Use of NMES for Swallowing Habilitation in Neonatal Intensive Care Units: A Survey of Clinical Practice

by

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Abstract

Purpose: The purpose of this investigation was to identify clinical practice patterns of speech language pathologists who use NMES with the neonate and young infant population, specifically, the modality treatment parameters and physiological rationale.

Method: An online survey was disseminated to query use of NMES by licensed speech language pathologists who routinely address swallowing habilitation in neonatal intensive care units (NICUs).

Results: Eleven of the forty practicing speech language pathologists who completed the survey indicated they have used NMES on neonates and infants in the NICU, indicating that most speech language pathologists do not use this modality with infants. Of the speech language pathologists who used this modality, primary reliance on clinical judgement for determination of NMES dose, frequency of treatments, electrode placement, and discharge determination was identified. While SLPs acknowledged that little empirical evidence is available, those who used this modality indicated that ASHA should support this modality in infants.

Conclusions: Reliance on clinical judgement, as indicated by SLPs who use NMES on neonates and young infants, is not consistent with the evidence-based practice triad which encourages the use of high-quality peer reviewed published evidence to inform clinical decision-making. Additional basic and applied research is needed to support use of NMES as a therapeutic modality in infants.

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List of Abbreviations

NMES	Neuromuscular Electrical Stimulation
SLP	Speech Language Pathologist
OT	Occupational Therapist
NICU	Neonatal Intensive Care Unit
ASHA	American Speech and Hearing Association
EBP	Evidence Based Practice

Chapter 1

Introduction

Neuromuscular electrical stimulation (NMES) is a method of treatment for muscle rehabilitation that involves the use of electrical stimulation to mimic voluntary muscle movement by activating the recruitment of motor units and inducing movement of the muscle, nerves or joints via electrodes positioned on the skin. This method of treatment involves application of high intensity electrical stimuli to generate muscle contractions. This treatment can be administered either transcutaneously or percutaneously. In both methods, an electrical current flows from the source and comes in direct contact with the body via the electrodes. The electrical current then creates a contraction by depolarizing the nerves that are responsible for motor innervation to a particular muscle (Humbert 2012). The use of NMES for dysphagia rehabilitation, involves small amounts of electrical currents that are administered in order to stimulate the muscles responsible for swallowing (Marcus et al. 2019).

Current dysphagia therapy treatment includes diet modifications, targeted exercises, and modification of positioning to enhance airway protection during swallowing (Ludlow 2010). NMES has been adopted in both research and clinical settings as a method of rehabilitation of muscle function following prolonged periods of disuse, for the improvement of muscle function, and as a preoperative strengthening modality (Maffiuletti, 2010). NMES is used by some occupational therapists (OTs) and speech language pathologists (SLPs) as a method for neuromuscular rehabilitation of dysphagia in adults (Rice 2012, Epperson & Sandage 2019).

Before new therapy methods are typically used on human participants, animal and human trials are conducted to support or contradict its use. Vulnerable populations such as neonates and infants cannot be willing participants of research studies, so careful measures are taken when taking these fragile populations into consideration for new therapy methods. Although some studies have explored the use of electrical stimulation on laryngeal muscles, they have been primarily on large animal models or mature adults. Currently, there is little research describing the use of NMES in fetal or juvenile animal models (Cheetham 2015) despite anecdotal evidence of the use of NMES for infant swallowing rehabilitation.

Proposed Physiologic Benefit of NMES

Multiple studies have investigated the overall effect of NMES as a method of therapy and have presented some benefits for its use. NMES has been used clinically as a method for rehabilitation, muscle preservation during immobilization and to improve muscle function (Maffiuletti 2010). The use of NMES has been implemented in many different fields, such as cardiovascular medicine, orthopedic medicine, neurological medicine, geriatric medicine and general medicine (Maffiuletti 2010). NMES is most commonly used as a rehabilitative method of therapy on the quadriceps femoris on adult, geriatric and competitive athlete populations (Maffiuletti 2018). For swallowing rehabilitation, the proposed benefits of NMES include improvements in swallowing function (Frost et al. 2018; Marcus et al. 2019; Poorjavaad et al. 2014; Rice 2012), improvements in sensory and muscle function (Carnaby-Mann et al. 2007), and improved feeding (Andreoli et al. 2019; Song et al. 2015).

The benefits for use of NMES in the pediatric population have not been well described. In the few studies done on medically complex children with dysphagia and acquired dysphagia, the use of NMES concurrently with traditional methods of therapy was not superior to traditional

methods of therapy alone (Rice 2012, Wright 2011, Song 2015, Christianeese 2011, Marcus 2019).

Proposed Limitation of NMES

Many of the studies that have explored the effect of NMES on patients with dysphagia, have studied well established methods of dysphagia treatment concurrently with NMES in a rehabilitation and retraining context (Maffiuletti 2010). In a series of five case studies on NMES in the young infant population, NMES was combined with conventional rehabilitation treatments (Rice 2012). The series presented a positive outcome of the use of NMES; however, given the combined use of oral stimulation, conventional swallowing habilitation treatment, and natural maturation factors along with the use of NMES, determination of the effectiveness of NMES specifically was unclear.

Similarly, in many of the adult dysphagia model studies, NMES was used concurrently with traditional rehabilitation therapy methods (Andreoli et al 2019; Frost 2018; Epperson & Sandage 2019; Ludlow 2010; Rice 2012; Song et al 2015; Wright et al, 2012; Vanderthommen and Duchateau 2007). In both adult and the limited pediatric research, the unique benefits of NMES are unclear. NMES used in conjunction with traditional methods of therapy demonstrated improvement in functional swallowing in patients, but did not prove beneficial when used in isolation (Frost 2018). Studies done on healthy subjects have also presented evidence that NMES is no more effective than traditional rehabilitative therapy methods (Maffiuletti 2010, Christianeese 2011). Although there have been multiple studies proposing the benefits of NMES as a method of therapy for muscle rehabilitation, they have only explored NMES in the context of rehabilitation and as a re-training modality. However, no research has presented evidence for the benefits of NMES in neonate and young infants with dysphagia since birth. Some authors

have suggested that the use of NMES in all populations with dysphagia, should be considered experimental and should not be used in clinical settings until more conclusive evidence and standardization of its use is established (Poorjavad 2014). The effectiveness of NMES in the pediatric population lacks sufficient empirical support to justify its use in vulnerable infants given the painful experience that is a feature of this modality.

NMES Parameters

NMES imposes a great muscular demand and naturally hastens the onset of muscle fatigue since there is repeated contractile activity within the same muscle fibers. These contractions produced by NMES may strengthen innervated muscles as well as protect muscles from atrophy. However, there is a difference in the pattern of motor unit recruitment in voluntary contraction and the contraction stimulated by NMES (Poorjavaad et al. 2014). In voluntary contractions, as force is increased, larger axons are recruited, and larger units are recruited increasing the strength of the muscle contraction (Lieber 1992); however, in NMES contractions, there is also a difference in the recruitment of motor units depending on the activity of muscles. For multifunctional muscles, motor units are recruited based on the task specific activation (Sale 1988). However, this motor unit recruitment may prevent the results from transferring over into the patient's everyday functional activities. This artificial contraction of the muscle may also interfere with typical neuromuscular development for swallowing habilitation in developing infants (Epperson & Sandage 2019). Despite the lack of evidence to support a physiological rationale for use of NMES on the pediatric population, occupational therapists and speech language pathologists use NMES as method of therapy for dysphagia.

Tolerance

Although researchers and clinicians have tried to minimize discomfort and maximize recruitment, the lack of homogeneity in the reported measures and the strong discomfort associated with the surrounding stimulation, greatly limits NMES as an effective and valid treatment intervention (Maffiuletti 2010). In Maffiuletti's (2018) review of the clinical use of NMES in neuromuscular rehabilitation, the main drawbacks stated for NMES are the excessive discomfort for the patient, limited muscle recruitment, premature muscle fatigue and the lack of standardization of treatment and use protocol. In a study by Frost et al. (2018), they found that subjects who received NMES and traditional therapy, experienced an increase in neck pain, skin irritation and expectoration. These drawbacks may be related to the limited standardization of dose of stimuli and the limited effectiveness of NMES due to subject frailty in research.

All these drawbacks are problematic for the neonate and infant population as they are a vulnerable population that cannot willingly communicate discomfort levels and are still developing a neuromuscular system postnatally. The Institutional Review Board (IRB) states that under the Protection of Human Subjects (45 CFR 46, Subpart D), research must present no more than minimal risk to a subject (Gordon 2003). Minimal risk is defined by The Collaborative Institutional Training Initiative (CITI Program) program, that the probability and extent of harm or discomfort anticipated in the research is not greater than that ordinarily experienced in daily life or during the performance of routine tests (Gordon 2003). In addition, the neonate and young infant population can only receive NMES therapy passively as opposed to adult rehabilitation where individuals pair already functioning swallowing with electrical stimulation (Epperson & Sandage 2019).

Dosage

Dosage is another aspect of NMES therapy that is highly controversial in both adult and pediatric population. The parameters for NMES should clearly differentiate the characteristics of the dose, dose response and intensity factors for dose. Currently, dosage levels are set by clinician judgement and patient tolerance (Bosques 2016; Humbert 2012; Maffiuletti 2010). Due to the limited research and the poorly reported parameters established in the research of the use of NMES in the pediatric population, the protocols for effective instrumentation and administration are not well defined. This lack of standardization in protocol and treatment led many of the studies to recognize the limitation of being able to set reliable physiological parameters for the subjects and there were insufficient trials to guide clinical practice around the use of NMES (Gobbo et al. 2014; Humbert et al. 2012; Maffiuletti 2010; Rice 2012; Song et al. 2015; Vanderthommen and Duchateau 2007; Wright 2010). In the few pediatric studies that were conducted, there was limited information on professional training of the occupational therapists and speech language pathologists who administered the NMES on the infant subjects. In one of the studies, data regarding swallowing function pre and post NMES taken by the speech language pathologist and radiologist were inconsistent and conflicted with one another (Rice 2012).

Placement

Electrode placement with regard to muscle-specific stimulation has not been established in NMES parameters. In adult models, NMES tolerance to the stimuli is extremely individual specific and certain studies have presented that a large percentage of both vulnerable people with chronic diseases and able-bodied elderly adults do not tolerate NMES well (Maffiuletti 2018). During the use of NMES, surface electrodes are placed on the neck depending on which muscle

group will be stimulated. Due to the lack of standardization of NMES parameters for dysphagia treatment, there is an inconsistency in electrode placements within the limited literature on infants and children with dysphagia. In a study conducted by Christianeese et al. (2011) only one pair of electrodes was used, as opposed to the 2 pairs normally used on adults, as they recognized that the standard 2 pairs of electrodes would cover a larger area than that of the infant's larynx size. Placement recommendations have been developed, despite lack of evidence to support the muscle specificity claims made for placement directions (Rice, 2012).

This lack of description of electrode placement protocol in the literature presents a limitation as the muscles of the infant face and neck are short and in close proximity of one another and have different functions compared to larger muscle groups that NMES is normally used for, like quadriceps muscle rehabilitation. In NMES, the electrical current creates a contraction by depolarizing the nerves responsible for motor innervation in a particular muscle or muscle fiber. If the stimulation is increased, then deeper muscles and structures in the body are stimulated while muscles closest to the surface receive a stronger current. Thus, muscles tissues within the range of the electrical current are stimulated at various degrees depending on the intensity of the stimulation and the distance of the muscle from the surface electrode. In a study done by Ludlow et al. (2007) comparing the effect of electrical stimulation at rest and during swallowing in chronic pharyngeal dysphagia, they found that surface stimulation was either too weak or not deep enough to stimulate axons innervating the muscles that produce hyoid and laryngeal elevation. The different positioning of the electrodes stimulates different muscles groups and will change the swallowing physiology in different ways. Thus, it is unclear which muscle groups are strengthened and lead to the reported improvement (Lee et al. 2015).

The current that flows from the electrodes and stimulates muscles at varying degrees, so that tissues closes to the surface electrodes receive the strongest current while the deeper muscles receive weaker currents; thus NMES does not offer specificity for muscle stimulation (Humbert et al. 2012). Since the muscle of the neck and face are small, short, in close proximity to each other and have different functions, this lack of specificity poses concern when attempting to target certain muscles for swallowing rehabilitation (Humbert, 2012).

