that toddlers were mobile or 'translocating' (i.e. a combination of the slow-easy, moderate and fast levels of exertion) 30% of the time with trunk and limb movements occurring the remaining 50% of the time.

5.3 Types of Socialization

Similar to mobility findings, the current study found that toddlers were almost constantly socializing and/or near others that were socializing. Socialization in

toddlers has been investigated in great detail (Parten, 1933)(Howes & Matheson,

1992). The literature shows that during toddlerhood, children are rapidly changing the frequency, duration and manner in which they interact with other people (Barbu et al., 2011) (Bakeman & Brownlee, 1980). The current study found that socialization (i.e. any type of socialization other than solitary play) occurred 70% of the time. This study confirms previous literature in that solitary play, parallel play and teacher interaction each occurred 1/3 of the time. Peer interaction occurred the least at 10% of the time.

5.4 Mobility and Socialization

The current study confirms the general proposal that toddlers are highly mobile, constantly moving and increasingly social. The current study extends the literature by determining the co-occurrence of movement and socialization. Only one study could be found that includes physical activity and socialization (B. Jones, 1972). The current study found that movement or socialization occurs 95% of the time and that movement and socialization co-occurred 55% of the time. Socialization without movement and movement without socialization each occurred about 20% of the time. The next section outlines briefly the co-occurrence of socialization, types of mobility and levels of exertion.

5.5 Socialization and Types of Mobility

No study was found that provided a comprehensive description of the cooccurrence of socialization and types of mobility. This study found that socialization and mobility co-occurred for majority of the time for all but one type of mobility and 70% or more of the time for the majority of the types of mobility (6 of 9 types).

5.6 Socialization and Levels of Exertion

No study was found that provided a comprehensive description of the cooccurrence of socialization and levels of exertion. This study found that socialization and levels of exertion co-occurred for the majority of the time for all levels of exertion and 60% or more of the time for motionless through slow exertion levels, and between 50-60% of the time for moderate and fast levels.

Chapter 6

IMPLICATIONS

6.1 Children with Disabilities: Cerebral Palsy, Spina Bifida, Down Syndrome and Autism Spectrum Disorder

Our results on the mobility and socialization of typically developing toddlers provide comparative data to evaluate current and future assessments and interventions with a range of young children with special needs. A few specific pediatric populations make up the major of children seen by special educators and pediatric rehabilitation specialists. For example, young children with disabilities or developmental delays such as Cerebral Palsy (CP), Spina Bifida (SB) and Down Syndrome (DS) occur approximately 51 out of every 10,000 births (Boyle et al., 2011). As of 2008, Autism Spectrum Disorder (ASD) occurred in 1 out of 88 children (Baio, 2012). ASD is a social disorder that is accompanied by repetitive and stereotypical behavior (Baio, 2012) as well as various movement and postural impairments (Ming, Brimacombe, & Wagner, 2007). As of 2006, CP occurred 3.6 times out of every 1,000 live births (Tilton & Delgado, 2011)(Kirby et al., 2011). As of 2004, Spina Bifida occurred 3.39 times out of every 10,000 live births (Boulet et al., 2008). CP and Spina bifida are nervous system injuries occurring early in life that can result in a range of mild, moderate or severe mobility and/or movement related

impairments (Kavcic & Vodusek, 2005)(Krigger, 2006). As of 2008, Down syndrome occurred 1.08 times out of every 1,000 live births. Down syndrome is a chromosomal abnormality that can result in a range mobility and movement related impairments as well as intellectual disability (Irving, Basu, Richmond, Burn, & Wren, 2008).

6.2 Disability and Movement

Disability has negative effects on the movement abilities of children with Cerebral Palsy, Spina Bifida, Down syndrome and Autism. CP is the most common pediatric diagnosis associated with movement and/or mobility limitations (Tilton & Delgado, 2011). In a recent study, 81% of 8 year olds with CP had spasticity which can limit their range of movement, 56% walked independently while 33% had limited or no walking ability (Kirby et al., 2011). Mobility of a child with Spina Bifida is related in part on the location of the neural lesion. About 1/3 of the children with lumber and thoracic lesions are able to walk (Northrup & Volcik, 2000). Accompanied with sitting or "lack of mobility", are flexion deformities of the knee which future limits full mobility (Northrup & Volcik, 2000). Although most children with Down syndrome eventually walk, most do so about a year later than typically developing children (Horovitz & Matson, 2011). Additional factors such as cardiovascular problems also limit these children's mobility (Short & Frimberger, 2012). Mobility impairments are increasingly report in ASD, a diagnosis traditional associated with limitations in socialization. In one study, 2-6 years old children with ASD displayed

various movement and/or mobility-related issues including hypertonia (stiff overactivated muscles, 63%), apraxia (loose under-activated muscles, 41%), toe-walking (25%) and gross motor delay (12%) (Ming et al., 2007). Thus, in general, many pediatric populations that involve significant physical (Whittingham et al., 2010) or social limitations (Bhat, Landa, & Galloway, 2011) are at risk for delays in both mobility and socialization.

