Evidence-Based Systematic Review: Effects of Oral Motor Interventions on Feeding and Swallowing in Preterm Infants

Authors

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Method: A systematic search of the literature published from 1960 to 2007 was conducted. Articles meeting the selection criteria were appraised by 2 reviewers and vetted by a 3rd for methodological quality.

Results: Twelve studies were included and focused on 3 OMIs—nonnutritive sucking (NNS), oral/perioral stimulation, and NNS plus oral/ perioral stimulation. Six studies addressed the effects of OMI on the feeding/ swallowing physiology outcomes of feeding efficiency or sucking pressures. Ten studies addressed the functional feeding/swallowing outcomes of oral feeding or weight gain/growth. No studies reported data on pulmonary health. Methodological quality varied greatly. NNS alone and with oral/perioral stimulation showed strong positive findings for improvement in some feeding/swallowing physiology variables and for reducing transition time to oral feeding. Pre-feeding stimulation showed equivocal results across the targeted outcomes. None of the OMIs provided consistent positive results on weight gain/growth. Conclusions: Although some OMIs show promise for enhancing feeding/swallowing in preterm infants, methodological limitations and variations in results across studies warrant careful consideration of their clinical use.

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ABSTRACT

Purpose: To conduct an evidence-based systematic review and provide an estimate of the effects of oral motor interventions (OMIs) on feeding/swallowing outcomes (both physiological and functional) and pulmonary health in preterm infants.
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ARTICLE

Approximately 12.7% of all births in the United States annually are preterm with a gestation period less than 37 weeks; since 1990, the survival rate of preterm infants has increased by 20% (Hamilton et al., 2007). This figure equates to more than 500,000 preterm infants entering the population each year (Centers for Disease Control and Prevention, 2008). Many of these infants present with a variety of medical and developmental complications (Ancel et al., 2006; Burklow, McGrath, Valerius, & Rudolph, 2002; Burklow, Phelps, Schultz, McConnell, & Rudolph, 1998; Hawdon, Beauregard, Slattery, & Kennedy, 2000; Mathews &MacDorman, 2006; Newman, Keckley, Petersen, & Hamner, 2001; Rommel, De Meyer, Feenstra, & Veereman-Wauters, 2003). Medical complications for this population include higher frequencies of respiratory distress, temperature instability, seizures, and feeding problems as well as higher rates of rehospitalization than for term infants (Raju, Higgins, Stark, & Leveno, 2006). Although there are multiple reasons for readmission, feeding difficulties and failure to thrive are among themost common diagnoses at readmission (Escobar, Clark, & Green, 2006).

Prevalence and incidence estimates of feeding problems in extremely preterm infants are limited. The incidence of dysphagia in children is unknown. Estimated prevalence of feeding disorders in the United States ranges from 25% to 45% in typically developing children and from 33% to 80% in children with developmental delays, per summaries of investigations reporting these figures (Burklow et al., 1998; Linscheid, 2006). Left unresolved, these difficulties may persist and have long-term consequences (Dodrill et al., 2004; Samara, Johnson, Lamberts, Marlow, &Wolke, 2009). In addition, common medical procedures with this population (e.g., intubation, tube feeding, and suctioning) may contribute to the disturbance of sucking and swallowing development, as well as oral sensory and motor dysfunction, because of negative experiences for the infant. Oral feeding in preterm infants is frequently characterized by immature sucking and/or incoordinated suck, swallow, and breathe sequencing (e.g., Lau, 2006; Mizuno & Ueda, 2003), which may lead to delays in successful breast- and bottle-feeding, poor weight gain, and dehydration during early postnatal weeks. Preterm infants often cannot attain total oral feeding status in early postnatal weeks. They receive gavage (tube) feedings until they develop sufficiently to transition to nipple feedings at the breast or by bottle.

The transition from gavage to independent oral feeding can be a challenge to preterm infants and those who care for them. Infants who experience these difficulties often require prolonged hospital stays that in turn may lead to maternal (and family) stress and increased financial burden (e.g., Amaizu, Shulman, Schanler, & Lau, 2008; Dole et al., 2003; Hawdon et al., 2000). The ability of the preterm infant

to make the transition from gavage feedings to total oral feeding depends on a number of factors that include global neurodevelopmental status related to behavioral organization, rhythmic sucking-swallowing-breathing coordination, and cardiorespiratory regulation (McCain, 2003). Other infant characteristics such as low birth weight, gestational age at birth, and neonatal illnesses can also affect the transition time to exclusive nipple feeding (Dodrill, Donovan, Cleghorn, McMahon, & Davies, 2008).

There are a number of essential clinical components to consider in the transition from gavage to oral feeding, including feeding efficiency and safety. Feeding efficiency involves sucking endurance and performance, the strength and efficiency of the sucking patterns, and suck-swallowbreathing coordination (Mizuno et al., 2007). Inefficient feeding may lead to excessive fatigue in the infant and contribute to weight loss or inadequate weight gain in this medically fragile population (McCain, 2003; Premji, Paes, Jacobson, & Chessell, 2002). Because infants with sucking or swallowing problems are at increased risk of aspiration, safety of infant feeding is also an important consideration of this transition (Arvedson, Rogers, Buck, Smart, & Msall, 1994). The three functions of sucking, swallowing, and breathing need to occur sequentially from the oral to pharyngeal to esophageal phases of swallowing with no negative pulmonary effects (Bosma, Hepburn, Josell, & Baker, 1990). Because the processes of respiration and feeding involve the same anatomic pathways, the synchronization of these functions is crucial (Amaizu et al., 2008). Components within each of the three functions mature at different times, which may translate into breakdowns in coordination that are encountered when preterm infants are faced with the task of oral feeding (Amaizu et al., 2008). For example, the suction and expression components of sucking mature at different times (Lau, Alagugurusamy, Schanler, Smith, & Shulman, 2000). The oropharyngeal swallow requires a number of pharyngeal muscles that control anatomic structures for sequential movements (Ertekin, 2002; J. L. Miller&Kang, 2007). During oral feeding, the mechanical generation of respiration involves proper activation of the diaphragmatic, intercostal, and upper airway muscles from nose to glottis (Timms, DiFiore, Martin, Carlo, & Miller, 1992). Amaizu and colleagues (2008) found that despite similar oral feeding outcomes in their study of stable preterm infants, maturation levels of sucking, swallowing, and breathing differed.

Facilitation of oral feeding skills is typically a key focus in the neonatal intensive care unit (NICU), and attainment of oral feeding is frequently a primary criterion for discharge from the NICU for healthy preterm infants (American Academy of Pediatrics, 1998). The NICU setting provides the foundation for continued feeding development after discharge from hospital. In this setting, professionals need to facilitate skills that will lead to the functional goal of oral feeding, or in some instances, help to determine when longer term supplemental

enteral tube feeding may be needed to discharge infants from the NICU.

Intervention approaches for infants in the NICU have evolved in recent years to focus on individualized developmental care (Als et al., 2003; McAnulty et al., 2009) that involved multiple disciplines, including speech-language pathologists (SLPs). Clinicians must understand the underlying medical and surgical conditions that affect physiological stability (e.g., all aspects of state, gross and fine motor skills, oral sensorimotor skills, and nutrition issues). Unless the treatment approach includes a focus on the "whole" infant, oral feeding is not likely to be successful. As integral members of the NICU team, SLPs' focus on oral feeding facilitation is vital to the overall developmental care in the NICU. It must be noted that a Cochrane Database Systematic Review by Symington and Pinelli (2006) concluded that multiple interventions were included in most studies, making it difficult to determine the effect of any single intervention. Evidence demonstrating more consistent effects of developmental care interventions on important short- and longterm clinical outcomes is needed before a clear direction for practice can be supported.