As described by Epperson and Sandage (2019), the lack of standardization of protocol and the artificially electrical induced muscular activity could potentially interfere with typical and optimal development of the neonate and infant neuromuscular system. For the young infant, polyneuronal innervation of the laryngeal muscles begins at 7 weeks and continues to develop postnatally. NMES could potentially interfere with development of neuromuscular junctions and the process of synapse pruning, both of which are still in process in the neonate and young infant. This population is particularly vulnerable group in that they cannot willingly participate in research and are unable to communicate the maximum tolerable level of stimulation.

The neonate condition in the NICU and allostatic load

Premature infants are exposed to multiple stressors in the neonatal intensive care unit (NICU) including, excessive noise and lights as well as the procedures they endure due to their vulnerable state. In an article published by Jadcherla (2016), the prevalence of feeding problems in premature infants born less than 37 weeks of gestation was about 10.5%, and this frequency increased to about 24.5% among those born with a very low birth weight. The article also stated that approximately 26% of prematurely born infants showed dysphagia and the underlying condition of bronchopulmonary dysplasia and in about 31% of those with persistent feeding

difficulties. In infants born at less than 28 weeks of gestation, oral feeding was significantly delayed, and the period of hospitalization was prolonged (Jadcherla 2016).

Premature birth interrupts critical neurodevelopment in the young infant as many neurological structures and processes are still undergoing differentiation at birth. The course and length of stay in the NICU, is a crucial factor that influences the health of the neonate as many of the neurological systems of the infant are still developing (Cong 2017). However, at premature birth, neonates are exposed to constant noise, lights and handling procedures from the surrounding environment and interactions with staff and caregivers in the NICU. It is possible that the neurodevelopment observed in premature infants is due to the alterations in the developing brain that results from repeated stressors from the NICU (Weber et al. 2012). Neonates living outside of the intrauterine environment are subjected to intensive treatment procedures, stressful diagnostics and interventions, and are isolated from parental contact (Cong 2017). Early life stressors in the fetal and neonatal stages have been associated with long term neurological morbidities, decreased head growth and brain function (Smith et al, 2011). Repeated pain and stress signals may lower their tactile threshold and immature inhibitory pathways (Cong et al. 2017). Neonates possess the anatomical and the neurochemical perceptions of pain and are more sensitive to prolonged pain and stress stimulation (Cong et al. 2017).

Weber et al. (2012) presents allostasis as a healthy process of maintaining homeostasis or stability through change in integrated physiological systems that mediates short term adaptations to environmental challenges or stressors. However, when the allostatic process is repeatedly disturbed and prolonged it no longer mediates a healthy adaptation to stress and can alter the brain structure of the premature infant. This overload of stressors creates a dysregulation in the

allostatic process, and it creates a change in the physiologic development of the young infant creating an allostatic load.

Preterm infants are more susceptible to allostatic load than infants born full term and are more susceptible to problems with poor oromotor function and are more likely to exhibit delays in engagement during the feeding process (Weber et al. 2014, Casavant et al. 2019). One of the main limitations of the use of NMES is its considerable discomfort on the patient. It is known that preterm infants exhibit dampened responses to physical pain, but this absence of response, is not an indicator of absence of pain (Casavant et al. 2019). Since premature birth results in the disruption of development at a critical time, the painful and stressful sensation of the muscle stimulation produced by NMES on the neonate infant, could only be an added stressor to the already stressed infant and adding to the allostatic load process.

Justification

The purpose of this investigation is to examine the prevalence for the use of NMES and the physiological rationale of speech language pathologists for their use of NMES in the neonate and young infant population with dysphagia. The lack of published standards for specificity and dosage of the NMES modality in infants requires further study of current clinical practice. Further, the heterogeneity of the research methodology and the lack of juvenile animal and human infant models make it difficult to compare the data described for adult dysphagia rehabilitation. Clinical use of NMES in this population has been reported; however, there is a lack of empirical evidence to support the physiological rationale for its use on such a vulnerable population. It is hypothesized that SLPs who report use of NMES for the habilitation of swallowing in neonates and young infants will report the following: 1) belief that NMES is effective, 2) lack of clear physiologic rationale for use of NMES, 3) lack of training specifically

targeted for the infant population, and 4) lack of specificity of modality with regard to dosage (frequency and intensity) of NMES intervention. The results of this survey will contribute to the limited research in the use of NMES in the neonate and young infant population and clarify current clinical practice for its use on the neonate and young infant population.

Chapter 2

Manuscript

Use of NMES for Swallowing Habilitation in Neonatal Intensive Care Units: A Survey of Clinical Practice

Introduction

The prevalence of feeding problems in premature infants born less than 37 weeks of gestation has been reported to be about 10.5%, and this frequency increased to about 24.5% among those born with a very low birth weight (Jadcherla, 2016). Approximately 26% of prematurely born infants demonstrated swallowing impairment at birth, with about 31% of those with persistent feeding difficulties. In infants born less than 28 weeks of gestation, oral feeding was significantly delayed, and the period of hospitalization was prolonged (Jadcherla 2016). Speech language pathologists (SLPs) play a vital role as team members in the neonatal intensive care unit (NICU) who implement medical and behavioral strategies to habilitate feeding and safe swallowing function. Neuromuscular electrical stimulation (NMES), used in both research and clinical settings as a method for neuromuscular rehabilitation of dysphagia in adults, has been adopted in recent years for infant swallowing habilitation, despite the lack of evidence to support a physiological rationale for use of NMES in the pediatric population (Cheetham 2015; Rice 2012; Epperson & Sandage 2019). Given that little is understood about clinical practice patterns for use of NMES with neonates and young infants, this investigation aimed to better understand

the manner in which SLPs who use NMES with young infants determine tolerance, dose, probe placement, and physiological rationale for clinical application.

NMES Evidence for Pediatric Patients

For swallowing rehabilitation, the proposed benefits of NMES include improvements in swallowing function (Frost et al. 2018; Marcus et al. 2019; Poorjavaad et al. 2014; Rice 2012) improvements in sensory and muscle function (Carnaby-Mann et al. 2007) and improved feeding (Andreoli et al. 2019; Song et al. 2015). In the few studies done on medically complex children with dysphagia and acquired dysphagia, the use of NMES concurrently with traditional methods of therapy was not superior to traditional methods of therapy alone (Rice 2012; Wright 2011; Song 2015; Christianeese 2011; Marcus 2019; Maffiuletti 2010). In a series of five case studies on NMES in young infant population, NMES was combined with conventional rehabilitation treatments (Rice 2012). The series presented a positive outcome of the use of NMES; however, the combined use of oral stimulation, conventional swallowing habilitation treatment, and natural maturation factors along with the use of NMES, made it difficult to discern the extent to which NMES added, if anything, to the clinical outcome.

Similarly, in many adult dysphagia model studies, NMES was used concurrently with traditional rehabilitation therapy methods but did not realize superior outcomes to use of the traditional swallowing therapy strategies without concurrent NMES (Andreoli et al 2019; Frost 2018; Ludlow 2010; Rice 2012; Song et al 2015; Wright et al, 2012; Vanderthommen and Duchateau 2007). In another study, that compared NMES use in conjunction with traditional methods of therapy against use of NMES in isolation, the use of NMES in isolation was not beneficial (Frost 2018). Studies done on healthy subjects have also presented evidence that

NMES is no more effective than traditional rehabilitative therapy methods (Maffiuletti 2010, Christianeese 2011).

From the limited pediatric swallowing habilitation research available, the unique benefits of NMES are unclear. Although there have been multiple studies proposing the benefits of NMES as a method of therapy for muscle rehabilitation, they have only explored NMES in the context of rehabilitation and as a re-training modality. The effectiveness of NMES in the pediatric population lacks sufficient empirical support to justify its use in vulnerable infants for two primary reasons; 1) pain and discomfort is a feature of this modality, and 2) there is little empirical evidence for the benefits of NMES for swallowing habilitation in neonates and young infants.

NMES Parameters

There are several aspects of NMES for improving swallowing function that are difficult to empirically study in an infant model: concurrent use of NMES with targeted swallowing exercises (i.e., supraglottic swallow), pain tolerance, dose determination, and muscle specific placement of electrodes. The use of swallowing-specific exercises for swallowing rehabilitation is an important acknowledgment that there is a difference in the pattern of motor unit recruitment in voluntary contraction versus the passive electrically stimulated muscle contraction of NMES (Poorjavaad et al. 2014). The neonate and young infant population can only receive NMES therapy passively as opposed to adult rehabilitation where individuals pair already functioning swallowing with electrical stimulation (Epperson & Sandage 2019). There is also a difference in the recruitment of motor units depending on the activity of muscles. For voluntary activation of multifunctional muscles, motor units are recruited based on the task specific activation (Sale, 1988). For example, we use the muscles of the velum differently for swallowing than for

articulation of speech sounds. As force is increased, larger axons are recruited, and larger units are recruited increasing the strength of the muscle contraction (Lieber 1992). However, in the involuntary activation in NMES, the motor unit recruitment pattern triggered by NMES may not transfer to the patient's everyday functional activities. This artificial contraction of the muscle may also interfere with typical neuromuscular development for swallowing habilitation in developing infants (Epperson & Sandage 2019).

Tolerance

Although researchers and clinicians have tried to minimize discomfort and maximize muscle fiber recruitment, the lack of homogeneity in the reported measures and the strong discomfort associated with the surrounding stimulation, greatly limits NMES as an effective and valid treatment intervention (Maffiuletti 2010). In Maffiuletti's (2018) review of the clinical use of NMES in neuromuscular rehabilitation, the main drawbacks stated for NMES are the excessive discomfort for the patient, limited muscle recruitment, premature muscle fatigue and the lack of standardization of treatment and use protocol. In a study by Frost et al. (2018), they found that subjects who received NMES and traditional therapy, experienced an increase in neck pain, skin irritation and expectoration. These drawbacks may be related to the limited standardization of dose of stimuli and the limited effectiveness of NMES due to subject frailty in research.

All these drawbacks are problematic for the neonate and infant population as they are a vulnerable population that cannot willingly communicate discomfort levels and are still developing a neuromuscular system postnatally (Epperson & Sandage, 2019). U.S. Department of Health & Human Services states that under the Protection of Human Subjects (45 CFR 46, Subpart D), research must present no more than minimal risk to a subject (Gordon 2003).

Minimal risk, as defined by The Collaborative Institutional Training Initiative (CITI Program) program, indicates that the probability and extent of harm or discomfort anticipated in the research is not greater than that ordinarily experienced in daily life or during the performance of routine tests (Gordon 2003).

In adult models, NMES tolerance to the stimuli is extremely individual specific and certain studies have presented that a large percentage of vulnerable people with chronic diseases and able-bodied elderly adults do not tolerate NMES well (Maffiuletti 2018). Premature infants are even more vulnerable. The course and length of stay in the NICU, is a crucial factor that influences the health of the neonate as many of the neurological systems of the infant are still developing (Cong 2017). Neonates are exposed to constant noise, lights, and handling procedures from the surrounding environment and interactions with staff and caregivers in the NICU. It is possible that the neurodevelopment observed in premature infants is due in large part to the alterations in the developing brain that results from repeated stressors from the NICU (Weber et al. 2012). Neonates living outside of the intrauterine environment are subjected to intensive treatment procedures, stressful diagnostics and interventions, and are isolated from parental contact (Cong 2017). Early life stressors in the fetal and neonatal stages have been associated with long term neurological morbidities, decreased head growth and brain function (Smith et al, 2011). These repeated pain and stress signals, lower their tactile threshold and their immature inhibitory pathways (Cong et al. 2017). Neonates possess the anatomical and the neurochemical perceptions of pain and are more sensitive to prolonged pain and stress stimulation (Cong et al. 2017).

Weber et al. (2012) presents allostasis as a healthy process of maintaining homeostasis or stability through change in integrated physiological systems that mediates short term adaptations

to environmental challenges or stressors. However, when the allostatic process is repeatedly disturbed and prolonged it no longer mediates a healthy adaptation to stress and can alter the brain structure of the premature infant. This overload of stressors, which could include painful NMES, creates a dysregulation in the allostatic process, and it creates a change in the physiologic development of the young infant creating an allostatic load.