6.3 Disability and Types of Mobility

Children with significant physical disabilities experience limited types of mobility (Missiuna & Pollock, 1991)(Palisano et al., 2009). This is due in part because significant physical disabilities often include various forms of muscle disorders, coordination and gross motor problems (Tervo, 2003). Coordination and gross motor skill for example can hinder the child's ability to perform crawling, walking, running, cycling and other gross motor activities (Leung, Chan, Chung, & Pang, 2011)(Bundonis, 2009).

6.4 Disability and Levels of Exertion

Children with significant physical disabilities likely experience limited levels of exertion due to physical disability for several reasons. Specifically, reduced cardio activity (Short & Frimberger, 2012) as well as spasticity and coordination problems (Tervo, 2003) can limit the frequency and duration of different levels of exertion. Cardiovascular problems often accompany the above-mentioned pediatric populations especially children with Down syndrome (Dodd & Shields, 2005). Spasticity can prevent a child's ability to move upper and lower extremities or trunk and limb movements (Krigger, 2006). High exertion levels often require coordination and gross motor movements (Leung et al., 2011).

6.5 Disability and Types of Socialization

Children with physical disabilities may also experience limited socialization for multiple reasons (Whittingham et al., 2010). For example, these children may be unable to 'keep up' with their peers. That is, they may not be able to produce the frequency and duration of the various types of mobility and movements including the use of use objects for the purpose of social interaction (Hay et al., 2004). In addition, typically developing children may perceive children with mobility and/or exertion limitations not being able to participate equally in the constant stream of social interactions requiring movement.

6.6 Implications to Children with Disabilities

The results of this study have implications in four areas of research in young children with and without disabilities. First, the results address clinical gaps in the

literature about mobility, socialization and mobile-social co-occurrences. Secondly, the results can be used to improve interventions as they provide general standards to aspire towards. Thirdly, the results increase the scientific knowledge of mobility and socialization in early development and its potential impact on the developmentally delayed and physically disabled. Finally, study methodology can be used to improve clinical assessments by creating simple techniques of tracking mobility, socialization and the co-occurrences. In the following paragraphs, each of the four major aspects and suggested future studies will be discussed.

This study seeks to aid in addressing clinical gaps in the literature about mobility, socialization and their co-occurrences in children with and without disabilities. Mobility, socialization and their co-occurrence can be observed in typically developing as well as developmentally delayed children. This method can compare typically and developmentally delayed age-matched peers and show deficits/surpluses in the three investigated measures, types of mobility, levels of exertion and types of socialization. The preliminary results from a case report serves as an illustration of the degree of differences between children with even 'mild' mobility impairments and those that are typically developing. In this case report, a 'highly' mobile and social preschool child who was mobile using one or two Loft strand crutches, was observed the methods of this study. The following graphs compare the types of mobility and levels of exertion to that of the typically developing toddlers within one ELC context, the gym. Several interesting comparisons can be noted from the preliminary data in Figure 19 and 20. From Figure 19, the DD child spent twice the time sitting, only 50% of the time walking and 30% or less of the time doing all other activities compared to TD children. From Figure 20, although the DD child spent 80% of the time moving (i.e. all levels of exertion combine minus motionless), however the distribution in terms of levels of exertion appears to be different. Specifically, the DD child spent 20% more time at the lowest two levels yet only 50% of the time in slow/easy movements and rarely if ever displayed moderate and fast movements. The preliminary data shown in Figure 19 and 20 provide an example of how, with group studies, important clinical gaps on the mobility of TD and DD can be addressed. It is important to note that the child in this case report is considered only 'mildly' impaired in terms of mobility and movement. Thus, the gap between TD children and the vast majority of pediatric populations seen clinically would be expected to be significantly larger.

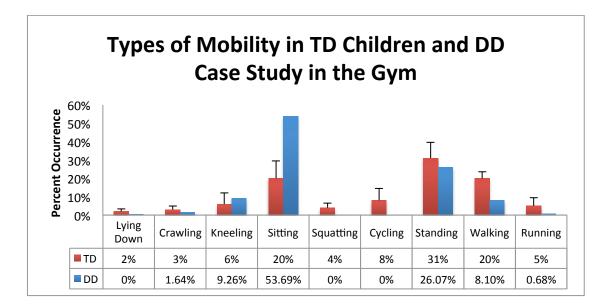


Figure 19: Types of Mobility in TD Children and DD Case Study in the Gym: On the x-axis are the types of mobility that occurred in the gym. The red bars represent the types of mobility occurring in 21 typically developing children. The blue bars represent the types of mobility occurring in the developmentally delayed case study. On the y-axis is the percent occurrence of each type of mobility. Standard deviations cannot be given for the developmentally delayed child.

