



A Comprehensive Review of Evidence and Current Recommendations Related to Pacifier Usage^{1,2,3}

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Pacifier usage is controversial, and published recommendations are contradictory. The purposes of this literature review were to provide a comprehensive summary of risks and benefits of pacifier usage based upon the highest levels of evidence available and to provide a reference for nurses to utilize while assisting mothers in making an informed decision. Results indicated that benefits include reported ability to soothe/comfort, decreased risk of sudden infant death syndrome, and a probable synergistic role in adjunctive pain relief. Greatest risks are an increased incidence of acute otitis media, possible negative impact on breast-feeding, and dental malocclusion particularly if usage is greater than 2–3 years. The frequency, intensity, and duration of pacifier use are related to type and extent of all risks. © 2012 Elsevier Inc. All rights reserved.

DESPITE DECADES OF controversy worldwide, many parents continue to offer pacifiers to their infants and young children. According to the 1995–1997 International Child Care Practices Study, there is wide variation across countries in pacifier usage at approximately 3 months of age, ranging from 12.5% in two cities in Japan to 71% in Odessa, Ukraine (Nelson, Yu, Williams & International Study Group Members, 2005). In a sample of American, Caucasian, college-educated mothers, Warren, Levy, Nowak, and Shenghui (2000) found 78% pacifier usage at 6 weeks, with significant dips to 42% at 9 months, 25% at 24 months, and 5% at 48 months. These data are congruent with another report of pacifier usage in the United States of 40% at 1 year and 1% at 5 years (Bishara, Warren, Broffitt, & Levy, 2006).

The body of research literature addressing the risks and benefits of pacifier usage is large and multidimensional. A number of recent literature reviews have attempted to summarize and critique this body of work. Each paper, however, has focused on only a limited number of risks or benefits, arrived at different conclusions, and made different,

sometimes contradictory recommendations (Adair, 2003; Callaghan et al., 2005; Castilho & Rocha, 2009; Sexton & Natale, 2009). These have contributed to the already perplexing array of published pacifier-related research available to pediatric nurses.

The primary aim of this article was to provide a comprehensive summary of current evidence and recommendations related to pacifier usage in full-term infants focusing on the highest quality sources available. A secondary aim is to provide an up-to-date and evidence-based reference for nurses to utilize as they assist parents in making an informed decision related to whether to introduce a pacifier and, if so, how to select one, care for it, and use it safely.

Literature Search Strategy

A search of the CINAHL and MEDLINE electronic databases was conducted for references available in English during the period 1990 to present using each of the search terms *pacifier*, *dummy*, and *soother*. According to the basic tenants of evidence-based practice, the highest levels of available evidence upon which to base practice are either randomized controlled trials (RCTs) or meta-analyses of

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RCTs (EBMWG, 1992; Sackett, Rosenberg, Gray, Hayes, & Richardson, 1996). To provide a broad scope, keep the overall number of references manageable and summarize the literature based upon the highest level of evidence available; references initially retrieved were limited to RCTs, meta-analyses, and critical reviews of the literature pertaining to pacifier usage in full-term infants or older children. Reference lists of relevant sources were also reviewed, and other potentially relevant studies were identified.

As references were categorized related to the risks and benefits of pacifier usage, additional reports of individual studies were gathered when insufficient meta-analyses, integrated literature reviews, or RCTs were available or to document the suspected etiology of various risks or benefits. Web sites of key professional organizations, product manufacturers, and consumer protection agencies were also accessed, published policies and guidelines were retrieved, and a number of well-known textbooks were consulted for the greatest possible summary of current knowledge.

Potential Benefits of Pacifier Usage

Developmental

Sucking is a basic newborn reflex, and most infants suck many times a day when either breast- and/or bottle-feeding. However, whether nonnutritive sucking on a pacifier or finger should be allowed or encouraged, and if so in what manner and for how long, continues to be controversial. The act of sucking, whether nutritive or nonnutritive, is widely acknowledged by developmental experts to be a healthy, reflexive means for an infant to self-comfort, calm, reorganize, and gain control when upset or stressed (Brazelton & Sparrow, 2001, 2006). Although little research has been conducted documenting why mothers chose to use a pacifier, in one small study, Pansy et al. (2008) found that perceived need to soothe their infant was the primary reason that mothers who had not originally intended to use a pacifier ultimately introduced one. Similarly, both mothers and health care providers in Vogel and Mitchell's (1997) study, although generally against pacifier use, thought it was appropriate for a very unsettled infant.

Following infancy, observational studies suggest that a "transitional object" such as a pacifier may help decrease anxiety and soothe a toddler through a key developmental challenge such as separation from a parent (Triebenbacher & Tegano, 1993). Some parents may express a preference for thumb sucking over pacifier use, and there is some evidence that thumb (or digit) sucking may be more effective in helping children cope with stress than other transitional objects such as a pacifier because a thumb is more readily available (Lookabaugh & Fu, 1992). Prolonged, intense digit sucking, however, can have profound negative consequences

equal to or greater than those generally associated with pacifier usage and thus should not be considered a benign alternative (Christensen, Fields, & Adair, 2005; VanNorman, 2001). It follows that the potential emotional/psychological benefits of nonnutritive sucking and the current level of stress in a child's life are important considerations when assessing the risk-versus-benefit ratio of either pacifier usage or digit sucking.