Preterm infants are more susceptible to allostatic load than infants born full term and are more susceptible to problems with poor oromotor function and are more likely to exhibit delays in engagement during the feeding process (Weber et al. 2014, Casavant et al. 2019). One of the main limitations of the use of NMES is its considerable discomfort on the patient. It is known that preterm infants exhibit dampened responses to physical pain, but this absence of response, is not an indicator of absence of pain (Casavant et al. 2019). Since premature birth results in the disruption of development at a critical time, the painful and stressful sensation of the muscle stimulation produced by NMES on the neonate infant, could only be an added stressor to the already stressed infant and adding to the allostatic load process.

Dosage

Dosage is another aspect of NMES therapy that is highly controversial in both adult and pediatric populations. The parameters for NMES should clearly differentiate the characteristics of the dose, dose response and intensity factors for dose. Currently, dosage levels are set by clinician judgement and patient tolerance (Bosques 2016; Humbert 2012; Maffiuletti 2010). Due to the limited research and the poorly reported parameters established in the research of the use of NMES in the pediatric population, the protocols for effective instrumentation and administration are not well defined. This lack of standardization in protocol and treatment led many of the studies to recognize the limitation of being able to set reliable physiological

parameters for the subjects and there were insufficient trials to guide clinical practice around the use of NMES (Gobbo et al. 2014; Humbert et al. 2012; Maffiuletti 2010; Rice 2012; Song et al. 2015; Vanderthommen and Duchateau 2007; Wright 2010). In the few pediatric studies that were conducted, there was limited information on professional training of the OTs and SLPs who administered the NMES on the infant subjects.

Placement

When taking into consideration the anatomy of the face and neck, NMES does not offer specificity for muscle stimulation (Humbert et al. 2012). Since the muscles of the neck and face are small, short, in close proximity to each other, and have different functions it is unclear which muscle groups are strengthened and led to the improvement, and this lack of specificity poses concern when attempting to target certain muscles for swallowing rehabilitation (Humbert 2012; Lee et al. 2015). The lack of muscle-specific NMES motor unit recruitment would be even more problematic for an neonate or young infant, yet , there is inconsistency in electrode placements within the limited literature on infants and children with dysphagia. In a study conducted by Christianeese et al. (2011) only one pair of electrodes was used, as opposed the 2 pairs normally used on adults, as they recognized that the standard 2 pairs of electrodes would cover a larger area than that of the infant's larynx size. Any placement recommendations developed were not based on empirical study of muscle-specific probe positioning in infants (Rice, 2012).

The purpose of this investigation was to examine the prevalence for the use of NMES and the physiological rationale of SLPs for their use of NMES in the neonate and young infant population with dysphagia. The lack of published standards for specificity and dosage of the NMES modality in infants requires further study of current clinical practice. Further, the heterogeneity of the research methodology and the lack of juvenile animal and human infant

models make it difficult to compare the data described for adult dysphagia rehabilitation. Clinical use of NMES in this population has been reported; however, there is a lack of empirical evidence to support the physiological rationale for its use on such a vulnerable population. It is hypothesized that SLPs who report use of NMES for the habilitation of swallowing in neonates and young infants will report the following: 1) belief that NMES is effective, 2) lack of clear physiologic rationale for use of NMES, 3) lack of training specifically targeted for the infant population, and 4) lack of specificity of modality with regard to dosage (frequency and intensity) of NMES intervention. The results of this survey will contribute to the limited research in the use of NMES in the neonate and young infant population and clarify current clinical practice for its use on the neonate and young infant population.

Methods

Participants

A total of 59 speech language pathologists consented and initiated participation in the survey. Two of the participants reported that they were not currently working as a certified speech language pathologist, and six participants reported that they did not currently treat pediatric dysphagia; thus, these participants did not meet inclusion criteria and were excluded from the data analyses. Eleven additional participants abandoned the survey before completing it, leaving a total of 40 speech language pathologists who met participant criteria completed the survey.

Inclusion criteria for participation were as follows: certified speech language pathologists with a master's degree or higher who are currently practicing as speech language pathologists in neonatal intensive care units. Participants who did not meet the criteria of certification and

education were directed to the end of the survey. Exclusion criteria include the following: not currently practicing as a SLP and/or not working in a NICU.

Materials

A questionnaire was designed to survey the clinical practice of certified speech language pathologists who use NMES as a treatment modality for swallowing habilitation in the neonatal and young infant population (see Appendix A). The format of the survey consisted of a mixture of multiple-choice answers, multi-select answers, and open text input responses. The survey contained a total of 34 questions divided into three main areas:

1) Background: Questions inquired as to general demographic questions including participant licensure, employment setting, population experience and length of employment. Questions with regard to whether or not the SLPs used NMES were organized with skip logic to allow only those clinicians indicating that they used NMES to proceed with questions pertaining to the clinical practice patterns for NMES use with infants. Participants who indicated they had not used NMES with infants were directed to the end of the survey.
2) Use of NMES in the NICU setting: Questions were used to obtain information about the determination of NMES parameters (tolerance, dose and specificity) and its use with neonatal and young infant population. The purpose of this section was to gather information regarding the parameters clinicians use when administering NMES therapy and whether other methods of therapy were used concurrently with NMES
3) Perception of the appropriate age range for the use of NMES on the pediatric population: This section included clinician agreement on ASHA's stance regarding the use of NMES on the neonate and young infant populations.

Survey Dissemination

Following approval from Auburn Universities Institutional Review Board, several strategies were implemented to reach the target population meant for this questionnaire. The information letter and link to the survey were posted to member communities of the following ASHA Special Interest Groups: Neurogenic Communication Disorders (2), Voice and Upper Airway Disorders (3), Craniofacial and Velopharyngeal Disorders (5), Swallowing and Swallowing Disorders (13). Access to the survey was also posted on the following ASHA community groups: Early Intervention, Early-Career Professionals, and SLP Health Care. The information letter and link to the survey were posted on the following speech language pathology Facebook community groups: Medical SLP Forum, Pediatric Therapy Discussion Board, Speech Pathologists and Feeding Therapy (Professionals Only), Medical Speech-Language Pathologist Professional Learning Community, Pediatric SLPs, NICU Lactation Support: Professionals Network, Pediatric Medical SLPs, Clinical Dysphagia News, Resources & Information, Dysphagia Journal Club, SLPs for Evidence Based Practice, Swallowing and Swallowing Disorders Journal Club, NICU Professionals, Acute Care SLPs. Participants were also recruited directly via email contact from various hospitals with Neonatal Intensive Care Units across the United States via electronic information letters.

Data Analyses

Descriptive statistics were used to characterize participant demographics. Participant responses to survey questions were manually quantified after cleaning up the Qualtrics data for pilot testing and “other” responses provided by participants.

Results

Participant Demographics

Of the 40 participants who completed the survey, participants represented all age ranges listed from the 20-29 and 60-69 years, with the mean age range of 30-39 selected. The participant pool was comprised of 92.50% female participants (*n*=37) and 7.50% male participants. (*n*=3).

Participants were prompted to identify their race and/or ethnicity via multiple-choice answers and a majority of respondents indicated their race to be White and two others indicated "Anglo" and "Euro-American" which were categorized as White (85%, n=34). Smaller numbers were recorded across the Latino/a (5%, n=2). Four participants selected "Other" (10%) as their choice of race/ethnicity, but either did not provide any additional information when prompted by a text box or indicated they did not wish to disclose their race/ethnicity.

Demographic data revealed that 20 of the 50 States in the United States were represented by speech language pathologists that participated in the survey. Degrees and credentials were gathered via multiple-select answers and length of clinical practice was gathered via multiple choice answers. The majority of participants indicated that they had a Master's CCC-SLP only (82.50%, n=33), while 7.50% (n=3) indicated they held a PhD. CCC-SLP only. Participants could also report that they held a BCS-S and/or a certification as a Swallowing Specialist. Of the remaining 4 respondents, 7.50% (n=3) indicated that they held both a Master's CCC-SLP and a BCS-S, 2.50% (n=1) indicated they held a Master's CCC-SLP, BCS-S and a certification as a Swallowing Specialist. The largest group of respondents reported that they had more than 20 years of experience (30%, *n*=12), 22.50% had 6-10 years of experience (*n*=9), 19.57% reported

11-15 years of experience (n=9), 22.50% reported 1-5 years of experience (n=7) and 7.50% reported 16-20 years of experience (n=3).

Employment setting data was collected via multiple-select answers to account for clinicians who work in more than one setting, thus responses will not total 100%. The majority of participants reported working in a NICU (52.50%, n=21), Acute care (35%, n=14), University Hospital (27.50%, n=11), Outpatient clinics (30% n=12) and PICU (25%, n=10). Lesser reported setting included Pediatric Hospitals (10%, n=4), University clinics (2.5%, n=1), Acute inpatient rehab (5%, n=2), Home care-Birth to 3 years old (5%, n=2) and chose not to report (2.5%, n=1). Participants then responded the amount of dysphagia or pediatric feeding related Continuing Education Credits they have currently taken, with the majority indicating More than 5 courses (82.50%, n=33), 10% (n=4) indicating 2-3 courses, 5% (n=2) indicating 4-5 courses, and 2.50% (n=1) indicating one course or less

Most participants reported treating dysphagia on more than 20 pediatric patients weekly (37.50%, n=15), while other participants reported treating dysphagia on 6-10 (15%, n=6) pediatric patients weekly, 11-15 (17.50%, n=7) pediatric patients weekly, 1-5 pediatric patients weekly (12.50%, n=5), 16-20 (12.50%, n=5) pediatric patients weekly, and 5% reported treating no pediatric patients (n=2). Respondents were then asked if their workplace provided a multidisciplinary team when assessing and treating pediatric patients with dysphagia. The majority of participants (82.92%, n=34) reported that their workplace did provide a multidisciplinary team when assessing and treating pediatric patients with dysphagia, while 14.63% (n=6) reported that their workplace did not and 7.31% (n=3) reported “Sometimes” and were prompted to provide a brief explanation for their answer. Answers under the “Sometimes” category, included conditional circumstances for multidisciplinary team involvement. Some

answers given under the “Sometimes” category were counted under the “Yes” category if the participant explanation answered the question of whether the participant workplace provided a multidisciplinary approach to therapy. Refer to Table I. for details regarding participant demographics.