Currently a number of treatment strategies exist to facilitate oral feeding in preterm infants. These include environmental/ physical modifications such as eliminating external stimuli during feedings, using therapeutic nipples to manipulate flow rate, positioning and swaddling to support the motor system and improve flexion, and oral motor intervention (OMI). OMI has been a topic of interest for some time with SLPs working in NICU settings (Mullen, 2005). The various types of OMI employed by SLPs typically include nonnutritive sucking (NNS) and/or oral stimulation.

NNS opportunities are commonly used with preterm infants in the NICU as a means to facilitate the transition from gavage to breast or bottle feeding. Pacifiers are the primary tools, usually introduced to preterm infants once they are medically stable at about 29–30 weeks' gestation. The reported rationale for NNS is that it facilitates the development of sucking behavior, improves digestion of enteral feedings, and has the potential for reducing length of hospital stay (e.g., Fucile, Gisel, & Lau, 2005; Pickler, Frankel, Walsh, & Thompson, 1996; Pinelli & Symington, 2005).

Outcomes reported with NNS in the NICU include decreased transition from tube to oral feedings (Sehgal, Prakash, Gupta, Mohan, & Anand, 1990), maturing suck pattern (Bernbaum, Pereira, Watkins, & Peckham, 1983), promoting oxygenation (Burroughs, Asonye, Anderson-Shanklin, & Vidyasagar, 1978), weight gain (Field et al., 1982), soothing during invasive procedures (Butt&Kisilevsky, 2000; Field & Goldson, 1984), regulating state (Gill, Behnke, Conlon,&Anderson, 1992), and fewer behavioral state changes (McCain, 1995). Reduced length of stay is a primary goal

for all hospitalized patients, particularly preterm infants in the NICU. A Cochrane review on this topic synthesized the results of 21 studies that included all infants born before 37 weeks' gestation (Pinelli & Symington, 2005). The main outcome was that NNS significantly decreased length of stay in preterm infants. Positive clinical outcomes also included transition from tube to nipple and better bottle feeding performance, although there was no definitive time frame stated. No consistent NNS benefit with respect to other major clinical variables such as weight gain, heart rate, oxygen saturation, age at full oral feeds, or behavioral state was revealed. These varied outcomes are not surprising given the underlying physiological states and contributing factors to oral feeding in young infants (Simpson, Schanler, & Lau, 2002) as noted by a wide range in gestational age for infants to reach total successful oral feeding.

Oral and perioral stimulation programs aimed at accelerating the process to attain total oral feeding are also common in the NICU. These programs typically consist of stroking or the application of gentle pressure to the lips, cheeks, tongue, or other oral structures. Reported rationales for oral or perioral stimulation consist of decreasing hypersensitivity and improving range of motion and strength (Fucile, Gisel, & Lau, 2002), increasing oral motor organization (Case-Smith, 1988), and activating reflex behaviors that would facilitate nutritive sucking (Leonard, Trykowski, & Kirkpatrick, 1980).

Exploratory studies investigating these interventions have notedmixed results. For example, Rendón-Macías et al. (1999) reported that prefeeding oral stimulation had a positive effect on the recovery of oral reflexes and increased breast milk/ formula volume at oral feedings. In contrast, Trykowski, Kirkpatrick, and Leonard (1982) found no significant differences in volume of oral feedings, sucking pressures, or rate of sucking in preterm infants receiving similar stimulation. These same authors also investigated the use of stimulation provided during feeding (Leonard et al., 1980; Trykowski et al., 1982). Positive effects were noted on volume taken during oral feeding and sucking rate but not on sucking pressures.

Mixed results related to outcomes following OMI make it difficult for clinicians to make individualized evidence-based clinical decisions for infants on their caseloads. Although the Cochrane review (Pinelli & Symington, 2005) provided some insight into the effects of NNS, it did not provide a comprehensive analysis of all OMI, nor did it address other outcomes of interest to SLPs (e.g., aspiration or aspiration pneumonia). SLPs actively involved in interdisciplinary, developmentally focused care in the NICU and those who follow these infants through post-NICU intervention need to be well-informed to practice ethically and effectively in this high-risk area of patient care. To assist SLPs with engaging in evidence-based practice and help inform their clinical

decision making, the American Speech-Language-Hearing Association's (ASHA's) National Center for Evidence-Based Practice in Communication Disorders (N-CEP) has begun conducting evidence-based systematic reviews (EBSRs) on a variety of clinical topics. Given the interest by SLPs, the inconsistent findings across studies, and the lack of a preexisting comprehensive systematic review, an EBSR on the use of OMI with preterm infants was considered warranted.

This report is part of a series of EBSRs examining the state of the evidence on OMI. As part of the review process, N-CEP convened a panel of experts to define the components of OMI and identify the primary clinical questions. In developing the clinical questions, key outcomes for preterm infants such as feeding efficiency, swallowing physiology, feeding safety, pulmonary health, oral feeding, and weight gain were considered. For the purposes of this series of reviews, OMI was defined as sensory stimulation to or actions of the lips, jaw, tongue, soft palate, pharynx, larynx, and respiratory muscles that are intended to influence the physiological underpinnings of the oropharyngeal mechanism in order to improve its functions. These activities for preterm infants may include NNS and variations of stroking, tapping, and stretching externally on the face or within the oral cavity. The clinical questions addressed by this review were as follows:

1. What is the effect of OMI on feeding and swallowing physiology (e.g., sucking pressures, feeding efficiency, rate of liquid transfer, aspiration, or total length of feeding time) in preterm infants?
2. What is the effect of OMI on functional oral feeding and swallowing outcomes (e.g., volume intake, days to oral feeding, weight gain, or growth) in preterm infants?
3. What is the effect of OMI on pulmonary health (i.e., aspiration pneumonia) in preterm infants?

EBSRs examining the impact of OMI on speech and swallowing in other age groups (i.e., children and adults) are beyond the scope of this article and will be addressed in separate publications.

METHOD

A single systematic search for this EBSR series was conducted from December 2006 through September 2007 and included 20 electronic databases (see the Appendix), all ASHA journals, and Google Scholar. Prior to the search, a set of expanded key words and a comprehensive search strategy were developed. The full author panel generated the initial core set of key words and search terms, which were intentionally broad to capture the span of interventions and outcomes addressed in the clinical questions. The search terms were developed across a variety of relevant categories including speech, swallowing, secretion management, speech

and swallowing anatomy and physiology, specific outcomes identified in the clinical questions (e.g., swallowing pressures and pulmonary health), and specific interventions meeting this EBSR's definition of OMI (e.g., stimulation and sucking). These key words were then mapped to medical subject headings (MeSH) from the National Library of Medicine or the controlled vocabulary specific to each of the searched databases. Each subheading under the identified MeSH term or controlled vocabulary was included as an additional key word and incorporated into the search strategy. The search was conducted based on a combination of the Pearl Growing strategy (Hawkins & Wagers, 1982) and plain text searching. Pearl growing consists of identifying relevant articles and incorporating the controlled vocabulary from each of these articles into the search strategy. This methodology ensures that all relevant key words and controlled vocabulary have been identified. All terms were then linked using the Boolean "OR" operator to locate as many citations as possible. The "AND" operator was also used to increase the specificity or relevance of the identified citations.

Once the controlled vocabulary searching for an individual database was completed, a plain text search of that database was performed. This process involved electronically searching the titles and abstracts of all articles within that database using the initial core set of search terms identified by the full author panel. Where appropriate, search terms were truncated to find any spelling or suffix variations of the search terms. Plain text searching was considered a necessary step due to multiple limitations in controlled vocabularyonly searches. These limitations include time delays in indexing articles, incorrect classification of articles, and lack of relevant index terms (Boynton, Glanville, McDaid, & Lefebvre, 1998; DeLuca et al., 2008). Additional citations were identified through hand searches of references and forward citation tracking of all relevant articles. The complete search strategy is available from the authors.

Study Inclusion

Studies were initially considered for this review if they met the following selection criteria:

1. The study was published between 1960 and 2007. The search date was established from the early accounts of dysphagia research and SLP involvement in the treatment of pediatric feeding and swallowing disorders. Although this literature primarily emerged in the 1970s (ASHA, 2004), the panel chose to broaden the search to 1960 to ensure the inclusion of all relevant pediatric swallowing studies.
2. The study was published in English. Studies published in other languages were excluded due to limited translation resources.