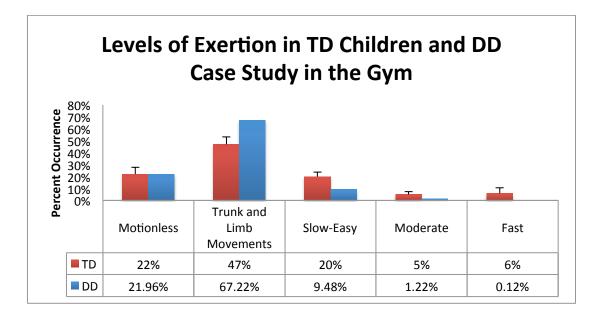


Figure 20: Levels of Exertion in TD Children and DD Case Study in the Gym: On the x-axis are the levels of exertion that occurred in the gym. The red bars represent the types of mobility occurring in 21 typically developing children. The blue bars represent the levels of exertion occurring in the developmentally delayed case study. On the y-axis is the percent occurrence of each level of exertion. Standard deviations cannot be given for the developmentally delayed child.

Information such as that generated in the case report comparison would allow special educators and pediatric rehabilitation specialists to quantify the degree to which the distribution of types of mobility and levels of exertion are different their children with special needs. Why, how and when to attempt to change the distribution in a child is an important set of basic clinical decision points. If the educational and clinical team in conjunction with the child's caregivers determine that mobility improvements are a goal, then technology and training can be implemented and evaluated. Next a follow-up case report on the same child as above will illustrate the usefulness of the current study's methodology and results.

The child from Figures 19 and 20 was provided a ride-on toy car to drive while on the ELC playground as a clinical intervention to improve his mobility and socialization. Figure 21 shows the types of socialization with and without the ride-oncar intervention.

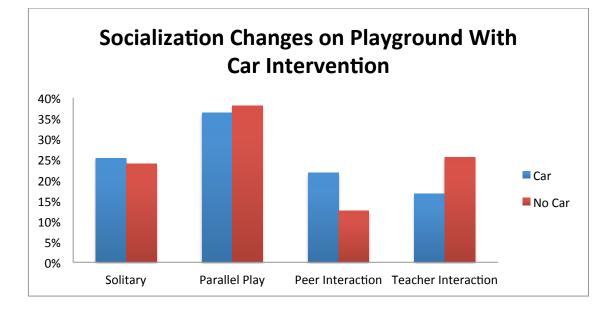


Figure 21: Socialization Changes on Playground With Car Intervention: On the xaxis are the types of mobility. The blue bars represent the socialization with the car intervention and the red bars represent the socialization with no car intervention or crutches. TD socialization data was not included as the DD child was a preschooler and TD data was from toddlers. Preschoolers and toddlers have significantly different socialization patterns. From Figure 21, several interesting comparisons are noted. Although the percent of socialization did not appear to change with the car intervention, the distribution of the type of socialization did appear to change. Peer interaction increased 10% with the car intervention whereas teacher interaction decreased 10%. Group studies are required to determine if this or any intervention is effective at normalizing mobility and socialization. This preliminary data does suggest however that the methods and comparisons are feasible and potentially useful.

The Infant Development Lab is using a new intervention called the, "Open Area Harness System" (OAHS) as a way to aid in mobility and socialization. OAHS is a XYZ Cartesian crane body weight support system that allows constant body weight support in any open area such as a classroom, gym, playground. A permanent version of this intervention equipment exists in the ELC gym and has been placed during pilot work within a home environment. This intervention has the potential to increase mobility within 'social settings' and thus to increase the co-occurrences in a child with a disability. Future work can apply the methods and TD results to address the many basic questions that remain.

Direct observation is a common assessment tool for educators, researchers and clinicians working with children with disabilities (Pellegrini, 2001). For example, observation is common in the study of the impact of augmented mobility or mobility aids on development (Bundonis, 2009)(Charlene Butler, 2009). The methods of the current study can be visualized in a simple way that would allow the tracking of

mobility and socialization behaviors in educational, research and clinical settings. The following graphs shows mosaic plots of the types of mobility in typically developing children and a second child with significant physical impairments due to CP. The data from the second child with significant physical impairments due to CP will be compared to that of typically developing toddlers.