Sudden Infant Death Syndrome Prevention

Among all of the potential benefits of pacifier usage for full-term infants, the one which is most strongly supported by evidence is a reduction in the incidence of sudden infant death syndrome (SIDS). Two recent meta-analyses have been conducted that reviewed many of the same case-control studies. Hauck, Omojokun, and Siadaty (2005) found that in studies where a variety of factors were controlled, "usual" pacifier use was associated with an approximately 30% reduction in the risk of SIDS. An approximately 50% reduction in risk was associated with "pacifier use at last sleep" among studies using univariate analysis, and a 60% reduction was found among those using multivariate analysis. Mitchell, Blair, and L'Hoir (2006) found an approximately 17% reduction in risk associated with "routine" pacifier use and an approximately 50% risk reduction associated with use at last sleep. Both groups of scholars concluded that current research strongly supports a significant reduction in risk of SIDS with pacifier use, particularly if used when placing an infant to sleep (Hauck et al., 2005; Mitchell et al., 2006).

Among the mechanisms theorized to explain the association between pacifier usage and decreased incidence of SIDS that have some evidential support include an increased arousal responsiveness in frequent pacifier users (Franco et al., 2000) and the forward positioning of the tongue required while using a pacifier that decreases the risk of oropharyngeal obstruction (Cozzi, Albani, & Cardi, 1979). As summarized by Hauck et al. (2005), other frequently cited theories are that pacifier use enhances an infant's ability to breath through the mouth if nasal obstruction occurs and the fact that pacifier usage encourages prone sleeping.

Despite the uncertain mechanism to reduce the risk of SIDS, the American Academy of Pediatrics (AAP) Taskforce on SIDS (2005/2009) recommends offering a pacifier when putting an infant to sleep during the first year of life. They suggest delaying usage until after 1 month of age in breast-feeding infants and avoiding force or reinserting during sleep. They further advise that pacifiers should never be coated with any type of sweetener and that they should be cleaned and replaced regularly.

Despite these recommendations, a recent study sampling a large number of African American, low-income women found that 73% of mothers had received no advice from a physician related to pacifier use during sleep (Smith et al., 2010). Similarly, in a large cross-sectional survey of U.S.

physicians, Moon, Kington, Oden, Iglesias, and Hauck (2007) found that 63% of physicians made no specific recommendations about pacifiers, 11% recommended pacifiers never be used, and 26% recommended limited use. Thus, although research findings support an association between pacifier usage, particularly at time of sleep, and a significant decrease in the incidence of SIDS, it does not appear that most physicians are making recommendations related to pacifier usage based on this evidence.

Adjunctive Pain Relief

The second most commonly cited potential benefit of pacifier usage in full-term infants is related to adjunctive pain relief. Stevens, Yamada, and Ohlsson (2010) conducted a review including 44 RCTs related to the use of sucrose to relieve pain. The authors concluded that sucrose is a safe and effective means of providing pain relief to neonates undergoing painful procedures with minimal to no side effects. A pacifier used along with sucrose (usually dipped in it) appeared to have a synergistic effect. The authors suggest that nonnutritive sucking should be considered in combination with sucrose to significantly reduce or eliminate procedural pain in neonates.

In another article, Shah, Aliwolas, and Shah (2009) conducted a systematic review and meta-analysis of 11 randomized and quasi-randomized trials testing the use of breast-feeding or breast milk to alleviate procedural pain. These authors found that breast-feeding was equally effective as higher concentrations of glucose/sucrose at decreasing pain-related outcomes and better than positioning, swaddling, or pacifier use alone. These findings suggest that either sucrose or breast milk, with or without nonnutritive sucking, appears to be safe and somewhat effective in relieving procedural pain in infants, and thus, one or the other should be considered when feasible.

Potential Risks of Pacifier Usage

Oral Health and Dentition

One of the primary concerns mothers express related to pacifier usage is the potential for malformation of the teeth or jaw (Pansy et al., 2008). Despite this fear, a recent meta-analysis concluded that pacifier use does not significantly impact dentition if use is stopped by age 2 to 3 years (Poyak, 2006). Use beyond age 3 years, and particularly beyond age 5 years, was found to contribute to a higher incidence of anterior open bite, posterior crossbite, and narrow intercuspid width. This conclusion has been confirmed by a more recent study that found that the odds of posterior crossbite at age 4 or 5 years were almost 22 times higher among pacifier users of greater than 36 months versus nonpacifier users, whereas the odds were only 3.6 times higher if pacifier usage

was limited to 18–35 months (Melink, Vagner, Hocevar-Boltezar, & Ovsenik, 2010).

Dental experts note that if a pacifier habit is discontinued when the child is still in the period of mixed dentition, many adverse changes will begin to reverse naturally (Christensen et al., 2005). The evidence also suggests that a minimum of 4–6 hours of force per day is necessary to cause tooth movement and that the types of changes that occur vary according to intensity, duration, and frequency (Warren & Bishara, 2002). The American Academy of Pediatric Dentistry (AAPD; 2000/2006) suggests that practitioners take an individualized approach to the evaluation of oral habits, including pacifier usage, and recommend treatment when appropriate to prevent and/or intercept dental malocclusion or skeletal dysplasia.

A second pacifier-related dental concern found in the literature is risk of cavities related to the pacifier acting as a bacterial reservoir. A recent review of the literature, however, did not find a strong or consistent association between pacifier use and early childhood caries (Peressini, 2003). It should be noted that none of the studies were evaluated by the authors as providing a strong level of evidence related to various methodological limitations; thus, more conclusive research is still needed in this area.

To promote good oral health, the AAPD, along with the AAP (1978/2008), suggests that parents should be instructed to minimize saliva-sharing activities (such as cleaning off a dropped pacifier by licking it). They also suggest establishing a “dental home” within 6 months of a child’s first tooth eruption or no later than 12 months of age. This involves having all members of the family see a dentist for a caries risk assessment and to allow for parental education and anticipatory guidance related to other issues such as risk for dental malocclusion.