3. The study was published in a peer-reviewed journal. The peer review process verifies that some independent vetting of the research has taken place and that the research was of adequate quality to publish. The exclusion of unpublished research, however, may introduce publication bias (i.e., the overrepresentation of positive findings in the published literature), which can artificially inflate estimates of treatment effects. Notwithstanding this fact, unpublished literature is characterized by timeconsuming and difficult searches (Eldredge, 2000), difficulties in designing comprehensive and systematic search strategies to ensure unbiased and representative results of the literature (Benzies, Premji, Hayden, & Serrett, 2006), and inadequate reporting of procedures as well as data discrepancies in reporting results (Dundar et al., 2006). Given these limitations and the benefit of additional scrutiny provided by the peer review process, the decision was made to limit the search to refereed publications.
4. The study incorporated an experimental, quasi-experimental, or multiple-baseline single-subject design. These designs were included because they are generally considered to demonstrate evidence of the causal effects of an intervention for a specific outcome.
5. The study did not include OMI paired with surgical, medical, or pharmacological treatments. Combined treatments were excluded because it is not possible to determine the true impact of a specific intervention if it is not examined separately or controlled for within a research design.
6. The study contained original data that specifically addressed at least one of the three clinical questions targeted in this review. Therefore studies had to be conducted on preterm infants and examine the effects of OMI (as defined by this EBSR) used as a treatment (not just a single application) to facilitate oral feeding and swallowing skills.

A total of 899 citations were identified for this review series. Two authors (the fourth and fifth authors), blinded from one another's results, reviewed each abstract and initially identified (with 91% agreement) 346 citations that met preliminary inclusion criteria. Of those, 250 were excluded because they did not directly address one or more of the larger set of clinical questions, nor did they report original data. Thus, 96 studies were identified for inclusion in this series of EBSRs, with 12 of these studies identified for final inclusion in this review. These 12 studies addressed one or more of the three clinical questions related to the effects of OMI on feeding, sucking, and swallowing in preterm infants.

Quality Appraisal

The ability to draw accurate conclusions from an EBSR depends on the validity of the findings of the included studies. Therefore, two authors, blinded to one another's results, independently assessed each study for methodological quality (with 87% agreement) based on ASHA's Levels of Evidence Scheme (Cherney, Patterson, Raymer, Frymark, & Schooling, 2008; Mullen, 2007). This structured system was used to appraise each study across eight domains: study design, assessor blinding, sampling/allocation, subject comparability/description, outcomes, significance, precision, and intention to treat (when applicable). These domains were selected to identify areas of possible bias or methodological characteristics that might influence estimates of treatment effects. Many of these domains for assessing individual studies are similar or common to those found in other evidence appraisal schemes. However, unlike many appraisal schemes, this system is not limited to randomized controlled trials and allows for the inclusion and reasonable assessment of a variety of study designs commonly used in communication sciences and disorders such as single-subject design research.

Each study received a study quality marker score based on the number of indicators that met the highest level of quality in each area (see Table 1). For studies incorporating controlled trials, all eight quality indicators were relevant, leading to a maximum quality score of eight. For all other study designs, where an intention to treat analysis was not applicable, the highest quality score was seven. This process was repeated for each clinical question that an individual study addressed. This was necessary because the targeted clinical questions and some of the appraisal domains were outcome-specific (e.g., significance and precision). Therefore, an individual study's quality marker score could change depending on which clinical question or outcome it addressed. For example, if an individual study reported a swallowing physiology outcome and a functional swallowing outcome but only reported the statistical significance of the physiology outcome, then the study would earn that appraisal point for Clinical Question 1 (What is the effect of OMI on feeding and swallowing physiology in preterm infants?) but not for Clinical Question 2 (What is the effect of OMI on functional oral feeding and swallowing outcomes in preterm infants?). Each critical appraisal was then reviewed by at least one member of the evidence panel who also completed the data extraction for the study. Agreement between the two initial reviewers and panel reviewers was greater than 98%. All discrepancies in ratings among authors were resolved via consensus.

Although a number of methodologies exist, there is currently no straightforward or widely accepted system for incorporating quality appraisal information into systematic reviews (Moja et al., 2005; Wood et al., 2008). While the

composite quality scores can be useful for presenting an overall assessment of a study, weighting study results based on these quality scores is problematic due to a number of statistical and empirical concerns (Balk et al., 2002; Detsky, Naylor, O'Rourke, McGeer, & L'Abbe, 1992; Juni, Altman, & Egger, 2001; Juni, Witschi, Bloch, & Egger, 1999). Instead, the results of the included studies were examined to ascertain whether differences in methodological quality were associated with differences in effect sizes. For each clinical question, the direction and magnitude of the effect sizes were investigated under different methodological conditions to determine the impact of an individual quality marker on overall study results.

TABLE 1. Quality indicators.

Indicator	Quality marker
Study design	• **Controlled trial** • Cohort study • Retrospective case control or single-subject design • Case series • Case study
Blinding	• **Assessors blinded** • Assessors not blinded or not stated
Sampling/allocation	• **Random sample adequately described** • Random sample inadequately described • Convenience sample adequately described • Convenience sample inadequately described or hand-picked sample or not stated
Group/participant comparability	• **Groups/participants comparable at baseline on important factors (between-subjects design) or participant(s) adequately described (within-subjects design)** • Groups/participants not comparable at baseline or comparability not reported or participant(s) not adequately described
Outcomes	• **At least one primary outcome measure is valid and reliable.** • Validity unknown, but appears reasonable; measure is reliable. • Invalid and/or unreliable
Significance	• ***P* value reported or calculable** • *P* value neither reported nor calculable
Precision	• **Effect size and confidence interval reported or calculable** • Effect size or confidence interval, but not both, reported or calculable • Neither effect size nor confidence interval reported or calculable
Intention to treat (controlled trials only)	• **Analyzed by intention to treat** • Not analyzed by intention to treat or not stated

Note. Boldface indicates highest level of quality marker.

Effect Sizes

When not reported in the study, effect sizes and 95% confidence intervals (CI) were calculated for outcome measures whenever possible. For group studies, Cohen's d was calculated from group means and standard deviations or estimated from results of analyses of variance or t tests. The magnitude of effect sizes was reported using Cohen's benchmarks for small, medium, and large as 0.2, 0.5, and 0.8, respectively (Cohen, 1988). However, confidence intervals surrounding these effect sizes should be considered when interpreting these results.

For multiple-baseline single-subject design investigations, weighted effect size estimates were calculated using a formula proposed by Busk and Serlin (1992) and described by Beeson and Robey (2006). Due to insufficient data, effect sizes were not calculable for the one single-subject design study included in this systematic review (Case-Smith, 1988).

Additional Analyses

For each clinical question, studies with reported or calculable effect sizes were included in additional analyses and combined (when appropriate) to determine the mean effect size of OMI for like outcomes. If a clinical question had subcategories of distinct outcomes, these were separated, and a mean effect for each subcategory was determined. For example in Clinical Question 2, weight gain/growth outcomes were analyzed separately from oral feeding outcomes. When a study reported multiple outcome measures for a single domain (e.g., weight gain), only one was selected for analysis. In making this determination, we chose the study outcome that was most comparable to the outcomes from other studies that were included in the analysis. Additionally, we selected end point outcomes (e.g., outcomes measured at hospital discharge or study conclusion) over interim outcomes. To maintain study independence and avoid duplication of subjects, for each outcome only one summary statistic from an individual study was used to calculate the average treatment effect. Weighted mean effect sizes were calculated based on the inverse variance of the included studies, which weights an individual study proportionate to its sample size.