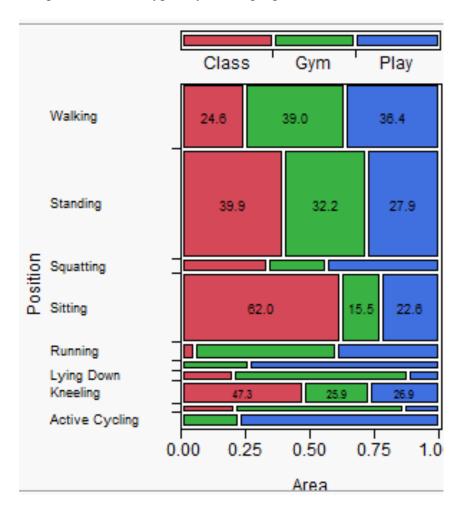


Figure 22: Types of Mobility Across Contexts in Typically Developing Toddlers: In the first graph at the top is the distribution of time spent in the Classroom, Gym and Playground. In the second graph, the distribution of each type of mobility across each context is given. On the x-axis is the distribution of each activity according to the time spent in each type of mobility. For example, out of all time spent walking, walking occurs 24.6% of the time in classroom. On the y-axis is the distribution of the activity regardless of context. For example, standing occurs more than any other types of mobility because it is the thickest row.

A preliminary analysis of Figure 22 shows that the distribution of types of mobility across contexts varies in the TD group. Specifically, of the three main types of mobility, sitting, standing and walking; walking occurred the least in the classroom and most in the gym whereas sitting the least in the gym and playground and most in the classroom. Standing occurred the most in the classroom.

A preliminary analysis of Figure 23 suggests there was a different distribution of the types of mobility across contexts for the child with CP. Specifically, of the three main types of mobility, sitting, standing and walking; standing and standing occurred the least in the gym and sitting the least in the gym. Walking did not occur in the second child with Cerebral Palsy, instead Lying Down occurs. Standing occurs the most in the gym and sitting occurs the most in the classroom. Lying down occurs the most in the classroom.

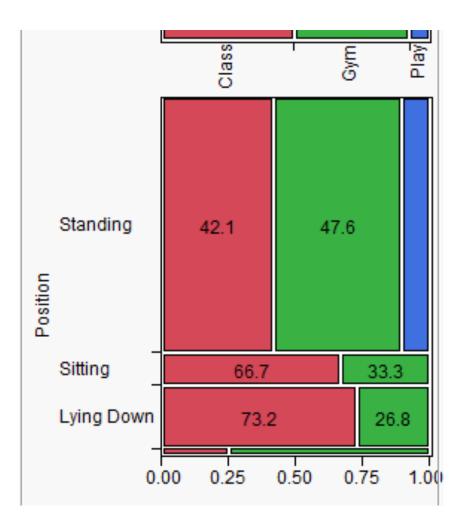


Figure 23: Types of Mobility Across Contexts in a Child with Cerebral Palsy: In the first graph at the top is the distribution of time spent in the Classroom, Gym and Playground. In this case, time spent in the classroom and gym are about equal with time in the playground being very minimal. In the second graph, the distribution of each type of mobility across each context is given. On the x-axis is the distribution of each activity according to the time spent in each type of mobility. For example, out of all time spent standing, standing occurs 42.1% of the time in classroom. On the y-axis is the distribution of the activity regardless of context. For example, standing occurs more than any other types of mobility because it is the thickest row.

Chapter 7

CONCLUSIONS

The above mosaic graph may be a relatively simple assessment tool that researchers, caregivers and developmentalist could use to track activity in children. This type of tool would provide both a quick comparison of how an individual child or group of children with special needs compares to a known database of other children. Comparisons could include the following: one child compared pre and post to him/herself; one child with CP compared to a group of similar children with CP or with a group of TD children; one child or a group of children compared to themselves in two contexts or involving two interventions.

This study provides methods and results that advance our measurement and understanding of mobility and socialization in typically developing children. This study confirmed several proposals from the literature on physical activity as well as extend our understanding of the co-occurrences of mobility, exertion and socialization in toddler aged children. Overall, toddlers were mobile or social 95% of the time and were mobile 80% of the time and social 70% of the time. Socialization co occurred with each type of mobility and level of exertion over 50% of the time in all but one case, and over 70-80% in most types and levels of exertion. Future work on assess technology and training will benefit from both longitudinal observational studies and more formal clinical trials with pediatric populations such as CP, Down Syndrome, ASD and Spina Bifida. Lastly, further automation of the coding of behavior such as with the Kinect system coupled with the use of mosaic graphs would allow a 'clinical kit' to be developed. This is a current focus of the Infant Behavior Lab.

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A. TITLE: RIDE-ON CARS TO ADVANCE MOBILITY AND DEVELOPMENT

Informed Consent Statement Infant Motor Behavior Lab Dept. of Physical Therapy University of Delaware

PURPOSE:

This study examines the ability of children to learn to drive a ride-on toy car, in the home and in the University of Delaware Early Learning Center (ELC), and will allow us to observe consequent changes in development. This project builds upon the previous work by Dr. Cole Galloway on how increasing a child's mobility effects development.