Breast-Feeding

One of the greatest concerns expressed by health care professionals and mothers related to pacifier use is the potential negative impact on breast-feeding (Pansy et al., 2008; Vogel & Mitchell, 1997). Leading health and professional organizations recommend avoiding the use of pacifiers with full-term newborn infants who are breast-feeding unless medically necessary (Academy of Breastfeeding Medicine [ABM], 2010; International Lactation Consultant Association, 2005; World Health Organization, 2010) or at least postponing pacifier usage until after breast-feeding is well established (AAP, 2005; ABM, 2010; American College of Obstetricians and Gynecologists, 2007; Association of Women’s Health, Obstetric and Neonatal Nurses, 2007). Despite these concerns and recommendations, the evidence related to an association between pacifier use and poor breast-feeding outcomes is contradictory.

In one large meta-analysis of 31 cross-sectional and cohort trials, Karabulut, Yalcin, Ozdemir-Geyik, and

Karaagaolu (2009) found that pacifier use was associated with double the risk of early weaning from breast-feeding before 6 months of age and a decrease in the duration of any level of breast-feeding by half. In contrast, Jaafar, Jahanfar, Angolkar, and Ho (2011), analyzing findings across two large RCTs, found that in healthy breast-feeding infants, pacifier use had no significant effect on exclusive breast-feeding at 3 or 4 months or the proportion of infants partially breast-fed at these times. In another systematic review, O'Connor, Tanabe, Siadat, and Hauck (2009) noted that an association between shortened breast-feeding duration and pacifier use was only found in observational studies, whereas no difference in breast-feeding outcomes was found in the stronger RCTs.

Based upon current knowledge of breast physiology, theoretically, the greatest negative impact on breast-feeding would occur when early and/or extensive pacifier usage dramatically limits an infant's time at the breast and therefore decreases breast stimulation and maternal milk production. The use of pacifiers by breast-feeding mothers to routinely and deliberately postpone feedings is thus not recommended (Riordan & Wambach, 2010). Other scholars have suggested, based on limited research, that pacifier usage may inhibit successful breast-feeding by encouraging infants to utilize a shallow suck. This may contribute to the development of nipple trauma in a mother and/or "nipple confusion" and poor weight gain in a breast-fed infant who must use a wide-mouth, deep suck to maximize milk transfer from the breast (Newman, 1990; Righard & Aldade, 1992).

In summary, evidence to date suggests that although an association between pacifier use and poor breast-feeding outcomes has been observed by multiple scholars, this association may not be causal. Some authors have suggested that excessive pacifier use in a breast-feeding infant may more frequently be an indicator of breast-feeding difficulties than a cause (Adair, 2003) or perhaps a marker of other socioeconomic, demographic, psychosocial, and/or cultural factors that influence the breast-feeding decision (Callaghan et al., 2005). Until less equivocal evidence becomes available, because of the theoretically strong potential for harm, leading breast-feeding experts join health and professional organizations in suggesting that breast-feeding mothers should be cautioned to avoid pacifiers except in limited situations (Smith & Riordan, 2010).

Otitis Media

Although many individual studies have been conducted investigating the relationship between pacifier usage and acute otitis media (AOM) in children, only a few small literature reviews were located and no meta-analyses. In one review of a single RCT and two cohort studies, Hanafin and Griffiths (2002) concluded that there is strong support for the presence of a causal relationship between these variables. In a second review including two of the same studies, Garrelts

and Melnyk (2001) also concluded that the "evidence is accumulating" that there is a relationship between pacifier usage and AOM in infants and young children. In addition Uhari, Mantyssari, and Niemela (1996) analyzed two studies related to AOM and pacifier usage and found that the pooled estimate indicated a statistically significant risk of AOM with pacifier usage.

More recent individual studies have continued to consistently support a causal relationship between pacifier usage and AOM. Warren, Levy, Kirchner, Nowak, and Bergus (2000), using multivariate regression analysis, found that the use of a pacifier was one of the few modifiable risk factors for AOM in infants during the first year of life. In addition, in a large dynamic population study, Rovers et al. (2008) followed a group of infants for 5 years and found that pacifier usage was associated with a 1.8 times greater risk of recurrent AOM.

Overall, the evidence supporting an association between pacifier usage and otitis media is very consistent. The mechanism, however, has not been definitively identified. Multiple authors have theorized that frequent pacifier sucking may negatively impact the functioning of the eustachian tube by altering internasal pressure, thus making the middle ear cavity more vulnerable to infection from reflux nasopharyngeal secretions (Jackson & Mourino, 1999; Niemela, Uhari, & Mottonen, 1995).

The AAP/AAFP Subcommittee on Management of Acute Otitis Media (2004) recommended that parents reduce or eliminate pacifier usage in the second 6 months of life to reduce the risk of otitis media. This recommendation, however, has not been reaffirmed because of the publication of the more recent AAP (2005/2009) recommendation related to SIDS prevention. As documented on the AAP policy Web site, "AAP policy statements automatically expire 5 years after publication unless reaffirmed, revised or retired at or before that time" (AAP, 2012, "AAP Policy" home page). According to this statement, the guideline pertaining to AOM may be considered to have "expired" because it is more than 5 years old, and there has been no published revision of this former recommendation.