Prior to combining the studies, the results were statistically analyzed to determine whether there was excessive heterogeneity that would preclude averaging the effect sizes. The degree of heterogeneity was determined by calculating the I^2 statistic (Higgins & Thompson, 2002). The I^2 test describes the proportion of variability across studies that can be attributed to heterogeneity rather than chance. Values for I^2 range from 0% (no heterogeneity) to 100% (maximum heterogeneity). Suggested classifications for interpreting I^2 values are 25%, 50%, and 75% for low, moderate, and

high heterogeneity, respectively (Higgins & Green, 2008; Higgins & Thompson, 2002). Therefore results with I^2 values greater than 75% were considered to have excessive heterogeneity, and the effect sizes were not averaged.

RESULTS

Twelve studies examined the effects of NNS and/or oral stimulation in preterm infants. Six of these studies examined the effects of these interventions on feeding and swallowing physiology (Question 1), and 10 studies examined functional feeding and swallowing outcomes (Question 2). (This total exceeds 12 because several studies addressed more than one clinical question.) No studies were found that examined the effectiveness of OMI on pulmonary health (Question 3).

Clinical Question 1: What Is the Effect of OMI on Feeding and Swallowing Physiology?

Table 2 details the participants, interventions, and outcomes included in the six studies. Five of the six studies were controlled trials. The final study used a single-subject design. Two studies (Bernbaum et al., 1983; Sehgal et al., 1990) examined the effects of NNS with a pacifier during gavage feedings; one study (Hill, 2005) investigated the use of NNS prior to oral feeding; one study (Fucile et al., 2005) compared the use of a prefeeding program that combined NNS and oral stimulation to a sham stimulation; and two studies (Case-Smith, 1988; Gaebler & Hanzlik, 1996) evaluated the effectiveness of oral stimulation with multimodal sensory input to other body parts (e.g., neck, shoulders, legs, and arms) before oral feedings. Several swallowing physiology outcomes were assessed across these six studies, including sucking pressures, the proportion of nutritive or nonnutritive sucks that were judged to be normal according to the Neonatal Oral-Motor Assessment Scale (NOMAS; Braun & Palmer, 1985), and various measures of efficiency (e.g., rate of milk transfer, number of sucks per sucking burst, total oral intake at 5 min, total length of oral feeding time, and time taken for first eight bottle feeds).

TABLE 2. Feeding and swallowing physiology outcomes (Question 1) summary table.

Citation	*N*	Age	Gender	Medical and/or SLP diagnosis	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Effect size [95% CI]	Quality marker score
Bernbaum et al. (1983)	30	*M* = 10 days	NR	Prematurity with birth weight < 1,500 g	Intervention group—NNS via pacifier during gavage feeding. No infant got a pacifier apart from feeds. Control group—no stimulation	Stimulation was provided during all feedings until infant reached 1,700 g.	Sucking pressures measured by nipple with pressure transducer Number of sucks per burst	$p < .05$ $p < .05$	1.97 [1.05, 2.78] 1.4 [0.58, 2.17]	4/8
Case-Smith (1988)	3	34–35 weeks' gestational age at time of evaluation	2 M, 1 F	High-risk premature infants with documented feeding difficulties	Multimodal sensory input including joint approximation through head and shoulders, head righting in prone and semi-sitting positions, linear vestibular stimulation, perioral stimulation and rhythmic pressure to the tongue, and gentle constant pressure at the base of the tongue during sucking	Duration of baseline and treatment ranged from 3 to 6 weeks. Treatment was administered 5 days/week for 20–30 min when no feeding was involved or for 45 min when feeding was part of the treatment session.	NOMAS Subject 1 Subject 2 Subject 3	 $p < .05$ $p < .05$ *ns*	NR	3/7
Fucile et al. (2005)	32	26–30 weeks' gestational age; *M* = 28.2	13 M, 19 F	Prematurity	Intervention group—prefeeding oral stimulation program and NNS via pacifier Control group—sham stimulation program	Once daily for 10 consecutive days	Rate of milk transfer (mL/min) 1–2 oral feedings/day 6–8 oral feedings/day	 $p = .02$ *ns*	 1.07 [0.31, 1.79] 0.74 [0.00, 1.43]	5/8
Gaebler & Hanzlik (1996)	18	3–33 days; *M* = 13.33	12 M, 6 F	Medically stable premature infants	Intervention group—oral and perioral stimulation plus 5 min stroking protocol focused on legs, arms, neck, and shoulders Control group—5 min stroking protocol only	Stimulation was performed 3 times/day, 5 days/week before feedings. Treatment was discontinued once infants were on nipple feedings only for 24 hr.	NOMAS completed on Day 5 Nonnutritive suck, normal Nonnutritive suck, abnormal Nutritive suck, normal Nutritive suck, abnormal Liquid intake during first 5 min of nutritive sucking (Day 5)	 *ns* *ns* $p = .03$ *ns* *ns*	NR 0.28 [–0.66, 1.19]	5/8

(table continues)

TABLE 2 (*continued*).

Citation	*N*	Age	Gender	Medical and/or SLP diagnosis	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Effect size [95% CI]	Quality marker score
Hill (2005)	156	32–34 weeks' postconception age	81 M, 75 F	Prematurity	OS group—cheek and jaw stability during feeding NNS group—pacifier sucking prior to oral feeding Control group—no intervention	Infants received 21 feedings as part of their intervention across 7 days at scheduled feeding times. OS was provided throughout the feeding, and NNS was allowed for 5 min prior to feeding.	Formula intake at 5 min: postintervention OS vs. NNS OS vs. Control NNS vs. Control Formula intake at 5 min: 1-week follow-up OS vs. NNS OS vs. Control NNS vs. Control Total length of feeding time—postintervention OS vs. NNS OS vs. Control NNS vs. Control Total length of feeding time at 1-week follow-up OS vs. NNS OS vs. Control NNS vs. Control	 $p = .001$ $p = .001$ $p = .01$ *ns* *ns* $p = .001$ $p < .05$ $p = .01$ $p = .01$ $p < .05$ $p = .01$ $p = .01$	NR	3/8
Sehgal et al. (1990)	40	*M* = 3.8 days	NR	Prematurity	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Pacifier was given for 3 min during feedings.	Time taken for first 8 bottle feeds (min/30 ml)	$p < .001$	2.65 [1.75, 3.43]	5/8

Note. SLP = speech-language pathologist; CI = confidence interval; NR = not reported or calculable; NNS = nonnutritive sucking; NOMAS = Neonatal Oral-Motor Assessment Scale (binomial test of statistical significance); *ns* = not statistically significant; OS = oral support.

Six effect sizes from four studies (Bernbaum et al., 1983; Fucile et al., 2005; Gaebler & Hanzlik, 1996; Sehgal et al., 1990) ranged from 0.28 to 2.65 (see Table 2). Of the six effect sizes, three were from studies investigating NNS during gavage feedings, two were from studies examining prefeeding NNS plus stimulation, and one was from a study exploring a prefeeding stimulation program. Excessive heterogeneity precluded combining these results to determine an average effect of OMI on feeding and swallowing physiology outcomes, I^2 = 84.99%, 95% CI [62.72%, 93.96%].

NNS. Bernbaum et al. (1983) reported that NNS had a large positive effect on sucking pressures during feeding, d = 1.97, 95% CI [1.05, 2.78], and on number of sucks per burst, d = 1.4, 95% CI [0.58, 2.17], compared to no stimulation. Sehgal et al. (1990) stated that NNS had a large positive effect, d = 2.65, 95% CI [1.75, 3.43], on the amount of time taken by infants for the first eight bottle feeds. Hill (2005) examined the effects of NNS, but no effect sizes were calculable. Intervention with NNS prior to oral feeding was compared with two other non-OMI conditions: oral support during feeding (cheek and jaw stability during feeding) and a no-treatment control group. Intervention effects were measured immediately after treatment and at 1-week follow-up. Infants in the NNS group and non-OMI oral support group made greater gains than the no-treatment group with less time required to complete the feeding immediately postintervention and at 1-week follow-up. Both intervention groups also demonstrated significantly greater gains than the no-treatment control group immediately after treatment in volume of formula intake at 5 min. However, at the 1-week follow-up, only the infants in the NNS group maintained those gains. Differences between the NNS group and oral support group were also reported: (a) The oral support group required less time than the NNS group to complete feeding both postintervention and at 1-week follow-up, and (b) the oral support group consumed significantly more formula within the first 5 min of feeding compared to the NNS group postintervention. However, at the 1-week follow-up, there was no significant difference in volume consumed in the first 5 min between the group with NNS before the feeding and the group with oral support during feeding.