Children born with movement impairments are at risk for additional developmental problems due to their inability to move independently to explore, learn, and play. This study tests whether a modified ride-on toy car may provide an alternative, easily accessible way for the family and therapists to improve mobility and development of the child at home or the ELC in an early stage. The results of this study will assist clinicians and researchers in improving a child's independent mobility.

<u>Computer and Video requirement</u>: An important requirement of participation is your ability to video record and upload videos to a private YouTube Channel. We will provide initial instructions but ultimately you will need to be independent in video recording and uploading these videos as outlined below. It is important that your family has access to a computer, a digital camera, and a reliable internet connection. You are also welcome (but not required) to participate on our public YouTube channel, which contains instructional videos on how to build your own rideon car, and on our public Facebook page, which keeps interested parties up-to-date on our lab's ride-on car research and activities. The Facebook page also enables you to connect with other involved families, health care professionals and researchers. During the retention part of the study, we will ask you about your experiences using digital media as part of the research process. We may also examine how, if at all, you and other study participants use the public YouTube and Facebook sites by observing your posts and interactions on them.

PROCEDURE:

Your child will be one of 10 participants, all of whom must be within the age range of 12 months to 5 years. Your child will be excluded from further participation if: a) your

child has severe sensory impairments such as blindness, deafness, b) you are not able to make a time commitment for the training phase, c) your home does not pass the Home Assessment. During the home assessment we visually and physically inspect all rooms of your home and yard for safe driving space including inspection of furniture and other objects for safety. You will then be asked to sign a form stating that you will only allow your child to drive in the appropriate areas.

This study involves: a Baseline phase (three months) in which we track your child's development and prepare a toy car for you to take home, a 'Training phase' (three months) in which you and your child use the toy car daily, and a 'Retention' phase (one month) in which we track your child's development without the toy car available to drive. In the training phase, you are responsible for playing with your child in the toy car for a minimum of 20 minutes and a maximum of 10-minutes for additional play. Thus, the total training time will be at least 30 minutes/per day, 5 days/per week for 3 months. You will be asked to complete a daily activity log of your child's driving time. Once per week during each phase of the study, you will video record and upload a 20-30 minute video of your child driving in the toy car.

Baseline (3 months)

During the Baseline period, your child's development will be assessed multiple times.

Home Assessment (30 minutes): During the first week of Baseline, investigators will visit your home to determine if: a) there is sufficient room for the child to drive, and b) you can allow the child to drive in certain locations. You are required to sign a home assessment agreement and a liability form regarding your use of the toy car. Your child is only allowed to drive the car in the determined areas, e.g., basement, living room, or community space. If there is any inappropriate use of the toy car determined by the Investigators during the process, including driving on unallowable areas, or letting other children use the car, your child will be excluded from further participation.

General Development (1-2 hours): Two separate assessments of your child's development are completed by a clinical therapist at the beginning and end of the Baseline month. Both assessments involve play with your child and questions to you as parent.

 Bayley's Scales of Infant and Toddler Development III: a set of general developmental measures of your infant's language, motor, cognition, and social behaviors.

- Pediatric Evaluation of Disability Inventory (PEDI): a measurement that gathers information on self-care, mobility, and social functions
- Pediatric Balance Scale (PBS): a measurement that gathers information on your child's ability to sit and stand by him/herself and complete other basic tasks that require balance such as turning completely around while standing in one spot.

Bone Density (40 minutes to 1 hour): One visit to the Human Performance Lab, University of Delaware, Newark, DE 19716. This will be completed twice during the study. Once after baseline and once after training.

- A research assistant will measure your child's height, leg length and trunk length. Weight will be measured while your child is wearing a tee-shirt, shorts and socks or baby clothing
- While your child is lying down on a table, a research assistant will take four pictures of your child's bones, muscles and other tissues using a special X-ray scanner. The picture will take 1 minute and the other picture will take 7 minutes. Your child will have to remain still for each picture. If needed, we will help your child



stay still using a 'BodyFix' system. We will place the plastic sheet over your child's legs and waist. When the vacuum machine is turned on, it will cause a slight pressure against your child's legs and waist which will help them hold still. This is actually a comfortable procedure and will not hurt your child.

Socialization (20 minutes): Every 1-2 weeks during the Baseline phase your family will video record you playing with your child. You will then upload this video to our UDGoBabyGo YouTube Channel. We will provide instructions and assistance to help you do the initial upload.

Driving Testing and Toy Car: During the Baseline phase, you will test your child's driving ability, we will purchase a toy car for your child's use and make minor modifications to fit the toy to your child's size and abilities.

 Driving Testing (30 minutes): Your child will be provided 30 minutes of driving time. Your family will video record the amount of driving and your interactions with your child as he/she drives.