Speech

Many mothers and health care professionals assume that another risk of excessive and prolonged pacifier usage is a negative impact on speech development related to the limits a pacifier necessarily puts on babbling and vocalization. Despite this logical assumption, the evidence supporting this causal link is weak. No meta-analyses or literature reviews and only a few descriptive studies were located investigating the impact of oral sucking habits, including pacifier use, on speech and language impairment.

While investigating the relationship between multiple risk factors and functional speech disorders, Fox, Dodd, and Howard (2002) found that a group of preschool and school-age children with speech disorder was more likely than a

control group of children with normal speech to have used a thumb, pacifier, or bottle for greater than 24 months. The relationship between pacifier use and the group however was not statistically significant. Pre- and perinatal risk factors and positive family history most clearly distinguished children with speech disorder. In another study, [Barbosa et al. \(2009\)](#) found that pacifier use had a negative impact on speech in 3- to 5-year-old children only if the pacifier had been used for greater than 3 years. In contrast, [Shotts, McDaniel, and Neeley \(2008\)](#) found no significant impact of prolonged pacifier use on speech articulation.

One recent study by [Verrestro, Sstefani, Rodrigues, and Wanderley \(2006\)](#) documented a greater incidence of inadequate lip tone and unfavorable tongue positions during speech in children with an anterior open bite related to pacifier sucking. Several other studies have documented that breast-feeding for greater than 9 months, an activity widely accepted as promoting oromuscular development, appears to offer a protective effect against speech impairment among pacifier users ([Harrison & McLeod, 2010; Tomblin, Hardy, & Hein, 1991](#)). This research offers indirect support of a possible association between pacifier usage and an increased risk of speech impairment, but a direct link between myofunctional disorders and pacifier usage has not been made.

Other scholars have suggested that the connection between pacifier usage and speech language pathology is secondary to an increased incidence of otitis media in pacifier users. Two recent meta-analyses, however, both concluded that there is little to no evidence to support an association between otitis media and poor language development ([Casby, 2001; Roberts, Rosenfeld, & Zeisel, 2004](#)). Overall, although prolonged pacifier use may negatively impact speech/language development, further research is needed before any evidence-based conclusions can reasonably be drawn.

Risks Specific to Type and Use of Pacifier

Structure, Durability, and Risk of Injury

During the period from 1980 to 2011, the [National Electronic Injury Surveillance System \(NEISS\)](#) documented 453 injuries related to pacifier usage. Death certificate data from the same period (1980 to July 22, 2011) confirm that 47 deaths were pacifier related ([United States Consumer Product Safety Commission \[CPSC\] National Injury Information Clearinghouse](#)). Most of these deaths occurred before 1999 and were related to asphyxiation or strangulation from some type of pacifier cord, ribbon, or string ([United States CPSC National Injury Information Clearinghouse, NEISS](#)).

[Wehner, Martin, and Wehner \(2004\)](#) reviewed the literature on asphyxia due to pacifiers from the 1960s to 2003 and also documented multiple reported cases of

injury or death. Likewise, [Feldman and Simms \(1980\)](#) found that multiple cases of strangulation injuries related to pacifiers had been reported. Other types of pacifier-related injuries documented in the literature include facial trauma or penetrating eye injury from falling forward on a rigid pacifier ([Stubbs & Aburn, 1996; Izenberg, Izenberg, & Dowshen, 1993](#)) and complete bowel obstruction from an ingested pacifier nipple ([Neville, Huaco, Vigoda, & Sole, 2008](#)).

To minimize pacifier-related injuries, the United States government has developed quality and safety standards for pacifiers sold in this country. According to current guidelines from the [U.S. CPSC \(2001\)](#), a pacifier cannot have a guard or shield at the base of the nipple so small or flexible that a child could aspirate or swallow it, and it cannot have a handle or protrusion long enough to force the pacifier into the child's mouth if a face-first fall occurs. In addition, pacifiers must have a label warning caregivers against tying a pacifier around a child's neck, and a pacifier should not pull apart when tested. Finally, a pacifier guard must have at least two holes that will allow a child to breathe, even if the pacifier is sucked into his or her mouth.

Despite governmental regulation, the [U.S. CPSC National Injury Information Clearinghouse](#) documented 622 "reported incidents" of accidents associated with pacifiers from 2001 to July 22, 2011. These most recent incidents include multiple reports of choking hazards associated with an entire pacifier becoming lodged in an infant's mouth or sometimes a pacifier becoming lodged backward or sideways. There also continue to be a significant number of reports of nipple breakage and separation of pacifier parts.

To further protect infants and children from potential harm, the [Consumer Product Safety Act of 2008](#) imposed a third-party-testing requirement on all consumer products intended for use primarily by children 12 years or younger, including pacifiers. Currently, an accredited independent testing laboratory must certify that pacifiers meet all applicable CPSC requirements including limits on lead and phthalates and standards related to structure and durability. Companies found to be out of compliance may be subject to civil action and/or a mandatory recall.

Type of Material and Risk of Allergy and Infection

Recent research suggests that parents may wish to consider the type of material a pacifier is made of before purchasing one for their child. Latex allergies have been increasingly documented over the past two decades among children ([Frankland, 1999](#)) and infants younger than 1 year ([Kimata, 2004](#)). Some early allergic symptoms that appear to be directly associated with latex pacifiers or nipples include repeated stridor ([Freishtat & Goepp, 2002](#)), wheezing and facial swelling ([Kimata, 2004](#)), persistent cough ([Venturi, Bertolani, Francomano, Piovano, & Ferrari, 1999](#)), and atopic

eczema (Makinen-Kiljunen, Sorva, & Juntunen-Backman, 1992). These findings suggest that parents should consider avoiding latex pacifiers and nipples particularly when there is a family history of latex allergy (Kimata, 2004).