Table 1. *Participant Demographics*

	Response Count (N = 40)	**Percentage (%)**
Sex		
Male	3	7.50%
Female	37	92.50%
Race/Ethnicity		
White	34	85.00%
Latino/a	2	5.00%
Other	4	10.00%
Age		
20-29	5	12.50%
30-39	18	45.00%
40-49	7	17.50%
50-59	9	22.50%
60-69	1	2.50%
Location		
Alabama	4	10.00%
California	4	10.00%
Florida	1	2.50%
Georgia	1	2.50%
Idaho	1	2.50%
Indiana	1	2.50%
Iowa	1	2.50%
Maryland	1	2.50%
Massachusetts	2	5.00%
Minnesota	1	2.50%
New Jersey	1	2.50%
North Carolina	2	5.00%
Ohio	1	2.50%
Pennsylvania	1	2.50%
Tennessee	2	5.00%
Texas	8	20.00%
Washington	1	2.50%
Wisconsin	6	15.00%
Not in U.S.	1	2.50%
Credentials		
Master's, CCC-SLP only	33	82.50%
PhD, CCC- SLP only	3	7.50%
Master’s CCC-SLP and BCS-S	3	7.50%
Master’s CCC-SLP, BCS-S, certified Swallowing Specialist	1	2.50%

Experience		
1-5 Years	7	17.50%
6-10 Years	9	22.50%
11-15 Years	9	22.50%
16-20 Years	3	7.50%
More than 20 Years	12	30.00%
Setting of Employment*		
NICU	21	52.50%
Acute Care	14	35.00%
Outpatient Clinic	12	30.00%
University Hospital	11	27.50%
PICU	10	25.00%
Pediatric Hospital	4	10.00%
Acute inpatient rehab	2	5.00%
Home care- Birth to 3 years old	2	5.00%
Chose not to report	1	2.50%
University Clinics	1	2.50%
Patients treated weekly		
1-5 patients	5	12.50%
6-10 patients	6	15.00%
11-15 patients	7	17.50%
16-20 patients	5	12.50%
More than 20	15	37.50%
Multidisciplinary Team		
Yes	34	85.00%
No	6	15.00%
Sometimes	3	7.50%
CEU's Taken		
More than 5	33	82.50%
One course or less	1	2.50%
2-3 courses	4	10.00%
4-5 courses	2	5.00%
N = total number of respondents. n = number of respondents per treatment method. % = percentage of respondents based on 40 respondents.	*Legend will exceed 100%	

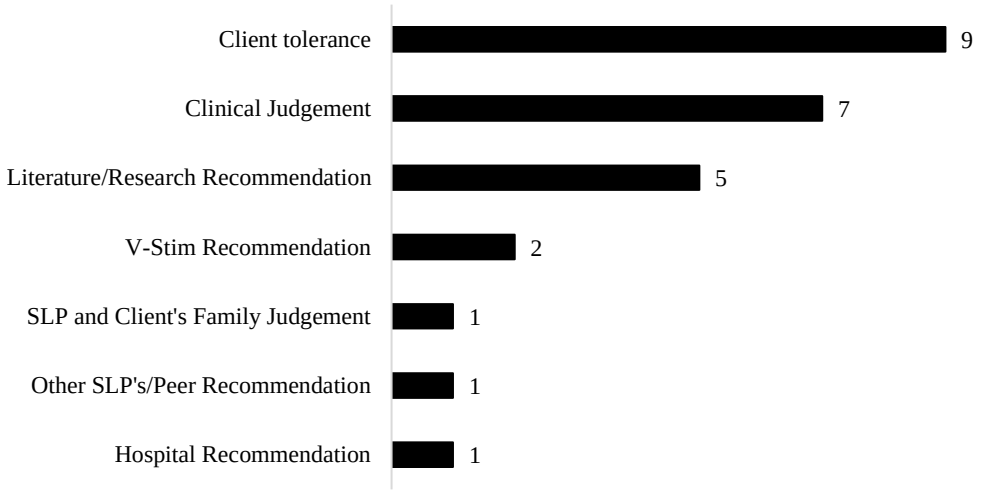
Use of NMES

Participants were asked if they were familiar with the use of NMES as a method of dysphagia treatment and if they currently use NMES on neonate and young infant populations. All participants indicated that they were familiar with the modality (100%, n=40). Of the 40 participants, 27.50% (n=11) speech language pathologists indicated that they currently use NMES as a method of therapy for dysphagia on neonate and young infant populations (3 years and younger), while 72.50% (n=29) indicated that they did not. Participants that indicated that

they did not currently use NMES as a method of therapy for dysphagia on neonate and young infant populations (3 years and younger) ended the survey and the remaining participants (N=11) answered additional questions regarding NMES and determining dose, tolerance, repetitions, muscle specificity, length of treatment, discharge criteria and the use of concurrent treatment methods.

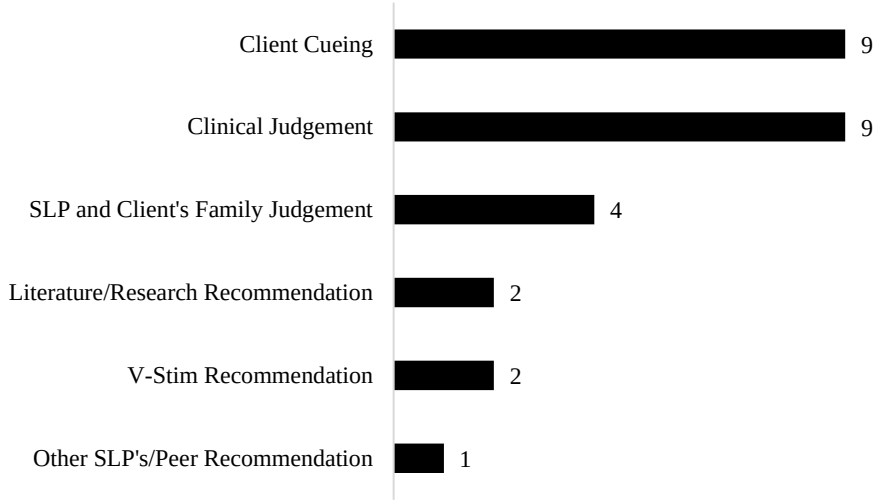
The remaining 11 participants were prompted with a variety of questions regarding their rationale for determining NMES parameters such as dose, tolerance, repetitions, specificity, number of sessions and discharge criteria from a variety of multi-select answers. Respondents were first asked to indicate, how they determine dose when administering NMES. With a prompt to “select all that apply,” the majority of participants indicated that they determine dose through client tolerance (81.81%, n=9). Participants also selected clinical judgment (63.63% n=7), literature/research recommendation (45.45%, n=5), v-stim recommendations (18.18%, n=2), hospital recommendation (9.9%, n=1), other SLP/Peer recommendations (9.9%, n=1), and clinician and family judgement (9.9%, n=1).

Figure 1. *Rationale for Determining Dose.*



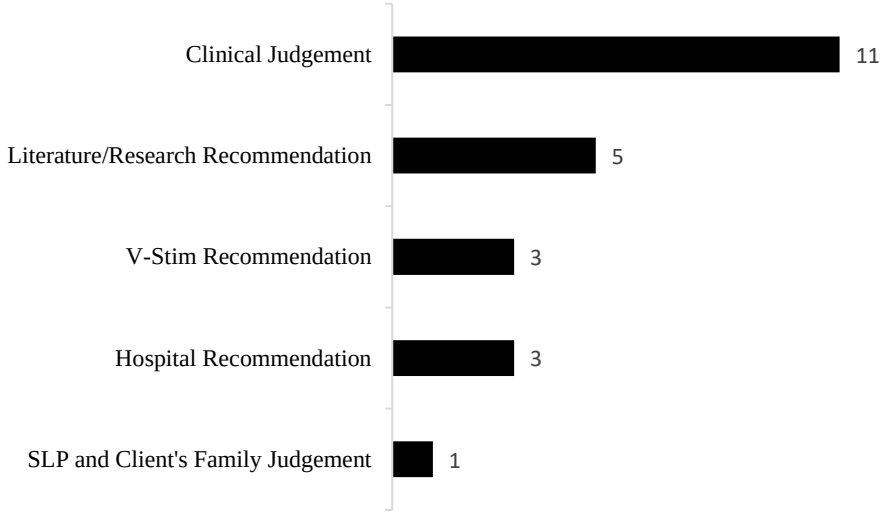
Participants were then prompted to indicate how they determined client tolerance when administering NMES during dysphagia treatment from the following choices, with direction to select all that applied: clinical judgement (81.81%, n=9), client cueing (81.81%, n=9), SLP and client's family judgement (36.36%, n=4), V-Stim Recommendation (18.18%, n=2), Literature/Research Recommendation (18.18%, n=2), and other SLP's/Peer recommendation (9.9%, n=1). When selecting “Client Cueing” respondents were prompted to describe the type of cueing they look for. Responses included consolability, facial expressions, vocalization, motor activity, body language, vital signs, physiological stability, and the child’s overall response.

Figure 2. *Rationale for Determining Tolerance.*



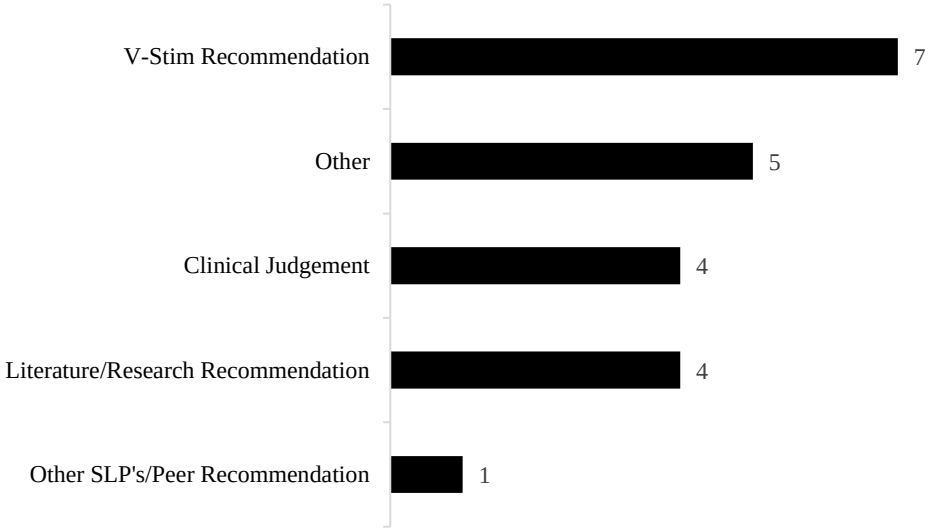
Participants indicated that they determined repetitions per session as follows: hospital recommendations (9.9% n=1), literature/research recommendations (45.45%, n=5) , V-Stim recommendations (27.27%, n=3), clinical judgement (100%, n=11), SLP and client's family judgment (9%, n=1). "Other" answer was included in V-stim recommendation as the participant indicated that they determined repetitions per session depending on the NMES unit or brand.

Figure 3. *Rationale for Determining Repetitions Per Session.*



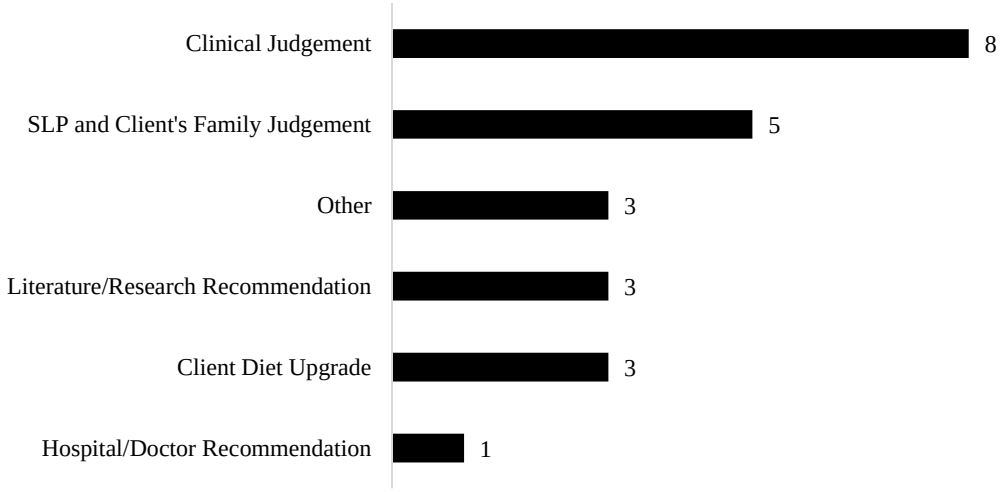
Participants were asked to indicate how they determine muscle specificity when placing electrodes for NMES therapy with the following responses: literature/research recommendations (45.45%, n=4) , V-Stim recommendations (63.63%, n=7) , clinical judgement (36.36%, n=4), other SLP/peer recommendation (9%, n=1). The selection of “Other” (45.45%, n=5) prompted a short text response. Answers included, MBSS and swallow study results, and the break down in function and evaluation results.