Oral and perioral stimulation. Gaebler and Hanzlik (1996) reported that prefeeding oral stimulation without NNS had a small effect, d = 0.28, 95% CI [–0.66, 1.19], on liquid intake during the first 5 min of feeding, but the difference was not statistically significant. The influence of this intervention on swallowing physiology as measured by the NOMAS was examined in two studies (Case-Smith, 1988; Gaebler & Hanzlik, 1996), but effect sizes were not reported or calculable for this measure. Gaebler and Hanzlik reported that the oral stimulation group exhibited greater gains than the control group on one of the two nutritive subscales of the NOMAS. However, no significant betweengroup differences were reported on the nonnutritive subscales

of the NOMAS. Case-Smith (1988) also noted mixed results for prefeeding oral stimulation, with two of the three infants demonstrating statistically significant changes on the NOMAS during the oral stimulation phase of treatment.

Combination of NNS and oral stimulation. Prefeeding NNS in combination with oral stimulation was examined by Fucile et al. (2005). NNS had a positive effect on the rate of milk transfer at both time intervals that were established prospectively: (a) one to two oral feedings per day, d = 1.07, 95% CI [0.31, 1.79], and (b) six to eight oral feedings per day, d = 0.74, 95% CI [0, 1.43]. However, the difference at six to eight oral feedings per day was not statistically significant.

Study quality and effect on results. Table 3 shows the methodological quality ratings for each study. Five of the six studies were controlled trials; therefore, all eight quality markers were applicable. The highest rating was five (Fucile et al., 2005; Gaebler & Hanzlik, 1996; Sehgal et al., 1990). Case-Smith (1988) was evaluated as a single-subject design study, so the eighth marker (intention to treat analysis) was not relevant. All six studies reported the statistical significance of their findings and provided an adequate description of subjects or group comparability. Most of the studies (four of the six) had valid and reliable outcome measures and reported or supplied sufficient data to calculate effect sizes. None of these studies reported blinding of assessors to the treatment condition or data analysis by an intention to treat standard. In addition, no study reported random allocation of participants to groups or provided an adequate description of randomization procedures.

TABLE 3. Feeding and swallowing physiology outcomes (Question 1) appraisal table.

Citation	Study design	Blinding	Allocation	Participants	Outcomes	Significance	Precision	Intention to treat
Bernbaum et al. (1983)	**Controlled trial**	Assessors not blinded	Not stated	**Groups comparable at baseline on important factors (between-subjects design)**	Validity unknown, but appears reasonable; reliable	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Case-Smith (1988)	Single-subject design	Assessors not blinded	Convenience sample/ hand-picked sample	**Participant(s) adequately described (within-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not applicable
Fucile et al. (2005)	**Controlled trial**	Not stated	Random sample inadequately described	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Gaebler & Hanzlik (1996)	**Controlled trial**	Assessors not blinded	Random sample inadequately described	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Hill (2005)	**Controlled trial**	Assessors not blinded	Random sample inadequately described	**Groups comparable at baseline on important factors (between-subjects design)**	Validity unknown, but appears reasonable; reliable	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not stated
Sehgal et al. (1990)	**Controlled trial**	Not stated	Not stated	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated

Note. Boldface indicates highest level of quality in each category.

Results from included studies were analyzed to determine whether some of the quality markers (i.e., study design, blinding, allocation, subject comparability, outcomes, and intention to treat) were associated with variations in effect size. Since there was no variation in quality scores for blinding, allocation, subject comparability, or intention to treat, no analyses for these markers were possible. All of the included studies except one were controlled trials. Although the one single-subject design study (Case-Smith, 1988) did not report effect size data, the results indicated generally positive effects of OMI on feeding and swallowing physiology outcomes comparable to the controlled trial studies. Two studies used outcome measures with unknown validity. One investigation (Hill, 2005) did not report effect size information but reported positive effects of NNS compared with a no-treatment control group similar to the other studies. Although the other study (Bernbaum et al., 1983) reported large effects of NNS, these were smaller relative to those calculated from the study examining NNS (Sehgal et al., 1990) using validated outcome measures.

Clinical Question 2: What Is the Effect of OMI on Functional Oral Feeding and Swallowing Outcomes?

Table 4 provides a description of the participants, interventions, and outcomes included in the 10 studies (four that had also addressed Question 1). Seven of the studies investigated the effectiveness of OMI on oral feeding, and eight focused on weight gain or growth. Amount, duration, and intensity of treatment varied greatly among the studies. Duration of treatment ranged from 3 days to more than 40 days, and frequency of intervention ranged from once a day to 12 times per day.

TABLE 4. Functional feeding and swallowing outcomes (Question 2) summary table.

Citation	*N*	Age	Gender	Medical and/or SLP diagnosis	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Effect Size [95% CI]	Quality marker score
Bernbaum et al. (1983)	30	*M* = 10 days	NR	Prematurity with birth weight < 1,500 g	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Stimulation was provided during all feedings until infant reached 1,700 g.	Weight gain—differences in weight gain between the two groups became significant during second week of study.	Values ranged from $p < .01$ to $p < .05$	NR	5/8
							Time from initial to total oral feeding (days)	$p < .001$	1.46 [0.62, 2.22]	
							Time to reach 2 kg weight from entrance (days)	$p < .02$	0.92 [0.14, 1.64]	
De Curtis et al. (1986)	10	*M* = 28 days	NR	Prematurity	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Pacifier was provided during all feedings over 3 days.	Volume intake	*ns*	0.06 [–0.82, 0.94]	4/8
Ernst et al. (1989)	18	8–23 days; *M* = 14.6	8 M, 10 F	Prematurity and very low birthweight	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Pacifier was given for 30 min with each feeding, 12 times/day until the infant reached 1,500 g and then the pacifier was given 8 times/day. Infants were treated for 14 days.	Absolute change in weight	*ns*	0.14 [–0.79, 1.06]	5/8
Field et al. (1982)	57	*M* = 32 weeks' gestational age	27 M, 30 F	Prematurity	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Pacifier was provided during all tube feedings.	Days of tube feeding	$p = .01$	0.15 [–0.37, 0.67]	6/8
							Number of tube feedings	$p = .05$	0.15 [–0.37, 0.67]	
							Average daily weight gain (g)	$p = .05$	0.54 [0.00, 1.06]	
Fucile et al. (2002)	32	26–30 weeks' gestational age; *M* = 28.2	13 M, 19 F	Prematurity	Intervention group—prefeeding oral stimulation program and NNS via pacifier Control group—sham stimulation program	Once daily for 15 min over 10 consecutive days	Time to achieve 1 oral feeding/day	$p = .01$	1.05 [0.29, 1.76]	7/8
							Time to achieve 4 oral feedings/day	$p = .019$	0.98 [0.22, 1.69]	
							Time to achieve 8 oral feedings/day	$p = .005$	1.23 [0.44, 1.95]	

(table continues)

TABLE 4 (*continued*).