The relative aseptic nature of various pacifier materials has also recently been called into question. DaSilveira, Charone, Maia, Soares, and Portela (2009) found that under laboratory conditions, various *Candida* species were able to form a biofilm on the same latex- and silicone-type surfaces used to make pacifiers. Silicone was found to be slightly more resistant to fungal colonization, although no statistically significant difference was observed. Likewise, Comina et al. (2006) documented the high incidence of a biofilm including primarily *Staphylococcus* and *Candida* on recently used latex pacifiers, and *Staphylococcus* on silicone pacifiers. Although this was another small study that did not control for multiple extraneous variables, these findings also suggest that pacifiers may be passive vectors of disease. Both of these authors speculate that because the latex surface was more irregular than the smooth silicone surface, it offered greater potential for colonization. Although this evidence is not strong, it does present another argument for the selection of a silicone over a latex pacifier and supports the need for regular pacifier sterilization.

Shape and Risk of Dental Malocclusion

Taking up the “thumb versus pacifier” debate, Christensen et al. (2005), in a classic dental textbook, suggest that a pacifier habit can create dental changes almost identical to those of a digit habit, although pacifier habits tend to end earlier than digit habits. They also suggest that a benefit of pacifier usage is that, theoretically, a pacifier habit is easier to stop because a pacifier can be gradually withdrawn, whereas limiting a child’s access to their own digits is necessarily more difficult. Although this might be true, the question remains which type of pacifier is “best”?

Theoretically, the shape of a pacifier might impact the incidence of certain risks of pacifier usage, such as dental malocclusion, little evidence to date supports this premise. In a small descriptive study, Adair, Milano, and Dushku (1992) examined dental occlusions in 24- to 59-month-old children in one of three groups: Nuk (orthodontic) pacifier users, conventional pacifier users, or nonpacifier or finger-sucking group. The authors found that users of the orthodontic pacifiers had significantly greater overjets and that a significantly higher number of subjects with open bite were in the conventional pacifier group. These findings, although statistically significant, were not believed to be clinically significant by the researchers.

In a second larger study, Adair, Milano, Lorenzo, and Russell (1995) studied the same age group and found almost no significant differences between the two pacifier groups related to measures of dental malocclusion. Similarly, Zardetto, Rodrigues, and Stefani (2002) found

no statistically significant differences in dental malocclusion between groups of children using a conventional (bulbous-shaped) pacifier versus a physiologically shaped pacifier (Nuk or MAM).

One prospective, longitudinal study found slightly different results. Zimmer, Barthel, Ljubicic, Bizhang, and Raab (2009) observed a group of newborns for 16 months to test the efficacy of a newly designed pacifier on the development of alterations in dental occlusion. The authors found that significantly fewer children developed an open bite using the novel pacifier when compared with those using the Nuk. Further, independent research is needed to build upon this preliminary evidence that a particular pacifier design may decrease the incidence and severity of associated dental malocclusion.

Discussion and Implications for Practice

A brief summary of the major risks and benefits of pacifier usage and the relative strength of the evidence, as summarized in this review, are provided in Table 1. In considering the clinical significance of these conclusions, it is important to remember that the frequency, intensity, and duration of pacifier usage impact the risk-versus-benefit ratio for the individual infant or child. Of course, these findings must also be considered in relation to each family’s situational context, preferences, and needs.

If a parent chooses to offer a pacifier, anticipatory guidance should be provided related to safety and other risks related to pacifier type and usage. Most importantly, parents should be warned that despite increasingly strict governmental regulation of the manufacturing of pacifiers, precautions must be taken to prevent potential injury. Among the precautions suggested by the current review are frequent inspection of the pacifier to assure that it is intact and showing no signs of wear. Adults should also supervise infants and children when using a pacifier while awake to minimize the risk of choking from improper positioning or sustaining an injury from falling on a pacifier while running. More detailed guidelines related to pacifier selection, use, and care congruent with current evidence have been published by Consumer Reports (2011) and have been summarized in Table 2. Pacifier use and care recommendations are also available on the Web sites of major pacifier manufacturers and have been summarized in Table 3.

Often, a parent may seek guidance in relation to whether to use a pacifier and how frequently or how long it is appropriate for his or her child to use a pacifier. As suggested in this review, it is appropriate for professionals to recommend only limited (judicious) use in breast-feeding infants once breast-feeding is firmly established, offering a pacifier at time of sleep for the first year to decrease risk of SIDS, avoiding or limiting usage in infants and children with a history of repeated AOM, and use of a

Table 1 Summary of Major Risks and Benefits of Pacifier Usage and Conclusions Based on the Evidence

Risk or Benefit	Level of Evidence/Conclusion
Developmental	Observational and qualitative data along with expert opinion suggest that pacifiers may help infants settle and serve as a transitional object
SIDS prevention	Multiple case-controlled studies and expert opinion suggest that pacifiers reduce risk
Adjunctive pain relief	RCTs suggest that pacifier use is safe for pain relief, and synergistic effect with sucrose or breast milk is probable
Oral health/Dentition	Longitudinal studies and expert opinion suggest little lasting impact on dentition if stopped by age 2 to 3 years
Breast-feeding	No strong or consistent evidence suggests an association between pacifier use and early childhood carries RCTs demonstrate no negative effect on breast-feeding outcomes Cross-sectional and cohort trials support negative impact
AOM	Expert opinion strongly suggests limited usage in breast-fed infants RCTs, cohort studies, population-based studies, and expert opinion all consistently suggest increased risk with pacifier usage
Speech	Descriptive studies show no strong or consistent association between prolonged pacifier usage and speech development

Note: Sacket, Richardson, Rosenberg, Hayes, and Haynes (2000) suggests that the highest level of evidence for practice is provided by the review of RCTs, with less strong evidence provided from well-designed studies of the following types (in descending order): at least one RCT, controlled studies (not randomized), case-controlled or cohort studies, descriptive or qualitative studies, a single descriptive or qualitative study, or the opinion of authorities/reports of expert committees.

silicone versus a latex pacifier in infants and children with a significant family history of allergies. In addition, cessation of pacifier usage by the age of 2–3 years should be recommended to limit the potential for irreversible impact on dentition.