Figure 4. *Rationale for Determining Muscle Specificity.*



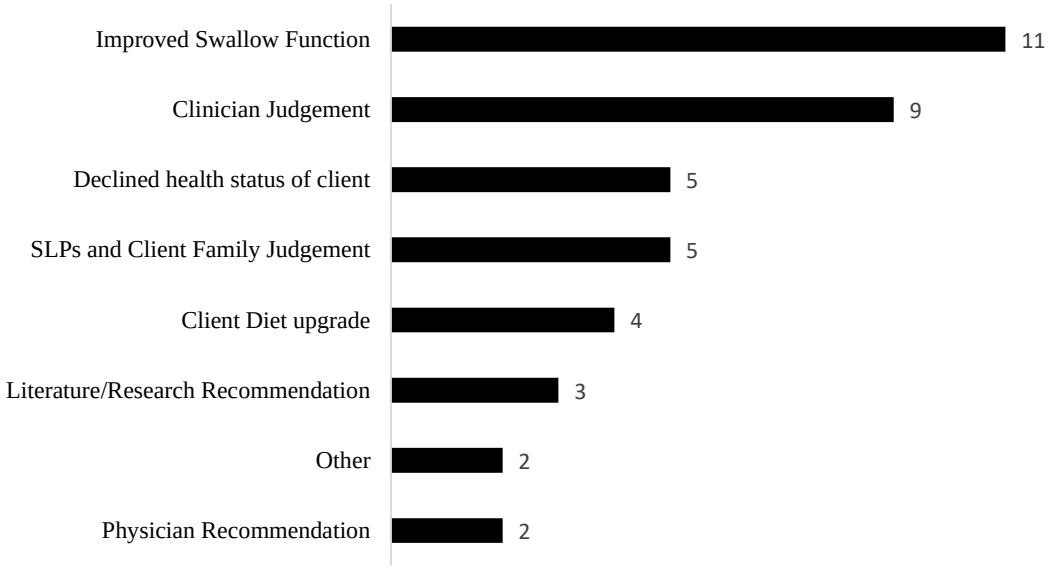
Participants were asked to select their rationale for determining the number of sessions they deemed appropriate for NMES dysphagia therapy from the following options: client diet upgrade (27.3%, n=3), clinical judgement (72.7%, n=8), SLP and client family judgement (45.5%, n=5), hospital/doctor recommendation (9%, n=1), Literature/Research recommendation (27.3%, n=3) and "Other" (27.3%, n=3) which consisted of answers regarding hospital protocols.

Figure 5. *Rationale for Determining Number of Sessions.*



Participants then indicated their criteria for patient discharge as follows: diet upgrade (36.4%, n=4), clinical judgement (81.8%, n=9), physician recommendation (18.2%, n=2), improved swallow function (100%, n=11), SLP and client's family judgment (45.5%, n=5), literature/research (27.3%, n=3), decline health statues of patient (45.5%, n=5). The selection of "Other" (18.2%, n=2) prompted a short text response which included answers regarding seeing no improvement in client.

Figure 6. *Discharge Criteria.*

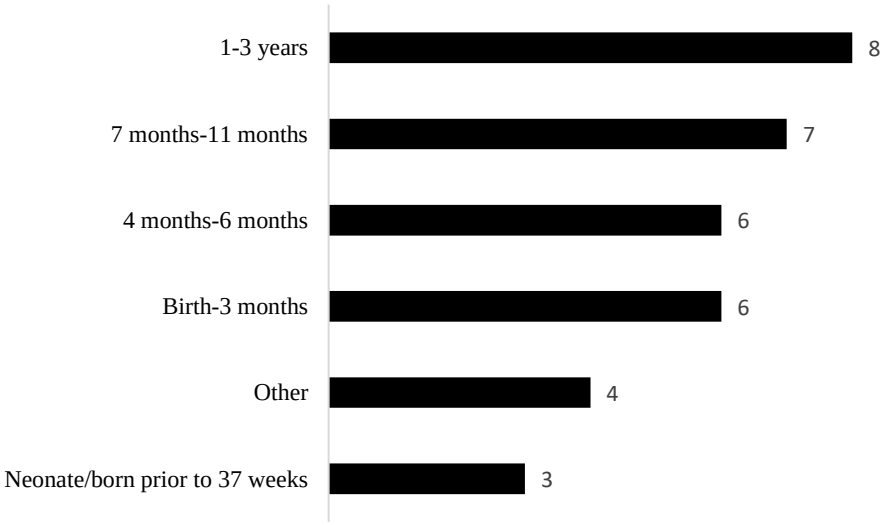


All respondents (100%, n=11) indicated that they used NMES concurrently with other methods of treatment for dysphagia and were then directed to provide a short description of the concurrent method of treatment via open text entry. Answer included: sensory modifications, elastic therapeutic taping; elicit oral reflexes with oral motor exercises, pacing, oral placement, cold bolts, traditional oral motor exercises, and diet modifications. One participants did not

specify on the methods used and two participants did not specify on the methods they used but only indicated that they used a wide variety of methods depending on patient needs and goals.

Participants were then prompted to indicate from a variety of multiselect answers, the age range they deemed appropriate to use NMES as a method of treatment for dysphagia. Answers included: Neonate/born prior to 37 weeks (27.3%, n=3), Birth-3 months (54.5%, N=6), 4 months-6 months (54.5%, N=6), 7 months-11 months (63.6%, N=7), 1-3 years (72.7%, n=8). Participants who selected "other" (36.4%, n=4) were prompted to provide an answer via open text box. Answers provided included if an infant were 38 weeks gestational age and that children younger than 37 weeks would be deferred.

Figure 7. *Age in Which Use of NMES is Appropriate.*



The last 3 questions of the survey were constructed as visual analog scales with the left side of the scale (zero) anchored with "strongly disagree" and the right end of the scale (100) anchored with "strongly agree". Participants were first asked whether they thought that current research supports the use of NMES for the treatment of neonates/young infants (3 years and

under) with dysphagia. Participants indicated a range of 25% - 100%, with a median score of 60% and mean score of 63.09% participant agreement for the statement that the current research supports the use of NMES for the treatment of neonates/young infants with dysphagia.

Participants were then asked to rate the current ASHA statement regarding the use of neuromuscular electrical stimulation on neonates and pediatric. The reported answers revealed a range of 0% - 82%, with a median score of 50% and mean score of 51.90% participant agreement on the current ASHA statement regarding the use of neuromuscular electrical stimulation on neonate and pediatric patients.

Finally, participants were asked to rate their opinion on whether ASHA should support the use of NMES for the treatment of neonate/young infant patients with dysphagia. The reported answers revealed a range of 50% - 100%, with a median score of 73% and mean score of 71.45% participant agreement on the stance that ASHA should support the use of NMES for the treatment of neonate/young infant patients with dysphagia

Discussion

The purpose of this investigation was to identify clinical practice patterns for use of NMES in the NICU for swallowing rehabilitation. It was hypothesized that SLPs who reported use of NMES for the habilitation of swallowing in neonates and young infants would report the following: 1) belief that NMES is effective, 2) lack of clear physiologic rationale for use of NMES, 3) lack of training specifically targeted for the infant population, and 4) lack of specificity of modality with regard to dosage (frequency and intensity) of NMES intervention.

Of the speech language pathologists who indicated that they were familiar with NMES as a method of dysphagia treatment, only 11 indicated that they currently used NMES as a method of dysphagia treatment on the neonate and young infant population. This indicated that although

some SLPs use NMES for treating dysphagia in neonates and young infants, most speech language pathologists are not likely to use this modality with infants.

The first study hypothesis, that SLPs who use NMES with infants will believe it is effective, was evidence-supported. When asked to rate their perception of whether the current research supports the use of NMES for the treatment of neonates/young infants (3 years and under) with dysphagia, the results indicated that most speech language pathologists who use NMES with infants, believe that NMES is effective and believe that the current literature and research supports the use of NMES on the neonate and young infant population. The results of the survey also indicated that the majority of SLPs who use NMES as a therapy modality with infants believe that the American Speech and Hearing Association should support the use of NMES on the neonate and young infant population.

The second hypothesis that there would be a lack of clear physiologic rationale for use of NMES in infants for swallowing habilitation was also evidence supported. Most participants who reported use of NMES with infants indicated that they relied on their own clinical judgement when making decisions regarding dosage, client tolerance, repetitions per session, number of sessions, muscle specificity and discharge criteria. Another common answer chosen by participants who use NMES with infants, was the use of literature and research recommendations when making decisions when making clinical decisions such as dosage, muscle specificity and discharge criteria. These findings are problematic for three primary reasons: 1) there is limited applied research available that describes benefits of the use of NMES for dysphagia on neonates and young infants; 2) there is a lack of basic research using juvenile animal models to support or contradict the efficacy of its use; and 3) there is a lack of evidence-based specifications for NMES dosage parameters for neonates and young infants.

The majority of SLPs who use NMES with infants also reported reliance on clinical judgment and patient cueing when making decisions about client tolerance despite evidence that preterm infants are more susceptible to allostatic load and that they exhibit dampened responses to physical pain (Cong et al, 2017). This absence of response is not an indicator of absence of pain (Casavant et al. 2019), indicating that a reliance on patient cueing may not be clinical best practice, particularly for this population.

The third study hypothesis, that SLPs who use NMES for the habilitation of infant swallowing will lack infant-specific training for use of this modality, was also evidence-supported. Participants were asked to describe the nature of the continuing education units (CE) related to pediatric dysphagia that they have taken throughout their career. The majority of respondents described the nature of their CE training to be courses related to infant feeding, instrumentation, diagnostics, and infants in the NICU. Of the 40 participants who described their CEs, only 5 participants noted that they had taken NMES specific training in their career. Of those 5 respondents, only 1 participant indicated they had taken an infant specific NMES training course. This indicates that although most SLPs gain knowledge about infant feeding, swallowing, and special considerations for infants in the NICU, few SLPs likely take NMES courses for use of NMES with neonates and infant. Respondent description of their courses taken, also indicated that a majority of SLP's gain knowledge of methods such as NMES from continuing education and heavily rely on continuing education after formative training is completed.

Given the likelihood that training in neuromuscular development and constructs of homeostasis and allostatic load are limited in most graduate training programs and CE courses, SLPs may not be able to discern the quality of the CEU courses related to NMES and infant

dysphagia. For the SLPs that reported using this modality, it is apparent that they are applying this modality absent the requisite basic and clinical research to warrant use of a painful intervention with infants who are still developing their neural pathways for pain perception and response as well as neuromuscular development. The lack of research for use of NMES on the neonate and young infant population, as well as the lack of juvenile animal trials, contradict SLP rationale for the use of NMES based on clinical judgement, current published research on the use of NMES on the neonate and young infant populations, and V-Stim® recommendations.

The final hypothesis, that SLPs who use NMES for infant swallowing habilitation will lack training in the specificity of the modality with regard to dosage (frequency and intensity), was also evidence-supported. Regarding the parameters of dosage, tolerance, specificity of electrode placement, and repetitions per session, most SLPs for all survey questions that they relied on clinical judgement when making clinical decisions regarding NMES parameters. Another frequently reported answer when asked to indicate the determination of specificity of the modality, was literature and research recommendation and V-Stim® recommendations. Given the paucity of literature on use of NMES in an infant model, including juvenile animal models, it is unclear where this evidence that the SLPs refer to is sourced. This suggests that clinicians with strong belief in the benefits of the NMES modality for infant use, are not basing their clinical application of this modality from the perspective of targeted physiological improvement.

The primary reliance on clinical judgement reported by SLPs who use NMES on neonates and young infants, is not consistent with an holistic, evidence-based practice approach that should include high-quality peer reviewed published evidence to inform clinical decision-making (Campbell & Douglas 2017; Finn & Bramlett 2005; Reilley 2011). The absence of

empirical evidence for the use of a potentially harmful and painful modality on vulnerable populations should serve as caution against use of a modality about which too little is understood for a developing neuromuscular system. Since the use of NMES is reliant on patient feedback regarding pain tolerance, which infants are unable to provide, and pain response is difficult to discern in the neonate, the use of NMES with infants is developmentally inappropriate and the literature and research about infant pain response is at odds with the rationale for its use (Casavant et al. 2019, Cong et al. 2017, Smith et al, 2011, Weber et al. 2014,)

Participants were also asked to describe some of the additional therapy methods they use concurrently with NMES when treating vulnerable infants with dysphagia, responses included: traditional oral motor exercises, paced feeding, oral stimulation, temperature stimulation and elastic therapeutic taping. Of the pediatric studies done on the effectiveness of NMES on pediatric dysphagia, many studies report using other methods of therapy concurrently with NMES (Kelvin and Radika 2015, Rice 2012, Wright 2011, Song 2015, Christianeese 2011, Marcus 2019). Of the studies that used only NMES as a treatment modality, gains observed could not be attributed to use of NMES or no gains were observed (Maffiuletti 2010, Christianeese 2011, Frost 2018). It may be that the clinicians who use NMES would realize similar clinical outcomes without use of NMES. Also, of the limited studies that looked at the effectiveness of NMES on infants with dysphagia, no studies had control groups for comparison, so swallowing improvement could not be definitively attributed to NMES. All participants who indicated use of NMES with preterm infants indicated they determined discharge criteria by the improved swallow function of the patient. However, improvement in swallow function could be due to the natural maturation of the patient and not due to the NMES specifically. Due to the combined use of treatments methods such as oral stimulation, conventional swallowing

habilitation treatment, and natural maturation factors along with the use of NMES, determination of the effectiveness of NMES is unclear.