Figure 1 Ride on Toy Car. Bottom view shows the typical modifications of a PVC roll cage and large red switch with a yellow

- *Modifications*: We will likely make several modifications to the toy to help your child learn to drive. Examples of modifications are shown on the right figure, and include a PVC 'roll bar' and a large red switch to make the car move.
- *Parent Interview (30 minutes):* You will be asked to complete a questionnaire on your perception of a toy car or a power wheelchair.

B) Training (3 months)

Toy Car: During the training period we will provide a toy car to you for your child's use in your home. You will receive an educational booklet as well as a personal training on the toy's use, safety and suggestions for initial games. You are to keep a log of the daily training time, location and general activities per day (10 minutes). You are responsible for playing with your child in the toy for a minimum of 20 minutes per day for 5 days per week. The 20 minutes includes 10 minutes of any play activity involving the car and 10 minutes for driving to a specific location.

Assessment: Using the same tests as in the Baseline period, you will video record your child during the 20 minutes of Socialization and Driving Test as outlined above every 1-2 weeks. You will then upload this video to our UDGoBabyGo YouTube Channel. This will allow us to assess your child's socialization and driving.

B) Retention (1 month)

At the end of the Training period, we will take back the toy car. During this month, you will again video record your child during the 20 minutes of Socialization and Driving Test once per week. You will then upload this video to our UDGoBabyGo YouTube Channel. Standardized assessments and questionnaire will again be completed. Bone density will also be measured a second time during this time.

CONDITIONS OF PARTICIPATION:

Participation in this study is voluntary and you are free to withdraw at any time without penalty and without loss of benefits to which you or your child are otherwise entitled. If you withdraw and would like data on computer files not to be used, you simply need to notify us in writing, and it will be discarded. If you withdraw and would like your videos not to be used, please notify us in writing and then remove your videos from YouTube.

In the event of physical injury resulting from participation in this research, the researcher and the family will immediately be notified. If you or your child requires additional medical treatment beyond first aid, you will be responsible for the cost. **IMPORTANT REQUIREMENT:**

<u>Confidentiality of videos uploaded to private YouTube Channel will not be</u> <u>guaranteed</u>. You will be required to post assessment videos as outlined above as a 'private' but not password protected video on our 'UDGobabyGo' YouTube Channel. By following instructions to make your video 'private', you can restrict who views your video, such as allowing only researchers from our lab to view. That is, the public cannot view these videos by standard search methods, however anyone you allow can view your videos. As such, these videos will be difficult for the public to view, however, we are not guaranteeing confidentiality as we do not control the YouTube Channel.

<u>Videos will show subjects, family, home and other environments</u>, and will be used to extract data. Although you will upload your videos to a 'private' YouTube Channel, access by the public may be possible. Videos may be used for future research. As outlined below, confidentiality of other data besides upload videos will be protected.

We will use video files with children's faces in presentations and for educational and lay media. Participating families may not 'opt out' of posting and data extraction of their public videos. When a video is requested by lay media, we will attempt to contact the families again prior to use.

How will subject identity be protected?

<u>Computer files containing data extracted from videos and from standardized tests</u> <u>will be protected</u>. We will store this data in a locked office. Computer files will be stored within password protected computers. In reporting the results, names may be used. Data is typically reported in aggregate form but an individual's data may be reported.

RISK AND BENEFITS:

Your child's safety is very important to us. We anticipate that your child's use of the toy car will be fun for him/her as well as you. There are however a risk of significant injury if the mobile device is used inappropriately. Your child should be securely strapped into the toy car but can easily be removed from the chair by an adult. The toy's speed is approximately the speed of a walking adult. Improper use of the toy car or a lack of direct supervision while your child uses the toy is not permitted, increases the risk of injury, including but not limited to, loss of or damage to personal property, accidental injury, illness, serious disabling injuries, trauma, and death. Certain stipulations are required for your child to gain permission to drive this toy car:

- You must sign a home assessment agreement outlining the appropriate areas to drive at home in order to participate.
- No one but your child is allowed to get in or drive the toy car.
- You will only allow your child to drive in certain home locations determined by the Investigators.

Bone Density

The total effective radiation dose of the bone and muscle scans is less than one-half the effective dose associated with a standard chest X-ray and less than one-half the effective dose of radiation naturally experienced during a round trip flight from New York to San Francisco. It is possible that the vacuum procedure we will use to keep your child still will cause your child some distress. However, we have tested more than 70 children without a child becoming distressed. To allow your child to become accustomed to the procedure, the vacuum pressure will be increased gradually.