Table 2 Pacifier Shopping/Care Recommendations Adapted from Consumer Reports.org (2011)

Shopping

- No recommendation related for shape/type (claim all similarly “orthodontic”)
- Silicone recommended over latex
 - Last longer
 - Top rack dishwasher safe and hypoallergenic (unlike latex)
- Buy proper size according to age of child (as listed on package)
- Avoid any type of accessory “clip on” ribbons, strings, or cords
- Check for ventilation holes on pacifier shield
- Avoid pacifiers with decorations that could fall off and become a choking hazard
- Check CPSC Web site (www.cpsc.gov) for pacifier recalls

Use/Care

- Boil new pacifier for 5 minutes
- Wash regularly, and when dropped, by hand with warm, soapy water and squeeze bulb to remove water
- Check carefully, often for signs of wear
- Discard pacifiers demonstrating the following: cracks, tears, swelling, grainy, or sticky texture
- Pull on pacifier bulb periodically to make sure it is firmly attached/discard if not
- Keep spares handy (in case one is lost or contaminated)
- Use between meals (not to replace); do not routinely dip in sweetener or juice

If breast-feeding difficulties, recurrent AOM, dental malocclusion, and/or other negative outcomes of pacifier usage supported by the evidence are not implicated, pacifier

Table 3 Major U.S. Pacifier Manufacturer Use and Care Recommendations

Gerber	Playtex
Available at: http://www.gerber.com	Available at: http://www.playtexproducts.com
<ul style="list-style-type: none"> • Consider avoiding pacifier use until infant has learned to breast-feed • Never use to replace a regular feeding or loving attention 	<ul style="list-style-type: none"> • Recommend pacifier use at time of sleep from 1 month through the first year <ul style="list-style-type: none"> • Boil silicone or latex pacifiers 5 minutes before first use and thereafter wash regularly in hot soapy water (silicone pacifiers are alternatively top rack dishwasher safe)
<ul style="list-style-type: none"> • Buy more than one to keep in reserve 	<ul style="list-style-type: none"> • Inspect all pacifiers regularly and replace when nipples are cracked, torn, or showing other signs of wear
<ul style="list-style-type: none"> • Never tie or clip a pacifier to a child or object 	<ul style="list-style-type: none"> • Latex pacifiers also should not be exposed to excessive heat or sunlight for extended periods; should be replaced after 2–3 months of regular use and if the nipple becomes sticky or swollen
<ul style="list-style-type: none"> • Offer a pacifier at naptime/bedtime • Wean between 12 and 18 months 	

usage is more a personal choice than a medical concern. Some developmental experts have suggested that the more intensely a parent sets up a prohibition against a sucking habit, then the more firmly it is likely to be adhered to by the child by means of unconscious reinforcement (Brazelton & Sparrow, 2001). Theoretically, from this perspective, the best course of action would be to reassure the child that the habit will likely soon go away, attempt to ignore it, and encourage the child to participate in age-appropriate activities (Brazelton & Sparrow, 2001). Certainly from the developmental perspective, it is also appropriate to suggest that because of the emotional/psychological benefits that some children appear to derive from pacifier usage, the current level of stress in a child's life should be considered when discussing cessation efforts with parents.

Interventions that may be used to wean an infant or child from a pacifier vary widely, dependent upon a variety of perspectives, and are beyond the scope of this article. However, it should be noted that the Oral Health Group of the Cochrane Collaboration is currently working on a protocol for a literature review entitled, "Interventions for the cessation of pacifier usage or digit sucking in children." Once published, this review will be a valuable, succinct resource for clinicians seeking to become more knowledgeable about the various intervention options available and the relative effectiveness of each.

Summary

This review constitutes the most comprehensive overview related to the risks and benefits of pacifier usage completed to date. As new research is conducted and professional guidelines written, the weight of this new evidence will need to be evaluated. Through utilizing high-quality, clinically relevant evidence, clinicians have the means to offer the best possible guidance and care to all patients and their families.