Clinical Implications

Clinical implications that can be made from this study suggest that there is currently an over reliance on infant cues and clinician judgment and an absence of quality evidence-based research, physiological rationale, and basic juvenile animal model research to support the use of these clinical approaches. According to ASHA, evidence based practice (EBP) is the integration of 1) clinical expertise: the knowledge, acquired through formal training and professional experience; 2) the best available information gathered from high-quality peer reviewed published evidence to inform clinical decision-making and from data and observations collected during clinicians' personal experience; and 3) the unique set of personal and cultural values, priorities, and expectations identified by the client (Evidence-Based Practice, n.d). The overreliance on clinical judgment may be due to the lack of basic and applied evidence available. The motivation for SLPs to pursue this modality given the absence of empirical support for NMES in neonates remains unclear.

When asked whether the current literature and research supports the use of NMES for the treatment of dysphagia on vulnerable infants, no agreement among the SLPs who use NMES was observed in the responses that ranged from strongly agree to strongly disagree. However, when asked whether ASHA should support the use of NMES for the treatment of neonate/young infant patients with dysphagia, those who indicated strong disagreement regarding availability of published evidence, indicated a higher level of agreement that ASHA should support the use of NMES. This indicates that although the participating SLPs were unsure whether the current research supported the use of NMES on infants, they believed that ASHA should still support its

use as a treatment modality. This mismatch between acknowledgment that published evidence is lacking and belief that ASHA should support the use of NMES with infants may be in part due to the vague wording of the ASHA statement. Given that the statement does not explicitly state a position on use of NMES with infants, clinicians are free to interpret the statement as indicating either caution or support. This mismatch in responses may also be due to a longstanding reliance on use of clinical judgment for clinical decision making, as evidenced by the survey findings.

Pressures from hospital administration, recommendations from other team members and the desire from parents to discharge infants from the NICU may also be driving clinicians to make clinical decisions without fully considering the potential long-term effects. Past conceptions of volume-driven standards for proper feeding development or meeting a certain discharge date set by hospital policies may lead clinicians to make feeding therapy modality decisions when the infant lacks readiness. However, evidence indicates that the concepts of an infant being able to eat a certain volume in the NICU does not always equate to safe or neuroadaptive feeding (Ferrara et al., 2015, Dumpa et al., 2020). Research has shown that preterm infants discharged home, frequently have not achieved fully organized and mature eating skills and that gestational age at birth influences the development of oral feeding skill more than the post-natal age of the infants (Amaizu 2008; Ross & Browne 2013). Establishing optimal feeding and education about feeding in the NICU should not only be a matter of how much volume the infant is able to ingest but should be seen as a foundation for a lifelong developmental skill (Ross & Browne 2013). Pressure to discharge infants may be one reason that clinicians choose to use modalities, such as NMES, that have not been fully vetted.

Physiologic, evidence-based clinical considerations regarding infant physiological stress while feeding and presence of comorbid conditions are vital components to determine infant

readiness for feeding. In a recent study of NMES use in young infants (Marcus, 2018), with a cohort of 10 infants and young children with severe dysphagia secondary to neurological impairment, three babies were unable to complete the treatment due to complications, decline in function, or death. Given the lack of empirical support for use of NMES in neurologically impaired infants, it is not clear what the physiological rationale was for use of NMES with such medically fragile patients.

There is also little knowledge for the long-term implications of the clinical use of NMES on developing infants. NMES introduces a non-physiological stimulation to the infant's still developing neuromuscular system and the long-term effects of NMES on developing muscles used for feeding and speech are currently not known (Epperson & Sandage, 2019). The painful pairing of NMES with the experience of feeding may not just interrupt optimal neuromuscular development and motor planning but may also create operant conditioning implications from the pairing of a painful stimulus with swallowing behavior (Staddon & Cerutti 2003). The painful experience of NMES while trying to coordinate feeding and breathing, may condition the infant to develop maladaptive feeding behaviors. Additionally, any short-term gains perceived to be attributed to NMES may contribute to later issues in child development that have not yet been identified. Preterm infants who are discharged from the NICU are already at risk of potential delays in feeding along with other delays in crucial milestones. The extent of prematurity and the number of medical interventions have been correlated with a delay in acquisition of eating skills (Ross & Browne 2013). It would be reasonable to postulate that the painful experience of NMES while feeding may negatively impact feeding in the child's later development.

The third aspect of EBP is patient perspective and the unique set of values and priorities set by the client. In the NICU setting, parents and caregivers are the decision makers when it

comes to the implementation of modalities such as NMES and it is the role of SLP to inform and educate the parent or caregiver of the risks and benefits of the treatment. Given the lack of empirical evidence for the risks and benefits of NMES in neonates and young infants, it is not clear how SLPs would be able to counsel caregiver decision making from an informed perspective. ASHA states in their practice policy regarding the role of SLPs in the NICU (American Speech-Language-Hearing Association, 2004), that SLPs need to, "Provide education, counseling, and support to families, other caregivers, and staff regarding preferred practices in the NICU to support current and future communication, cognition, feeding, and swallowing skills." Due to the limited studies done on pediatric patients and the use of NMES as a treatment for dysphagia, more evidence is needed for SLPs to be able to confidently adhere to practice policy regarding preferred practice. This is further complicated by caregivers who may be overwhelmed by the NICU environment. Research has shown that symptoms of post-traumatic stress are common in parents of infants who were admitted and discharged from the NICU (Lefkowitz et al. 2010), yet clinicians ask overwhelmed caregivers with variable levels of healthcare literacy to make complicated medical decisions regarding their infant's care.

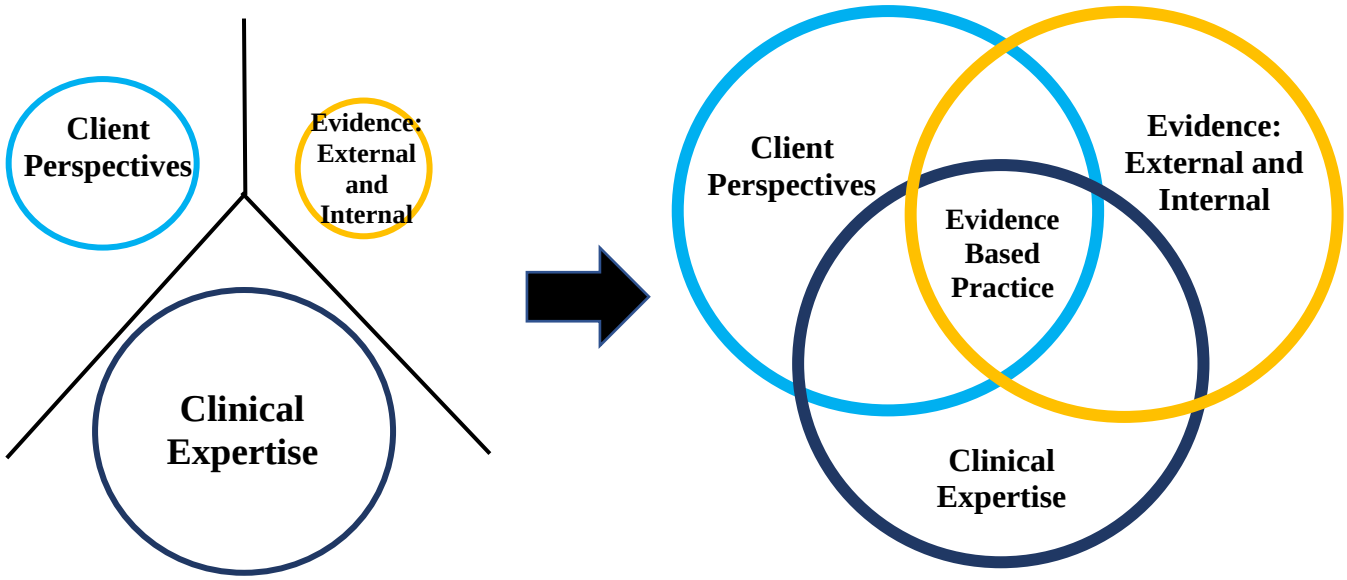
There are many perceived barriers to attaining the ideal balance of EBP for SLPs who use NMES in the NICU, some of which may reside at the level of the individual clinician and others at the level of the health care system (Campbell & Douglas 2017). Modalities, like NMES, can only be evaluated for their benefits and limitations after an excellent foundation of comprehensive physiologic development has been established and both basic and applied research conducted and peer-reviewed. A solution-oriented approach to improving swallowing habilitation clinical service provision to neonates would be to include more basic physiologic training in the areas of neuromuscular development and pain response development in graduate

training programs. Given the small body of literature that indicates no significant contribution from NMES for swallowing improvement in young children, the painful experience of NMES, and the still developing neuromuscular and pain perception pathways, this modality should never be applied in the medically-fragile, developing infant until more basic research has been completed and peer-reviewed.

Strengths, Limitation, and Future Directions

This is the first survey of its kind to query clinical practitioners about their use of NMES with infants. While the majority of respondents indicated that they do not use NMES with infants, it is imperative that we understand why some clinicians do. A primary strength of this investigation was the identification of the degree to which SLPs who use NMES with infants rely on clinical judgment to determine electrode placement, dose, specificity of the modality, and discharge criteria. Clinical judgment remains an important pillar of the evidence-based practice approach to patient care; however, optimal patient care should include all three parameters when possible, as illustrated in Figure 1.

Figure 8. *Major Components of Evidence Based Clinical Decision Making.*



The primary limitation of this study was the small number of participants who met inclusion criteria. While the small sample size limits the generalization of the findings, the limitation is mitigated by the evidence that few SLPs have the privilege of employment in the NICU despite a high level of interest in this work (Leonard et al. 2016). Limitations for survey dissemination are acknowledged. Due to the narrow inclusion criteria, efforts were made to reach out to SLPs practicing in the NICU through posts to relevant ASHA Communities and personal contact; however, NICU clinicians were likely missed. Future efforts should be made to reach out to specific NICUs and pursue SLP qualitative interviews to further query the motivations and clinical decision of NMES use in neonates.

Findings indicate the need for further basic research in the areas of SLP use of NMES on neonate and young infant populations, caregiver education regarding this modality and its long-term implication on feeding and speech. The need for additional clinical research in the areas of

foundational physiologic constructs such as homeostasis, allostasis and allostatic load is also apparent. It is not currently well understood whether graduate education programs provide training in neuromuscular or pain development in the infant.

Conclusions

NMES is a method of treatment for muscle rehabilitation that is currently being used by some SLPs to treat dysphagia in the neonate and young infant population. The findings of this study indicate that, for SLPs who use NMES with young infants, there is a heavy reliance on clinical judgement when making clinical decision regarding NMES for dysphagia treatment and they are not fully aware of the lack of research and literature to make informed decisions. However, the lack of standardized parameters of its implementation, and the absence of quality evidence-based research, physiological rationale, and basic juvenile animal model research calls into question the motivation for SLPs to use this modality with neonates and young infants.

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Appendix A

Survey Questions

You are invited to participate in a research study to examine the prevalence for the use of Neuromuscular Electrical Stimulation (NMES) and the physiological rationale of speech language pathologists for their use of NMES in the neonate and young infant population with dysphagia. The study is being conducted by Deborah Acevedo Bustamente, Graduate Student, under the direction of Dr. Mary Sandage, Associate Professor at Auburn University in the Auburn University Department of Speech, Language, and Hearing Sciences.

You are invited to participate because you are a speech-language pathologist (SLP) practicing in the United States who obtains the following: a degree in speech-language pathology, a state license to practice, and current CCC's and are currently treating neonate and young infant swallowing disorders.