Citation	*N*	Age	Gender	Medical and/or SLP diagnosis	Intervention	Treatment schedule and amount	Outcome measure(s)	Significance	Effect Size [95% CI]	Quality marker score
Fucile et al. (2005)	32	26–30 weeks' gestational age; *M* = 28.2	13 M, 19 F	Prematurity	Intervention group—prefeeding oral stimulation program and NNS via pacifier Control group—sham stimulation program	Once daily for 10 consecutive days	Weight	*ns*	–0.28 [–0.97, 0.42]	5/8
							Number of days to reach full oral feeding	$p = .005$	1.23 [0.44, 1.95]	
							Overall intake (volume taken/volume prescribed, %) at 1–2 oral feedings/day	$p = .01$	1.00 [0.24, 1.71]	
							Overall intake (volume taken/volume prescribed, %) at 6–8 oral feedings/day	*ns*	0.70 [–0.03, 1.39]	
Gaebler & Hanzlik (1996)	18	3–33 days, *M* = 13.33	12 M, 6 F	Medically stable premature infants	Intervention group—oral and perioral stimulation plus 5 min stroking protocol focused on legs, arms, neck and shoulders Control group—5 min stroking protocol only	Stimulation was performed 3 times/day, 5 days/week before feedings. Treatment was discontinued once infants were on nipple feedings only for 24 hr.	Weight gain	*ns*	0.70 [–0.28, 1.62]	5/8
Measel & Anderson (1979)	59	28–34 weeks' gestational age; *M* = 33	22 M, 37 F	Prematurity	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Pacifier was provided during all tube feedings. Treatment duration ranged from 5 to 40 days.	Daily weight gain	*ns*	NR	4/8
Rocha et al. (2007)	98	*M* =11.1 days	NR	Prematurity and very low birthweight	Intervention group—sensory-motor-oral stimulation and NNS Control group—sham stimulation program	Stimulation was performed for 15 min until infant began exclusively oral diet (minimum 10 days).	Weight at discharge	$p = .05$ (favoring control)	–0.34 [–0.73, 0.07]	7/8
							Weight gain (first week)	*ns*	0.28 [–0.12, 0.68]	
							Weight gain (second week)	$p < .05$	0.23 [–0.17, 0.63]	
							Days of life at full oral feeding	$p = .01$	0.51 [0.10, 0.91]	
Sehgal et al. (1990)	40	*M* = 3.8 days	NR	Prematurity	Intervention group—NNS via pacifier during gavage feedings Control group—no pacifier	Pacifier was given for 3 min during feedings.	Time for transition from all tube to all bottle feeds	$p < .001$	1.76 [1.00, 2.45]	5/8
							Weight gain	*ns*	NR	
							Length	*ns*	NR	
							Head circumference	*ns*	NR	

Oral Feeding

Across the seven studies examining the effect of OMI on oral feeding, 11 effect sizes were calculable. They ranged from 0.06 to 1.76. Four of the seven studies (Bernbaum et al., 1983; De Curtis, McIntosh, Ventura, & Brooke, 1986; Field et al., 1982; Sehgal et al., 1990) evaluated the use of NNS during gavage feedings, and three studies evaluated nonnutritive oral stimulation programs and NNS before feedings (Fucile et al., 2002, 2005; Rocha, Moreira, Pimenta, Ramos, & Lucena, 2007). Similar to the results in Question 1, the effect sizes for oral feeding presented with considerable heterogeneity, $I^2 = 77.95\%$, 95% CI [46.98%, 90.83%]. Therefore, weighted mean effect sizes were not calculated.

NNS. Of the four studies examining NNS during gavage feedings, two studies (Bernbaum et al., 1983; Sehgal et al., 1990) reported positive treatment effects, while the other two studies (De Curtis et al., 1986; Field et al., 1982) reported no effects. Bernbaum and colleagues (1983) found NNS to have a large positive effect on the number of days from initial oral feeding to total oral feeding, d = 1.46, 95% CI [0.62, 2.22]. Sehgal and colleagues (1990) reported this same effect, d = 1.76, 95% CI [1.00, 2.45], on transition time from total tube to total bottle feeding. Conversely, De Curtis and colleagues indicated that NNS had no effect on total volume intake, d = 0.05, 95% CI [–0.82, 0.94]. Although Field and colleagues (1982) reported p values showing statistically significant differences, the effect sizes calculated for days of tube feeding, d = 0.15, 95% CI [–0.37, 0.67], and the total number of tube feedings, d = 0.15, 95% CI [–0.37, 0.67], were negligible.

Combination of NNS and oral stimulation. All three studies examining a prefeeding stimulation program consisting of oral and perioral stimulation and NNS reported positive changes in oral feeding skills compared with a sham stimulation program. Fucile and colleagues (2002) reported a large effect on the time to achieve one oral feeding per day, d = 1.05, 95% CI [0.29, 1.76], four oral feedings per day, d = 0.98, 95% CI [0.22, 1.69], and eight oral feedings per day, d = 1.23, 95% CI [0.44, 1.95]. Fucile and colleagues (2005) described the positive effects of this program on the number of days to reach full oral feeding, d = 1.23, 95% CI [0.44, 1.95], overall intake at one to two daily oral feedings, d = 1.0, 95% CI [0.24, 1.71], and overall intake at six to eight daily oral feedings, d = 0.70, 95% CI [–0.03, 1.39]. In Rocha et al. (2007), the group receiving the NNS plus stimulation program achieved full oral feeding, d = 0.51, 95% CI [0.10, 0.91], sooner than the control group.

Weight Gain and Growth

Eight studies examined the effects of OMI on weight gain and growth in preterm infants. Five studies (Bernbaum

et al., 1983; Ernst et al., 1989; Field et al., 1982; Measel & Anderson, 1979; Sehgal et al., 1990) examined the effects of NNS. One study (Gaebler & Hanzlik, 1996) evaluated the use of oral and perioral stimulation alone (i.e., without the addition of NNS). Two studies (Fucile et al., 2005; Rocha et al., 2007) compared the effectiveness of oral and perioral stimulation paired with NNS to a sham stimulation program. Six studies (Bernbaum et al., 1983; Ernst et al., 1989; Field et al., 1982; Fucile et al., 2005; Gaebler & Hanzlik, 1996; Rocha et al., 2007) provided sufficient information to calculate effect sizes. The effect sizes calculated from these six studies ranged from –0.34 to 0.92, with moderate heterogeneity noted, $I^2 = 57.9\%$, 95% CI [0%, 84.35%].The mean effect estimate did not show a significant difference between OMI versus no treatment (or sham stimulation) on measures of weight or weight gain, d = 0.01, 95% CI [–0.25, 0.28].

NNS. The studies addressing NNS reported mixed results. Bernbaum and colleagues (1983) reported that NNS had a large positive effect, d = 0.92, 95% CI [0.14, 1.64], on the number of days to achieve 2-kg weight. The NNS group also showed significant improvements in weight gain compared with the control group; however, an effect size was not reported or calculable. Field and colleagues (1982) reported a positive effect, d = 0.54, 95% CI [0, 1.06], of NNS via pacifier during gavage feedings over no NNS in average daily weight gain. However, Ernst and colleagues (1989) reported a negligible effect, d = 0.14, 95% CI [–0.79, 1.06], for the use of NNS on absolute change in weight. Two other studies (Measel & Anderson, 1979; Sehgal et al., 1990) provided further evidence of effects of NNS on growth or weight gain; however, effect sizes were not calculable. Neither study reported significant differences in weight gain between the NNS group and control group. In addition, one study (Sehgal et al., 1990) reported no significant differences in length or head circumference between the NNS and control group.

Oral and perioral stimulation. The effect of oral and perioral stimulation without NNS was reported by Gaebler and Hanzlik (1996). They noted positive changes, d = 0.70, 95% CI [–0.28, 1.62], on overall weight gain, but these differences were not statistically significant (p = .07).

Combination of NNS and oral stimulation. The two studies (Fucile et al., 2005; Rocha et al., 2007) investigating the effects of oral stimulation plus NNS on functional swallowing also reported mixed results. Rocha and colleagues (2007) reported that their intervention had a small effect on weight gain during the first week, d = 0.28, 95% CI [–0.12, 0.68], and second week of the study, d = 0.23, 95% CI [–0.17, 0.63]. However, it was shown to have a small negative effect on weight, d = –0.34, 95% CI [–0.73, 0.07], at discharge from the study. Fucile and colleagues (2005) also reported a negative effect of their program on weight gain, d = –0.28, 95% CI [–0.97, 0.42].