CONTACT:

If you have further questions about this study or its procedures, please contact the principal investigator, Cole Galloway, Ph.D., PT at (302) 831-3697; Infant Motor Behavior Lab, Dept. of Physical Therapy; 320 McKinly Lab; University of Delaware; Newark, DE 19716. You may also contact Samuel Logan, post-doctoral researcher and Christina Ragonesi, graduate student in the Infant Motor Behavior Lab at the University of Delaware at (302) 353-6605. General questions regarding research participation and the rights of participants should be directed to the Chair of Human Subjects Review Board; 210 Hullihen Hall; Univ. of Delaware; (302) 831-2137.

PARENT OR GUARDIAN CONSENT SIGNATURES:

1) Consent signature for child participation:

I,______, the parent of ______, to participate in the study described above. I have read and understand all of the above and have had all of my questions regarding the study and the procedures fully and satisfactorily answered. I understand that my child's participation is not confidential and that videos of my child will be posted online publically. I understand that my child's name may be used when the results of this study are reported. I understand that I can stop the session at any time without penalty. I have received a copy of this document for my records.

(Signature of parent)

(Date)

2) Consent signature for parent participation:

I,______, voluntarily agree to participate in the study described above. I have read and understand all of the above and have had all of my questions regarding the study and the procedures fully and satisfactorily answered. I understand that my participation is not confidential and that videos of myself will be posted online publically. I understand that my child's name may be used when the results of this study are reported. I understand that I can stop the session at any time without penalty. I have received a copy of this document for my records.

(Signature of parent or guardian)

(Date)

3) Consent signature for parent participation:

I,______, voluntarily agree to participate in the study described above. I have read and understand all of the above and have had all of my questions regarding the study and the procedures fully and satisfactorily answered. I understand that my participation is not confidential and that videos of myself will be posted online publically. I understand that my name may be used when the results of this study are reported. I understand that I can stop the session at any time without penalty. I have received a copy of this document for my records.

(Signature of parent or guardian)

(Date)

B. PARENT/GUARDIAN CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

PURPOSE AND DESCRIPTION OF RESEARCH

Families enrolled at the University of Delaware's Early Learning Center - Newark (ELC-N), the ELC-Wilmington (ELC – W), and the University's Laboratory Preschool (hereafter referred to as the Centers) will participate in a number of research activities. This form describes the core research activities in which you and your child might participate during the next year. This form will formally document your willingness to participate in these research activities. If you have questions about enrollment, please speak with Peg Bradley, the Director of the Centers.

We will be using information collected during these activities to address the following and related questions:

- How do school and home environments affect children's physical, psychological, and emotional development during early childhood?
- How do early environments affect children's development in later years?

Any information obtained from interviews or individually administered procedures will be available only to researchers and professional staff affiliated with the Centers.

PARTICIPANT ACTIVITIES

Each year you will complete questionnaires about how your child and family are doing. In particular, you will complete questionnaires regarding your contact information (address, telephone number, etc.), income and education; your child's behaviors; how you discipline your child; how much support you get from others; problems with emotional issues or drug or alcohol use; your satisfaction with marriage; your ideas about raising children; your expectations of children, and how your family shows emotion. A fuller description of measures is attached to this consent form. Usually these activities will not take longer than three hours to complete each year. If you need staff to read the items to you, it may take a little longer.

While not all children will participate in every activity, your child may participate in any number of the activities described below.

 Your child may be videotaped and/or audiotaped during classroom and play activities at any point during the day, either while alone or while in a group of children. Parents who are in the classroom may also be taped. Researchers will sometimes observe children from behind one-way glass. Cameras and microphones are mounted in the classrooms and other spaces used by children. Portable cameras and camcorders may also be used. The tapes/recordings will be stored in locked cabinets either at the Center or in the laboratories of individual researchers for use by them or their staff.

PARTICIPANT ACTIVITIES (continued)

- Teachers may make ratings of children's behaviors from time to time. They
 will rate how children behave in the classroom and when playing with other
 children, how children are developing academically, and how children seem
 to feel.
- ٠ Children may also be tested in individual sessions by trained researchers. Tasks may be presented to children that assess how they are doing physically, emotionally, and mentally. In particular, children's physical development may be assessed by researchers who ask children to do some things that use large and small muscles or by measuring children's height, weight, blood pressure, heart rate (pulse), and respiratory rate (how often they take a breath). Children's emotional development may be assessed by videotaping children's facial expressions as they interact with one another, play, read a book, or listen to music. Children's mental development may be assessed through tasks that assess how children solve problems, remember things, and use language. When children are infants and young toddlers, standard measures will be used to assess mental development by having the child play with toys and blocks. When they are toddlers and preschoolers, age-appropriate versions of math, language, and block tasks will be used. When they are school-aged, Delaware State Testing Program scores on file at the Center may be reviewed.
- Samples of children's saliva (spit) may be collected at various times during the day and during various activities so that we can measure the amount of a stress hormone (cortisol) that is present. The types of activities in which the children may participate will vary depending on their age. When they are toddlers or preschoolers, children may be asked to play with a series of toys or engage in certain games, some of which are designed to produce mild annoyance or frustration, thereby providing information about the child's temperament. School-aged children may be asked to tell a short story in front of a researcher or complete a math test. These activities have been shown to produce a small amount of stress in school-aged children. Saliva will be collected no more often than about 10 days per year. Children who are two or older will be asked to suck on a cotton swab for several seconds and then give the swab back to the researcher. Saliva from younger children