Your participation is completely voluntary. If you decide to participate in this research study, you will be asked to complete a confidential survey. Your total time commitment will be approximately 10 minutes.

The risks associated with participating in this study are risk of loss of confidentiality. To minimize these risks, we will analyze and report data anonymously, using Qualtrics security protection and measures.

If you change your mind about participating, you can withdraw at any time by closing your browser window. Once you've submitted data, it cannot be withdrawn since it will be unidentifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University or the Department of Speech, Language, and Hearing Sciences at Auburn University

Any data obtained in connection with this study will remain anonymous. We will protect your privacy and the data you provide by using Qualtrics, a password protected survey software that features the following: firewall system protection, regular security scans, usage of transport layer security (TLS) encryption, and backups saved daily. Information collected through your participation will be used to complete a graduate thesis project and be submitted for publication in a professional journal.

If you have questions about this study, please contact Deborah Acevedo Bustamante at dra0023@auburn.edu

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334) 844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

o Yes, I consent to participate in this survey. (1)

o No, I do not consent to participate in this survey. (2)

Q38 What is your gender?

o Male (1)

o Female (2)

o Prefer to self-describe (3) _____

o Prefer not to say (4)

Q40 What is your age?

o Less than 20

o 20-29

o 30-39

o 40-49

o 50-59

o 60-69

o 70-79

o 80+

Q37 What is your Race/Ethnicity?

o African American

o White

o Latino/a

o American Indian and Alaska Native

o Native Hawaiian and Other Pacific Islander

o Asian

o Other _____

Q13 In which U.S state are you currently employed?

▼ Alabama (1) ... Not in U.S (50)

Q1 Are you currently a working certified Speech Language Pathologist?

o No

o Yes

Q34 Do you currently treat pediatric dysphagia?

o Yes

o No

Q2 What is your current degrees/credentials?

▢ Master's, CCC-SLP

▢ PhD, CCC- SLP

▢ Specialist with Swallowing Degree

▢ BCS-S

▢ None of the above

Q3 How long have you been employed as a Speech Language Pathologist?

o Less than 1 year

o 1-5 years

o 6-10

o 11-15

o 16-20

o +20

Q5 Which setting best describes your place of employment?

▢ University Hospital

▢ University Clinic

▢ PICU

▢ Home Care- Birth to 3

▢ Home Health-Hospice

▢ Skilled Nursing Facility

▢ Outpatient Clinic

▢ NICU

▢ Acute care

▢ Acute Inpatient Rehab

▢ Other _____

Q6 Have you taken any CEUs for pediatric dysphagia or related content?

o One course or less

o 2-3 Courses

o 4-5 Courses

o More than 5 Courses

o None

Q7 If so, which courses or additional content related to pediatric dysphagia have you taken? (A general and brief description)

Q41 Approximately how many pediatric patients do you treat for dysphagia weekly?

o None

o 1-5

o 6-10

o 11-15

o 16-20

o +20 _____

Q42 Does your place of employment use a multidisciplinary team when assessing and treating pediatric patients with dysphagia?

o Yes

o No

o Sometimes (Explain) _____

o Other _____

Q44 Are you familiar with physiological construct of homeostasis?

o Yes

o No

Q45 Where did you gain knowledge about homeostasis?

o High School

o College

o Graduate School

o Other _____

Q46 Are you familiar with the physiological construct of allostasis?

o Yes

o No

o Probably not

Q47 Where did you gain knowledge about allostasis?

o High School

o College

o Graduate School

o Other _____

Q48 Are you familiar with the physiological construct of allostatic load?

o Yes

o No

Q49 Where did you gain knowledge about allostatic load?

o High School

o College

o Graduate School

o Other _____

Q43 Are you familiar with Neuromuscular Electrical Stimulation (NMES) as a method of dysphagia treatment?

o Yes

o No

Q15 Do you currently use NMES as a method of therapy for dysphagia on the neonate and young infant population (3 years and under)?

o Yes

o No

o Other _____

Q18 How do you determine dose in the use of NMES?

- ▢ Hospital Recommendation
- ▢ V-Stim Recommendation
- ▢ Literature/Research Recommendation
- ▢ Other SLP's/Peer Recommendation
- ▢ Clinical Judgement
- ▢ SLP and Client's Family Judgement
- ▢ Client tolerance
- ▢ Other _____

Q20 How do you determine tolerance the use of NMES?

- ▢ Hospital Recommendation
- ▢ V-Stim Recommendation
- ▢ Literature/Research Recommendation
- ▢ Other SLP's/Peer Recommendation
- ▢ Clinical Judgement
- ▢ SLP and Client's Family Judgement
- ▢ Client Cueing (Explain) _____
- ▢ Other _____

Q22 How do you determine repetitions per session?

- ▢ Hospital Recommendation
- ▢ V-Stim Recommendation
- ▢ Literature/Research Recommendation
- ▢ Other SLP's/Peer Recommendation
- ▢ Clinical Judgement
- ▢ SLP and Client's Family Judgement
- ▢ Other _____

Q24 How do you determine which muscles to target?

- ▢ V-Stim Recommendation
- ▢ Literature/Research Recommendation
- ▢ Other SLP's/Peer Recommendation
- ▢ Clinical Judgement
- ▢ Other _____

How do you determine number of sessions?

- ▢ Client Diet Upgrade
- ▢ Clinical Judgement
- ▢ SLP and Client's Family Judgement

- ▢ Hospital/Doctor Recommendation
- ▢ SLP and Client's Family Judgement
- ▢ Literature/Research Recommendation
- ▢ Other _____

Q27 How do you determine discharge criteria?

- ▢ Client Diet upgrade
- ▢ Clinician Judgement
- ▢ Physician Recommendation
- ▢ Improved Swallow Function
- ▢ SLPs and Client Family Judgement
- ▢ Literature/Research Recommendation
- ▢ Declined health status of client
- ▢ Other _____

Q30 Do you use any other treatment concurrently with NMES?

- o Yes
- o No; I use NMES alone
- o Sometimes
- o Other _____

Q32 What methods of treatment do you use concurrently with NMES?

Q35 At which age range do you think it is appropriate to use NMES on an infant?

- ▢ Neonate/born prior to 37 weeks
- ▢ Birth-3 months
- ▢ 4 months-6 months
- ▢ 7 months-11months
- ▢ 1-3 years
- ▢ Other _____

Q36 Do you think that the current research supports the use of NMES for the treatment of neonates/young infants (3 years and under) with dysphagia?

Strongly Disagree Disagree Somewhat disagree Neither agree nor disagree Somewhat agree Agree Strongly agree

0 10 20 30 40 50 60 70 80 90 100

Q35 ASHA statement on neuromuscular electrical stimulation on neonate and pediatric populations is as follows: "Questions as to whether pediatric patients (defined broadly as preterm infants to children) with swallowing dysfunction as a result of neurological insult or other conditions may benefit from surface electrical stimulation remain unanswered.

Empirical data regarding the effect of electrical stimulation specific to swallowing function primarily in adults are beginning to appear in peer-reviewed publications. Some of the results are

conflicting, and there appears to be mixed evidence in regard to electrical stimulation's rehabilitative effects on swallowing recovery...ASHA does not endorse any products, procedures, or programs, and therefore does not have an official position on the use of electrical stimulation or specific workshops or products associated with electrical stimulation"

Do you agree with this stance?

Strongly Disagree Disagree Somewhat disagree Neither agree nor disagree Somewhat agree Agree Strongly agree

0 10 20 30 40 50 60 70 80 90 100

Q39 Do you think ASHA should support the use of NMES for the treatment of neonate/young infant patients with dysphagia?

Strongly Disagree Disagree Somewhat disagree Neither agree nor disagree Somewhat agree Agree Strongly agree

0 10 20 30 40 50 60 70 80 90 100

Appendix B

Scripts

Hello,

You are invited to participate in a research study to examine the prevalence for the use of Neuromuscular Electrical Stimulation (NMES) and the physiological rationale of speech language pathologists for their use of NMES in the neonate and young infant population with dysphagia.The study is being conducted by Deborah Acevedo Bustamante, Graduate Student, under the direction of Dr. Mary Sandage, Associate Professor at Auburn University in the Auburn University Department of Speech, Language, and Hearing Sciences,

You are invited to participate if you are a speech-language pathologist (SLP) practicing in the United States who obtains the following: a degree in speech-language pathology, a state license to practice, and current CCC's and are currently treating neonate and young infant swallowing disorders.Your participation is completely voluntary. If you decide to participate in this research study, you will be asked to complete a confidential survey. Your total time commitment will be approximately 10 minutes. You can also find this post/survey in relevant ASHA community groups.

The study information letter is attached following the link.

Thank you for your consideration!

Appendix C

Approved IRB

AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS
RESEARCH PROTOCOL REVIEW FORM
FULL BOARD or EXPEDITED

For Information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**, 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 **e-mail:** IRBAdmin@auburn.edu **Web Address:** http://www.auburn.edu/research/vpr/ohs/index.htm

Revised 5.19.2020 **Submit completed form to IRBsubmit@auburn.edu or 115 Ramsay Hall, Auburn University 36849.**

***Complete this form using Adobe Acrobat** Writer **(versions 5.0 and greater).** Hand written copies not accepted.*

1. **PROPOSED START DATE of STUDY:** 7/31/20 **Today's Date:** 7/8/20

PROPOSED REVIEW CATEGORY (Check one): ☐ **FULL BOARD** ■ **EXPEDITED**

SUBMISSION STATUS (Check one): ■ **NEW** ☐ **REVISIONS (to address IRB Review Comments)**

2. **PROJECT TITLE:** Use of NMES for Swallowing Habilitation in Neonatal Intensive Care Units: A Survey

3.

Deborah Acevedo Bustamante	Graduate Student	CMDS	Dra0023@gauburn.edu
PRINCIPAL INVESTIGATOR	**TITLE**	**DEPT**	**AU E-MAIL**
821 Castlemaine Ct, Birmingham AL 35226		703 608 5726	Deboracevedo07@gmail.com
MAILING ADDRESS		**PHONE**	**ALTERNATE E-MAIL**

4. **FUNDING SUPPORT:** ■ N/A ☐ Internal ☐ External Agency: _____ ☐ Pending ☐ Received

For federal funding, list agency and grant number (if available). _____

5a. List any contractors, sub-contractors, other entities associated with this project:
n/a

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):
n/a

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

- ☒ **Research Protocol Review Form** (All signatures included and all sections completed)
  (Examples of appended documents are found on the OHSR website: http://www.auburn.edu/research/vpr/ohs/sample.htm)
- ☒ **CITI Training Certificates** for all Key Personnel.
- ☒ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.
- ☒ **Appendix A**, "Reference List"
- ☒ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.
- ☒ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.
- ☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).
- ☐ **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission letter** from the site / program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB approval** from each entity is required prior to initiating the project.
- ☐ **Appendix F** - Written evidence of acceptance by the host country if research is conducted outside the United States.

Version Date (date document created):_____ page __ of __

6. GENERAL RESEARCH PROJECT CHARACTERISTICS

6A. Research Methodology

Please check all descriptors that best apply to the research methodology.

Data Source(s): ☒ New Data ☐ Existing Data

Will recorded data directly or indirectly identify participants? ☐ Yes ☒ No

Data collection will involve the use of:

- ☐ Educational Tests (cognitive diagnostic, aptitude, etc.)
- ☐ Interview
- ☐ Observation
- ☐ Location or Tracking Measures
- ☐ Physical / Physiological Measures or Specimens (see Section 6E.)
- ☑ Surveys / Questionnaires
- ☐ Other: _____
- ☐ Internet / Electronic
- ☐ Audio
- ☐ Video
- ☐ Photos
- ☐ Digital Images
- ☐ Private records or files

6B. Participant Information

Please check all descriptors that apply to the target population.

☒ Males ☒ Females ☐ AU students

Vulnerable Populations

☐ Pregnant Women/Fetuses ☐ Prisoners ☐ Institutionalized

☐ Children and/or Adolescents (under age 18 in AL)

Persons with:

☐ Economic Disadvantages ☐ Physical Disabilities

☐ Educational Disadvantages ☐ Intellectual Disabilities

Do you plan to compensate your participants? ☐ Yes ☒ No

6C. Risks to Participants

Please identify all risks that participants might encounter in this research.