Study Quality and Effect on Results

Table 5 reports the methodological quality ratings for each study. The 10 studies were all controlled trials. All eight quality markers applied. Quality scores ranged from four to seven out of eight possible markers. All 10 studies used validated outcome measures and provided information regarding statistical significance of the findings. All but one (De Curtis et al., 1986) provided an adequate description of comparability between groups. In addition, nine of 10 studies provided effect size data. The one exception was Measel and Anderson (1979). A number of methodological weaknesses were apparent across all studies. These weaknesses included lack of assessor blinding, randomization, and intention to treat analysis. Only two studies (Fucile et al., 2002; Rocha et al., 2007) reported blinded assessment. Three studies (Field et al., 1982; Fucile et al., 2002; Rocha et al., 2007) reported random allocation of subjects and provided an adequate description of randomization procedures. No studies reported using an intention to treat standard for data analysis.

There was no variability among the included studies on the quality indicators of study design, outcomes, or intention to treat, so no examination of these markers was feasible. The one study that did not indicate group comparability at baseline (De Curtis et al., 1986) reported smaller effects for volume intake than those with comparable groups. Of the studies that incorporated assessor blinding, one (Fucile et al., 2002) yielded effect sizes of comparable magnitude for oral feeding, and the other (Rocha et al., 2007) also showed positive effects albeit somewhat reduced. Rocha et al. (2007) reported mixed results for weight, similar to the mixed findings for weight gain and growth across the included studies. These same two studies (Fucile et al., 2002; Rocha et al., 2007) also reported random allocation of participants with results similar to other included studies as noted above. An additional study (Field et al., 1982) also randomly allocated participants and indicated smaller effects on oral feeding than almost all of the other studies. Interestingly these effects were also much smaller than those found in the other two studies that also randomly allocated participants.

TABLE 5. Functional feeding and swallowing outcomes (Question 2) appraisal table.

Citation	Study design	Blinding	Allocation	Participants	Outcomes	Significance	Precision	Intention to treat
Bernbaum et al. (1983)	**Controlled trial**	Assessors not blinded	Not stated	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
De Curtis et al. (1986)	**Controlled trial**	Not stated	Random sample inadequately described	Comparability not reported	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Ernst et al. (1989)	**Controlled trial**	Assessors not blinded	Random sample inadequately described	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Field et al. (1982)	**Controlled trial**	Not stated	**Random sample adequately described**	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Fucile et al. (2002)	**Controlled trial**	**Assessors blinded**	**Random sample adequately described**	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Fucile et al. (2005)	**Controlled trial**	Not stated	Random sample inadequately described	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Gaebler & Hanzlik (1996)	**Controlled trial**	Assessors not blinded	Random sample inadequately described	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Measel & Anderson (1979)	**Controlled trial**	Assessors not blinded	Convenience sample/ hand-picked sample	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	Neither effect size nor confidence interval reported or calculable	Not stated
Rocha et al. (2007)	**Controlled trial**	**Assessors blinded**	**Random sample adequately described**	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated
Sehgal et al. (1990)	**Controlled trial**	Not stated	Not stated	**Groups comparable at baseline on important factors (between-subjects design)**	**At least one primary outcome measure is valid and reliable.**	***P* value reported or calculable**	**Effect size and confidence interval reported or calculable**	Not stated

Note. Boldface indicates highest level of quality in each category.

DISCUSSION

The aim of this EBSR was to determine the effects of OMI on oral feeding and swallowing outcomes (physiological and functional) and pulmonary health in preterm infants. A systematic search of the scientific literature published before 2008 yielded 12 studies that addressed two of the three clinical questions. No studies were found to address the effect of OMI on pulmonary health. Interestingly, no studies examined pharyngeal swallowing function via instrumental swallow analyses (i.e., videofluoroscopic swallow study, flexible endoscopic evaluation of swallowing, or ultrasonography). Although the panel sought to identify any OMIs used to facilitate oral feeding and swallowing in preterm infants, the primary focus of the included studies was limited to three interventions:NNS, oral stimulation, or a combination of NNS and oral stimulation. Analysis of the findings with respect to specific treatment methods makes it possible to synthesize the outcomes and note trends that may help clinicians in their decision making for intervention possibilities with preterm infants and to provide directions for future research.

NNS

The majority (seven of 12) of the included studies examined the effects of NNS provided either during (six of seven) or immediately prior to gavage feeding (one of seven). These seven studies were controlled trials that compared NNS to a control group with no pacifier, and in one instance NNS was also compared to a group that received oral support during feeding (Hill, 2005). The 11 effect sizes for NNS ranged from 0.05 to 2.65. Analysis of the effect sizes revealed a subset of six studies in which the 95% CI did not include a d value of zero and that were therefore considered noteworthy. All of the NNS effect sizes calculated for swallowing physiology outcomes were a part of this subset and included such outcomes as sucking pressures, number of sucks per burst, and time taken for first eight bottle feeds (as defined by minutes taken to ingest 30 ml).

Certain functional swallowing outcomes were also part of this subset and included time to reach 2-kg weight from entrance into study, time from initial oral feeding to total oral feeding, and time for transition from total gavage feeding to total nipple feeding. NNS demonstrated less effect on other functional oral feeding and swallowing outcomes such as volume intake, absolute change in weight, days of tube feeding, number of tube feedings, and average daily weight gain. Several of the included studies reported outcomes for NNS, but effect sizes were not calculable. Hill (2005) reported an advantage of NNS over a control group on formula intake at 5 min and total length of feeding time. NNS was shown to have a significant effect on weight gain (Bernbaum et al., 1983), but in two other studies there were no significant differences in weight gain (Measel&Anderson, 1979; Sehgal et al., 1990). NNS did not produce any significant change in length or head circumference (Sehgal et al., 1990). Overall, NNS was consistently associated with significant positive changes on measures of swallowing physiology and reducing the number of days to reach total oral feeding in preterm infants. NNS produced mixed results for other oral feeding outcomes (e.g., volume intake and number of tube feedings prior to attainment of total oral feeding) and measures of weight gain and growth.

Clinicians are encouraged to review these studies independently following similar processes as used for this critical review. They are also encouraged to review an earlier Cochrane Database Systematic Review of 21 studies that focused on NNS only (Pinelli & Symington, 2005). Similar to this more current EBSR, the Cochrane review reported that NNS intervention showed positive outcomes in transition from tube to bottle feeding and better bottle feeding performance, but it did not reveal a consistent benefit of NNS on weight gain. Additionally, the Cochrane review found that infants receiving NNS had a significant decrease in length of stay. The findings from these two reviews are promising for the clinical use of NNS with preterm infants.

Oral and Perioral Stimulation

Two of the 12 included treatment studies investigated the use of prefeeding stimulation. Gaebler and Hanzlik (1996) reported on a controlled trial that compared oral and perioral stimulation to a stroking protocol involving the head neck, shoulders, arms, and legs. Case-Smith (1988) used a single-subject design that compared stimulation to a no-treatment baseline phase. Two effect sizes were calculable. Both the effect size for the swallowing physiology measure of liquid intake during the first 5 min of nutritive sucking, d = 0.28, 95% CI [–0.66, 1.19], and the effect size for the functional swallowing outcome of weight gain, d = 0.70, 95% CI [–0.28, 1.62], had wide CIs that included a d value of zero. Additionally, equivocal results were noted across both studies on swallowing physiology as measured by the NOMAS. Given the limited number of studies examining the use of oral and perioral stimulation on the swallowing skills of preterm infants and the mixed findings of those studies, there is insufficient research evidence to support or refute the use of this specific intervention in clinical practice.