References

- Academy of Breastfeeding Medicine Protocol Committee. (2010). ABM clinical protocol #7: Model breastfeeding policy (revision 2010). *Breastfeeding Medicine*, 5, 173–177.
- Adair, S. M. (2003). Pacifier use in children: A review of recent literature. *Pediatric Dentistry*, 25, 449–458.
- Adair, S. M., Milano, M., & Dushku, J. C. (1992). Evaluation of the effects of orthodontic pacifiers on the primary dentition of 24 to 59-month old children: Preliminary study. *Pediatric Dentistry*, 14, 13–18.
- Adair, S. M., Milano, M., Lorenzo, I., & Russell, C. (1995). Effects of current and former pacifier use on the dentition of 24- to 59-month-old children. *American Academy of Dentistry*, 17, 437–444.
- American Academy of Pediatrics. (2012). *AAP policy*. Retrieved from <http://aappolicy.aappublications.org/>.
- American Academy of Pediatrics and American Academy of Family Physicians Subcommittee on Management of Acute Otitis Media. (2004). Diagnosis and management of acute otitis media. *Pediatrics*, 113, 1451–1465.
- American Academy of Pediatric Dentistry. (2000/ Reaffirmed 2006). Policy on oral habits. *Reference Manual*, 30, 51–52.
- American Academy of Pediatric Dentistry and American Academy of Pediatrics. (1978/Revised 2008). Policy on early childhood caries (ECC): Classifications, consequences, and preventive strategies. *Reference Manual*, 32, 41–44. Retrieved from http://www.aapd.org/media/Policies_Guidelines/P_ECCClassifications.pdf.
- American Academy of Pediatrics Section on Breastfeeding. (2005). Policy statement: Breastfeeding and the use of human milk. *Pediatrics*, 115, 496–506.
- American Academy of Pediatrics Task Force on Sudden Infant Death Syndrome. (2005). Policy statement: The changing concept of sudden infant death syndrome: Diagnostic coding shifts, controversies regarding the sleeping environment, and new variables to consider in reducing risk. *Pediatrics*, 116, 1245–1255 (Reaffirmation published January 2009).
- American College of Obstetricians and Gynecologists. (2007). Breastfeeding: Maternal and infant aspects. *ACOG Clinical Review*, 12(Supplement), 1S–16S.
- Association of Women's Health, Obstetric and Neonatal Nurses. (2007). *Breastfeeding support: Prenatal care through the first year evidence-based clinical practice guideline* (2nd ed.). Washington, DC: Author. Retrieved from <http://www.guideline.gov/content.aspx?id=24065>.
- Barbosa, C., Vasquez, S., Parada, M. A., Carlos, J., Gonzales, V., Jackson, C., et al. (2009). The relationship of bottle feeding and other sucking behaviors with speech disorder in Patagonian preschoolers. *GMC Pediatrics*, 9, 66–73.
- Bishara, S. E., Warren, J. J., Broffitt, B., & Levy, S. M. (2006). Changes in the prevalence of nonnutritive sucking patterns in the first eight years of life. *American Journal of Orthodontics and Dentofacial Orthopedics*, 130, 31–36.
- Brazelton, T. B., & Sparrow, J. D. (2001). *Touchpoints three to six: Your child's emotional and behavioral development*. Cambridge, MA: Perseus Publishing.
- Brazelton, T. B., & Sparrow, J. D. (2006). *Touchpoints the essential reference: Your child's emotional and behavioral development* (2nd ed.). Cambridge, MA: Perseus Publishing.
- Callaghan, A., Kendall, G., Lock, C., Mahony, A., Payne, J., & Verrier, L. (2005). Association between pacifier use and breast-feeding, sudden infant death syndrome, infection and dental malocclusion. *International Journal of Evidence Based Healthcare*, 3, 147–167.
- Casby, M. W. (2001). Otitis media and language development: A meta-analysis. *American Journal of Speech-Language Pathology*, 10, 65–80.
- Castilho, S. V., & Rocha, M. A. M. (2009). Pacifier habit: History and multidisciplinary view. *Jornal de Pediatria*, 85, 480–489.
- Christensen, J. R., Fields, H. W., & Adair, S. M. (2005). Chapter 6 oral habits (pp. 431–439). In J. Pinkman, p. Casamassimo, H. W. Fields, D. J. McTigue, & A. Nowak (Eds.), *Pediatric dentistry infancy through adolescence* (4th ed.). St Louis, MO: Elsevier Saunders.
- Consumer Product Safety Act of 2008, 15 USC 2051 et seq. (GPO). Retrieved from <http://www.cpsc.gov/cpsia.pdf>.
- Consumer Reports. (January 2011). *Pacifier guide from consumer reports*. Retrieved May 21, 2011, from <http://www.consumerreports.org/cro/babies-kids/baby-toddler/pacifiers/pacifier-buying-advice/>.
- Comina, E., Marion, K., Renaud, F. N. R., Dore, J., Bergeron, E., & Freney, J. (2006). Pacifiers: A microbial reservoir. *Nursing and Health Sciences*, 8, 216–223.
- Cozzi, F., Albani, R., & Cardì, E. (1979). A common pathophysiology for sudden cot death and sleep apnea. "The vacuum-glossoptosis syndrome." *Medical Hypotheses*, 5, 329–338.
- DaSilveira, L. C., Charone, S., Maia, L. C., Soares, R. M. D., & Portela, M. B. (2009). Biofilm formation by *Candida* species on silicone surfaces and latex pacifier nipples: An in vitro study. *The Journal of Clinical Pediatric Dentistry*, 33, 235–240.
- Evidence-Based Medicine Working Group (EBMWG). (1992). Evidence-based medicine: A new approach to teaching the practice of medicine. *Journal of the American Medical Association*, 268, 2420–2425.