will usually be collected by dabbing the inside of their mouths with a cotton swab. During the school day, researchers who have experience collecting saliva will collect the samples. When samples are collected at home, parents will be trained on how to collect the samples. This collection of saliva will allow us to study stress levels of children as they go through the usual day to day activities at the Centers and at home. The saliva will not be used for any other purpose than for measurement of cortisol levels.

PARTICIPANT ACTIVITIES (continued)

- Educational programs will be similar across classrooms (within age groups); however, there may sometimes be different "extra" activities in one or more classrooms. This will allow us to study whether the extra activities affect children's development. Examples of these extra activities include programs designed to help children understand emotions better, programs that help children develop physically, and programs that help children learn how to play with other children better.
 - In addition to your annual intake or re-enrollment visit, you may be asked to participate in a task at the Centers or other University of Delaware campus location with your child. (If you are at the Early Learning Center Wilmington, all activities will occur in Wilmington.) These tasks will be different depending on the age of your child, as described below. These additional tasks may take between 1 and 2 hours of your time.

When children are between birth and 2 years of age, they may be observed doing several things with you. Children may be asked to play with a toy or game designed to produce mild annoyance or frustration. When your child looks to you for help you may be asked keep a still, serious face for 30 seconds as your baby tries to get your attention.

When children are between 1 and 2 years of age they may be videotaped as they are separated and reunited with you. For example, children may be in a room that you are asked to leave. After a short while, you will be asked to return to the room. If children are very upset by the separations, the separations can be very short. When children are between 2-4 years of age, they may be watched as they try to solve difficult problems with you, as they decide whether to wait to get a big reward or take a small reward right away and other such tasks.

With all of these activities you will have the right to decide whether the procedures should be shortened or stopped.

RISKS AND BENEFITS

- 1. Although there may be no direct benefit to your child, your participation and the participation of your child are expected to help children in childcare programs by helping researchers learn about what is important for healthy development.
- 2. There is minimal risk of harm to you or to your child as a result of participating in this research, although you or your child may feel somewhat uncomfortable in completing some questionnaires or procedures.

CONFIDENTIALITY

- All information you provide will be kept strictly confidential, and any report of the various studies will not identify you or your child personally in any way. Only researchers and the administrative and research staff at the Centers will have access to the information collected. If your responses indicate that you are experiencing severe depression, you may be contacted by a clinician about counseling options.
- 2. You should understand that State Law mandates we report any case of possible child abuse or neglect to the appropriate authorities.
- 3. Data will be kept for use by researchers for an indefinite period of time. If a child withdraws from any of the Centers, researchers will continue to use the child and family's data collected prior to withdrawal. Saliva samples will be stored for a period of no more than two years and will be used only to test the child's cortisol levels. No saliva will be used to identify or analyze DNA.
- 4. In order to help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH) so that researchers cannot be forced to release any information you provide, even if ordered to do so by a court subpoena.
- 5. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below:
 - a. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be

disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

b. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

ASSURANCES

- Children of all ages will be encouraged to participate in research activities. If a child communicates that he or she does not want to participate in a research activity through verbal or non-verbal means, his or her wishes will be honored and enrollment status will not be affected.
- 2. Research is an integral part of the ELC-N, ELC-W or Laboratory Preschool experience. Nonetheless, you may refuse to answer a single question or set of questions within a particular questionnaire without affecting your child's enrollment.
- 3. Any research activities that are not described in this consent form will require that researchers obtain additional consent from you. If you refuse to complete additional consent forms, it will not affect your child's enrollment status.
- 4. Researchers will explain what we are learning from the research projects at least every year.

If you have any questions, we encourage you to ask them. If you want information in the future regarding your participation in research, feel free to contact Dr. Mary Dozier, ELC Director of Research, at (302) 831-2271.

If you have questions about your rights as a participant, please call the Chair, Human Subjects Review Board, at (302) 831-2137.

CONSENT SIGNATURES

I, _____, understand each of the above items relating to my (Print your name/s)

participation and my child's participation ______in the (Print your child's name)

research of the Early Learning Centers and/or Laboratory Preschool and hereby agree to our participation in these research activities.

Signature of Parent/Guardian	Date	
I have explained the above items to that he/she understands each of the items.		and believe
Signature of Research Staff Member	Date	
Child's Name		_