Combination of NNS and Oral Stimulation

Three controlled trials (Fucile et al., 2002, 2005; Rocha et al., 2007) examined the use of NNS in combination with oral stimulation compared with a sham stimulation program. The 11 effect sizes ranged from –0.34 to 1.23. A subset of six of the included effect sizes had 95% CIs without a d value of zero. This subset included one measure of swallowing physiology (i.e., rate of breast milk/formula transfer at one to two oral feedings per day) and five functional swallowing outcomes (i.e., time to achieve one oral feeding per day, time to achieve four oral feedings per day, time to achieve eight oral feedings per day, number of days to reach full oral feeding, and overall intake at one to two oral feedings per day). NNS and oral stimulation had less effect on other outcomes, such as rate of breast milk/formula transfer at six to eight oral feedings per day and overall intake at six to eight oral feedings per day. Moreover, this combination had a minimal or negative effect on measures of total weight and weight gain.

Similar to NNS alone, NNS combined with stimulation showed large positive effects on reducing the time to transition to total oral feeding. Additionally, this combination was associated with large positive effects on other outcomes such as rate of breast milk/formula transfer and overall intake. However, these effects were limited only to the early stages of oral feeding (i.e., one to two oral feedings per day), and similar results were not noted at the later stages of oral feeding (i.e., six to eight oral feedings per day). The difference in outcomes between these two stages could perhaps be due to ceiling effects of the outcome measure or maturation effects of the study participants. Although studies

examining NNS alone showed mixed findings on weight gain and growth, the combination of NNS and stimulation showed essentially no effect or a negative effect on measures of weight or weight gain. Given that this treatment combination showed similar effects to NNS alone on overall oral feeding performance and that the studies investigating stimulation showed mixed findings, it is unclear what added value stimulation may have in treatment targeting the feeding and swallowing outcomes examined in this review.

Methodological Quality Indicators

An analysis of the results of this EBSR and their implications for clinical decision making must be considered in combination with information about the methodological quality of the included studies. Several methodological limitations were apparent across the 12 included studies. For example, none of the controlled trials reported data analysis by an intention to treat standard, and only two studies (Fucile et al., 2002; Rocha et al., 2007) reported assessor blinding. Both of these factors are important to minimize confounders that threaten the validity of a study or its findings. These methodological shortcomings may limit the applicability and utility of even the strongest findings.

Future Research

An important purpose of EBSRs is to identify gaps in current research and highlight areas for future research within a specific clinical topic. Based on the results of this EBSR, several areas of need are evident. First, no studies were identified for effects of OMI on pulmonary status in infants. Given the integral relationship between oral feeding and pulmonary status, randomized controlled trials are needed to examine the effects of OMI on pulmonary function. Moreover, future investigations of OMI should determine whether there are any additional outcomes (not included in this EBSR) that may benefit from these interventions. Next, the study designs of the included articles sought to determine whether OMI was an efficacious treatment compared to a no-treatment control group. Future studies are needed to determine the relative efficacy of varied approaches to OMI as well. These studies should not only evaluate one form of OMI compared with another (e.g., NNS in isolation compared to NNS plus stimulation) but also compare OMI to other interventions such as managing flow rate, providing pacing during oral feedings, and thickening of feedings. An additional topic not addressed by the current review is the effect of timing (i.e., prefeeding NNS vs. NNS provided during gavage feeding), frequency, intensity and duration of OMI treatment on oral feeding and swallowing outcomes. Further research is needed to address these clinical questions.

Limitations of the Current Review

There are several limitations to be considered when interpreting the results of this EBSR. First, only articles published in English were included. Although the impact of this language bias on the overall results of EBSRs is unclear (Grégoire, Derderian, & Le Lorier, 1995; Juni, Holstein, Sterne, Bartlett, & Egger, 2002), it is possible that some relevant studies were not identified. The results of this EBSR should be interpreted in light of the possible publication bias introduced by the decision to include only published, peer-reviewed studies. Therefore, positive effects may be overrepresented in this review. Other limitations include difficulties interpreting the results due to the heterogeneity of the findings and the variability in the participants, interventions, and frequency and intensity of treatment provided. Although only studies examining preterm infants were included in this EBSR, infants varied in degree of prematurity and medical status across studies. Interventions also differed across studies. For example, treatments defined as stimulation involved a range of interventions including oral stimulation, perioral stimulation, stroking protocols, or some combination of these three approaches. In addition, treatment schedules varied widely. Duration of treatment ranged from 10 days to 6 weeks across studies, and frequency of intervention ranged from one time per day tomultiple times per day, depending on the infant's feeding schedule. Additionally, it should be noted that progress in some of the outcomes targeted in this review may be influenced by external variables independent of the intervention provided. For example, the transition to oral feeding is dependent not only on an infant's oral feeding abilities but also on a medical order to advance oral feeding skills. Similarly, members of the NICU team may provide nutritional supplements to the infant to maintain adequate weight gain. Given that many of these factors are not typically described in articles, it is difficult to ascertain their impact on the results of this review. Finally, this systematic review should be considered current as of September 2007. Any relevant studies published after this date were not included. Because new studies continue to emerge, it is critical that clinicians reexamine the available evidence on this topic frequently.

Conclusion

This systematic review of OMI for facilitation of oral feeding and swallowing in preterm infants revealed mixed findings overall, but a few intervention-specific patterns did emerge. NNS has been the most extensively studied, with strong positive findings for improvement in oral feeding and swallowing physiology variables and for reducing the time to transition to total oral feeding by some investigators. Prefeeding stimulation has been explored in fewer studies, with equivocal results across the outcomes targeted in this review.

Although less thoroughly investigated than NNS in isolation, the combined effect of NNS plus oral stimulation produced a similar pattern of findings to NNS alone. None of the OMIs provided consistent positive results on weight gain and growth in this population.

Clinicians and researchers can use some of these findings to guide and support their decisions in the management of oral feeding and swallowing facilitation with preterm infants. However, professionals are reminded that only a small number of research reports met criteria for this critical review, a limited number of effect sizes were reported, and findings showed considerable variability. Moreover, it is not clear what effect these interventions may have on other outcomes relative to preterm infants that were not included in this review. In addition to evidence related to specific interventions, it is important for clinicians and researchers to be aware of the multiple intrinsic and extrinsic factors that play a role in determining preterm infants' readiness for nipple feeding (Howe, Sheu, Hinojosa, Lin, & Holzman, 2007). Howe and colleagues (2007) stated that these factors include, but are not limited to, postmenstrual age, weight at each observed feed, oral motor skills, feeding experience, and feeding techniques, in addition to age (often 34 weeks' gestational age) and weight (1,500 g) criteria as indicators for oral feeding. Those factors have to be taken into account when clinicians consider options with preterm infants to facilitate oral skill development for sucking, swallowing, and breathing coordination.

Clinicians and researchers must be critical reviewers of studies that describe intervention procedures, findings, and outcomes, as they seek to elevate their practice on the basis of the best possible evidence available to them. Evidencebased practice is an important foundation for management decision making with these high-risk infants. However, there are many instances in which no evidence is available for specific intervention procedures. In those instances, clinicians should use their knowledge and clinical judgment in areas of anatomy, embryology, physiology, neurodevelopment, maturation of oral feeding skills in preterm infants (e.g., Amaizu et al., 2008; Delaney & Arvedson, 2008; Lau, 2007), relationship of respiratory control and oral feeding (J. J. Miller & Kiatchoosakun, 2004; Thoyre & Carlson, 2003), and physical indicators related to preterm infants' bottle feeding performance (Howe et al., 2007) to assist with clinical decision making.

EBSRs are important tools for SLPs seeking to incorporate current best evidence into their practice. Based on the guiding principles of evidence-based practice, clinicians should also consider their own knowledge and expertise along with the values and preferences of their patients when determining the best course(s) of treatment (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). The results of this EBSR can assist SLPs in collaboration with other professionals

in the NICU to determine the most effective developmental care options for preterm infants while focusing on facilitation of sucking, swallowing, and breathing coordination needed for successful oral feeding.

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