- ☒ Breach of Confidentiality*
- ☐ Deception
- ☐ Psychological
- ☐ None
- ☐ Other:
- ☐ Coercion
- ☐ Physical
- ☐ Social

*Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk.

6D. Corresponding Approval/Oversight

- Do you need IBC Approval for this study?
  ☐ Yes ☑ No

  If yes, BUA #_____ Expiration date _____

- Do you need IACUC Approval for this study?
  ☐ Yes ☑ No

  If yes, PRN #_____ Expiration date _____

- Does this study involve the Auburn University MRI Center?
  ☐ Yes ☑ No

  Which MRI(s) will be used for this project? (Check all that apply)
  ☐ 3T ☐ 7T

  Does any portion of this project require review by the MRI Safety Advisory Council?
  ☐ Yes ☐ No

  Signature of MRI Center Representative: _____
  Required for all projects involving the AU MRI Center

  Appropriate MRI Center Representatives:
  Dr. Thomas S. Denney, Director AU MRI Center
  Dr. Ron Beyers, MR Safety Officer

Version Date (date document created):_____ page __ of __

7. PROJECT ASSURANCES

A. PRINCIPAL INVESTIGATOR'S ASSSURANCES

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Auburn University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with Auburn University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Auburn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
    a. Conducting the project by qualified personnel according to the approved protocol
    b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Research Compliance
    c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
    d. Promptly reporting significant adverse events and/or effects to the Office of Research Compliance in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise ORC, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Research Compliance before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

Deborah Acevedo Bustamante	Deborah Acevedo Bustamante Digitally signed by Deborah Acevedo Bustamante Date: 2020.07.08 12:29:36 -05'00'	7/8/20
Printed name of Principal Investigator	**Principal Investigator's Signature**	**Date**

B. FACULTY ADVISOR/SPONSOR'S ASSURANCES

1. I have read the protocol submitted for this project for content, clarity, and methodology.
2. By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
3. I agree to meet with the investigator on a regular basis to monitor study progress. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant incidents and/or adverse events and/or effects to the ORC in writing within 5 working days of the occurrence.
5. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the ORC by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.

Mary J. Sandage, Assoc Prof	Mary J Sandage Digitally signed by Mary J Sandage Date: 2020.07.08 13:13:36 -05'00'	7/8/20
Printed name of Faculty Advisor / Sponsor	**Faculty Advisor's Signature**	**Date**

C. DEPARTMENT HEAD'S ASSSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

Laura W. Plexico, PhD	Laura W. Plexico Digitally signed by Laura W. Plexico Date: 2020.07.08 13:05:02 -05'00'	7/8/20
Printed name of Department Head	**Department Head's Signature**	**Date**

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8. **PROJECT OVERVIEW: Prepare an abstract that includes:**
(**350** word maximum, in language understandable to someone who is not familiar with your area of study):

a) **A summary of relevant research findings leading to this research proposal:**
(*Cite sources; include a "Reference List" as Appendix A.)*
b) **A brief description of the methodology, including design, population, and variables of interest**

Neuromuscular electrical stimulation (NMES) is a method of treatment for dysphagia that is currently being implemented in neonative intensive care units. Clinical use of NMES in this population has been reported; however, there is a lack of empirical evidence to support the physiological rational for its use on such a vulnerable population. The lack of published standards for specificity and dosage of the NMES modality in infants requires further study of current clinical practice. Included survey participants are SLP's with a degree in speech-language pathology, a state license to practice speech-language pathology, and are currently employed as an SLP in neonative or pediatric intensive units. The Qualtrics survey link will be electronically distributed via email to the following: members of multiple ASHA Special Interest Groups; ASHA's Facebook and community board groups; speech-language pathology Facebook pages; and general email distribution. The survey link will navigate to a brief introductory message, explaining the justification for the survey and allowing for consent and anonymous participation. The anonymous survey is composed of one open ended question and multiple questions with fixed responses. Qualtrics software will anonymously analyze quantitative data and thematic analyses will be incorporated for qualitative analysis.

9. **PURPOSE.**
a. **Clearly state the purpose of this project and all research questions, or aims.**

The purpose of this investigation is to examine the prevalence for the use of NMES and the physiological rational of speech language pathologists for their use of NMES in the neonate and young infant population with dysphagia. It is hypothesized that SLPs who report use of NMES for the habilitation of swallowing in neonates and young infants will report the following: 1) belief that NMES is effective, 2) lack of clear physiologic rationale for use of NMES, 3) lack of training specifically targeted for the infant population, and 4) lack of specificity of modality with regard to dosage (frequency and intensity) of NMES intervention.

b. **How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)**

The results of this project will be used for completion of graduate level thesis and manuscript submission to a scientific journal.

10. **KEY PERSONNEL.** Describe responsibilities. Include information on research training or certifications related to this project. **CITI is required. Be as specific as possible.** (Include additional personnel in an attachment.) *All key personnel must attach CITI certificates of completion.*

Principle Investigator Deborah Acevedo Bustam **Title:** Graduate Reseacher **E-mail address** dra0023@auburn.edu
Dept / Affiliation: CMDS, Liberal Arts, Auburn University

Roles / Responsibilities:

Survey development, participant recruitment, monitoring survey, data analyses, manuscript preparation.

Individual: Mary Sandage, Ph.D. **Title:** Assistant Professor **E-mail address** sandmj@auburn.edu
Dept / Affiliation: CMDS, Liberal Arts, Auburn University

Roles / Responsibilities:

Faculty advisor, participant recruitment, monitoring survey, data analysis, manuscript preparation.

Individual: Allison Plumb **Title:** Assistant Professor **E-mail address** amp0016@auburn.edu
Dept / Affiliation: CMDS, Liberal Arts, Auburn University

Roles / Responsibilities:

Thesis committee member, editing survey, reviewing survey analysis, and manuscript preparation.

Individual: Dallin Bailey **Title:** Assistant Professor **E-mail address** djb0053@auburn.edu
Dept / Affiliation: CMDS, Liberal Arts, Auburn University

Roles / Responsibilities:

Thesis committee member, editing survey, reviewing survey analysis, and manuscript preparation.

Individual: Megan Ondrizek **Title:** Undergraduate Researcher **E-mail address** mro0013@auburn.edu
Dept / Affiliation: CMDS, Liberal Arts, Auburn University

Roles / Responsibilities:

Survey development, survey analyses, manuscript preparation.

Individual: _____ **Title:** _____ **E-mail address** _____
Dept / Affiliation: _____

Roles / Responsibilities:

11. **LOCATION OF RESEARCH. List all locations where data collection will take place.** (School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) **Be as specific as possible. Attach permission letters in Appendix E.**
(See sample letters at http://www.auburn.edu/research/vpr/ohs/sample.htm)

All data collection will take place via the Qualtrics survey platform.

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12. **PARTICIPANTS.**

a. **Describe the participant population you have chosen for this project including inclusion or exclusion criteria for participant selection.**

☐ **Check here if using existing data, describe the population from whom data was collected, & include the # of data files.**

Inclusion criteria include the following: a graduate degree in speech-language pathology, a state license to practice speech-language pathology, currently has Certificate of Clinical Competence (CCC) from the American Speech Language Hearing Association (ASHA) , is currently employed as a speech-language pathologist and is currently treating infant and young child swallowing disorders.

b. **Describe, step-by-step, in layman's terms, all procedures you will use to recruit participants.** *Include in Appendix B a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate. (See sample documents at http://www.auburn.edu/research/vpr/ohs/sample.htm.)*

Survey participants will contacted via email lists originating from the following groups: a) members of the following ASHA Special Interest Groups (SIGs): Neurogenic Communication Disorders, Voice and Upper Airway Disorders, Craniofacial and Velopharyngeal Disorders, Swallowing and Swallowing Disorders; b) ASHA's Facebook and community board groups; c) relevant speech language pathology Facebook community groups and d) various hospitals with Neonatal Intensive Care Units across the United States vial electronic information letter (see Appendix B for script). Contact methods a and b will use ASHA resources (SIG groups and ASHA membership messaging portals) to contact individuals.

c. **What is the minimum number of participants you need to validate the study?** 30

How many participants do you expect to recruit? 100

Is there a limit on the number of participants you will include in the study? ☒ **No** ☐ **Yes – the # is** _____

d. **Describe the type, amount and method of compensation and/or incentives for participants.**

(If no compensation will be given, check here: ☒)

Select the type of compensation: ☐ Monetary ☐ Incentives

- ☐ Raffle or Drawing incentive (Include the chances of winning.)
- ☐ Extra Credit (State the value)
- ☐ Other

Description:

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13. **PROJECT DESIGN & METHODS.**

a. **Describe, step-by-step, all procedures and methods that will be used to consent participants. If a waiver is being requested, check each waiver you are requesting, describe how the project meets the criteria for the waiver.**

- ☐ **Waiver of Consent (including using existing data)**
- ☒ **Waiver of Documentation of Consent (use of Information Letter)**
- ☐ **Waiver of Parental Permission (for college students)**

Participant consent will be included as the first item in the Qualtrics survey. The information letter content will appear in the first Qualtrics query, at which point the participant will provide consent and then proceed with the survey items.

b. **Describe the research design and methods you will use to address your purpose. Include a clear description of when, where and how you will collect all data for this project.** Include specific information about the participants' time and effort commitment. *(NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the Auburn University IRB will not be able to review this protocol. If additional space is needed for this section, save the information as a .PDF file and insert after page 7 of this form.)*

Potential participants will receive a Qualtrics link via email during intentional time frames (7: 00am-9:00am and 8:00-10:00pm) to improve survey participation. The link navigates to the Qualtrics survey developed with the first item being the Information Letter (in Appendix B) from which participant consent is obtained. The participant will then complete the survey items, all responses of which will be anonymously collected. Open-ended survey responses will be analyzed qualitatively and responses will be organized into themes responses. Closed-ended responses will be descriptively analyzed and reported as percentages of the total number of respondents. Survey is estimated to take10 minutes or less.

13. **PROJECT DESIGN & METHODS.** *Continued*

c. **List all data collection instruments used in this project, in the order they appear in Appendix C.**
(e.g., surveys and questionnaires **in the format that will be presented to participants**, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

See Appendix C: Survey.

d. **Data analysis: Explain how the data will be analyzed.**

The Qualtrics survey software will calculate the average percentages based upon the number of participants. Quantitative analysis will be analyzed with descriptive statistics addressing demographic information and answers to closed-ended questions. Qualitative analyses will address the open ended questions using thematic analysis.

14. **RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter in this research.** ***If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use in Appendix D.*** *(Examples of possible risks are in section #6D on page 2)*

There is always a risk of loss of confidentiality.

15. **PRECAUTIONS.** Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals. ***Provide a copy of any emergency plans/procedures and medical referral lists in Appendix D. (Samples can be found online at http://www.auburn.edu/research/vpr/ohs/sample.htm#precautions)***

Risk of loss of confidentiality is mitigated by use of Qualtrics. All survey responses will be collected, analyzed and reported anonymously.

If using the Internet or other electronic means to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.

No identifiable data will be collected. Qualtrics security is described as follows: password protection, firewall system protection,regular security scans, usage of transport layer security (TLS) encryption, and backups are performed daily. Data collected via Qualtrics will be transferred to an Excel spreadsheet for analysis. The spreadsheet will be saved on Dr. Sandage's password protected research share drive, which is backed up daily.

16. **BENEFITS.**

a. **List all realistic direct benefits participants can expect by participating in this specific study.**
(Do not include "compensation" listed in #12d.) Check here if there are no direct benefits to participants. ☐

Benefits for the participants would include self-reflection of their own clinical practice patterns as well as contributing to our discipline-specific understanding of use of NMES as a clinical intervention.

b. **List all realistic benefits for the general population that may be generated from this study.**

Realistic benefits for the general population, as a result of this study, are current quantifications of reported understanding and prevalence of the use of NMES among SLP's. This study might contribute to the limited research in the use of NMES in the neonate and young infant population and clarify current clinical practice for its use on the neonate and young infant population.