- Feldman, K. W., & Simms, R. J. (1980). Strangulation in childhood: Epidemiology and clinical course. *Pediatrics*, 65, 1079–1085.
- Fox, A. V., Dodd, B., & Howard, D. (2002). Risk factors for speech disorders in children. *International Journal of Language and Communication*, 37, 117–132.
- Franco, P., Scaillet, S., Wermenbol, V., Valente, F., Groswasser, J., & Kahn, A. (2000). The influence of a pacifier on infants' arousals from sleep. *Journal of Pediatrics*, 136, 775–779.
- Frankland, A. W. (1999). Latex-allergic children. *Pediatric Allergy and Immunology*, 10, 152–159.
- Freishtat, R. J., & Goepf, J. G. K. (2002). Episodic stridor with latex nipple use in a 2-month-old infant. *Annals of Emergency Medicine*, 39, 441–443.
- Garrelts, L., & Melnyk, B. M. (2001). Pacifier usage and acute otitis media in infants and young children. *Pediatric Nursing*, 27, 516–518, 491.
- Hanafin, S., & Griffiths, P. (2002). Evidence based practice: Pacifier use and ear infections. *Community Practitioner*, 75, 50–53.
- Harrison, L. J., & McLeod, S. (2010). Risk and protective factors associated with speech and language impairment in a nationally representative sample of 4- to 5-year-old children. *Journal of Speech, Language, and Hearing Research*, 53, 508–529.
- Hauck, F. R., Omojokun, O. O., & Siadaty, M. S. (2005). Do pacifiers reduce the risk of sudden infant death syndrome? A meta-analysis. *Pediatrics*, 116, e716–e723.
- International Lactation Consultant Association. (2005). *Clinical guidelines for the establishment of exclusive breastfeeding* (2nd ed.). Raleigh, NC: Author.
- Izenberg, N., Izenberg, P., & Dowshen, S. A. (1993). Facial trauma from a rigid infant pacifier face shield: A patient report and review of pacifier safety. *Clinical Pediatrics*, 32, 558–560.
- Jaafar, S. H., Jahanfar, S., Angolkar, M., & Ho, J. J. (2011). Pacifier use versus no pacifier use in breastfeeding term infants for increasing duration of breastfeeding. *Cochrane Database of Systematic Reviews*, 3: CD007202.
- Jackson, J. M., & Mourino, A. P. (1999). Pacifier use and otitis media in infants twelve months of age or younger. *Pediatric Dentistry*, 21, 255–260.
- Karabulut, E., Yalcin, S. S., Ozdemir-Geyik, P., & Karaagaoglu, E. (2009). Effect of pacifier use on exclusive and any breastfeeding: A meta-analysis. *The Turkish Journal of Pediatrics*, 51, 35–43.
- Kimata, H. (2004). Latex allergy in infants younger than 1 year. *Clinical and Experimental Allergy*, 34, 1910–1915.
- Lookabaugh, S. L., & Fu, V. R. (1992). Children's use of inanimate transitional objects in coping with hassles. *The Journal of Genetic Psychology*, 153, 37–46.
- Makinen-Kiljunen, S., Sorva, R., & Juntunen-Backman, K. (1992). Latex dummies as allergens. *Lancet*, 339, 1608.
- Melink, S., Vagner, M. J., Hocesvar-Boltezar, I., & Ovsenik, M. (2010). Posterior crossbite in the deciduous dentition period, its relation with sucking habits, irregular orofacial functions, and otolaryngological findings. *American Journal of Orthodontics and Dentofacial Orthopedics*, 138, 32–39.
- Mitchell, E. A., Blair, P. S., & L'Hoir, M. P. (2006). Should pacifiers be recommended to prevent sudden infant death syndrome? *Pediatrics*, 117, 1755–1758.
- Moon, R. Y., Kington, M., Oden, R., Iglesias, J., & Hauck, F. R. (2007). Physician recommendations regarding SIDS risk reduction: A national survey of pediatricians and family physicians. *Clinical Pediatrics*, 46, 791–800.
- Nelson, E. A. S., Yu, L., & Williams, S.; The International Child Care Practices Study Group Members. (2005). International child care practices study: Breastfeeding and pacifier use. *Journal of Human Lactation*, 21, 289–294.
- Neville, H. L., Huaco, J., Vigoda, M., & Sola, J. E. (2008). Pacifier-induced bowel obstruction—Not so soothing. *Journal of Pediatric Surgery*, 43, E13–E15.
- Newman, J. (1990). Breastfeeding problems associated with the early introduction of bottles and pacifiers. *Journal of Human Lactation*, 6, 59–63.
- Niemela, M., Uhari, M., & Mottonen, M. (1995). A pacifier increases the risk of recurrent otitis media in children in day care centers. *Pediatrics*, 96, 884–889.
- O'Connor, N. R., Tanabe, K. O., Siadaty, M. S., & Hauck, F. R. (2009). Pacifiers and breastfeeding: A systematic review. *Archives of Pediatric Adolescent Medicine*, 163, 378–382.
- Pansy, J., Zotter, H., Sauseng, W., Schneuber, S., Lang, U., & Kerbl, R. (2008). Pacifier use: What makes mothers change their mind? *Acta Paediatrica*, 97, 968–971.
- Peressini, S. (2003). Pacifier use and early childhood caries: An evidence-based study of the literature. *Journal of the Canadian Dental Association*, 69, 16–19.
- Poyak, J. (2006). Effects of pacifiers on early oral development. *International Journal of Orthodontics*, 17, 13–16.
- Righard, L., & Alade, M. O. (1992). Sucking technique and its effect on success of breastfeeding. *BIRTH*, 19, 185–189.
- Riordan, J., & Wambach, K. (2010). *Breastfeeding and human lactation* (4th ed.). Sudbury, MA: Jones & Bartlett.
- Roberts, J. E., Rosenfeld, R. M., & Zeisel, S. A. (2004). Otitis media and speech and language: A meta-analysis of prospective studies. *Pediatrics*, 113, e238–e248.
- Rovers, M. M., Numans, M. E., Langenbach, E., Grobbee, D. E., Verheij, T. J. M., & Schilder, A. G. M. (2008). Is pacifier use a risk factor for acute otitis media? A dynamic cohort study (2008). *Family Practice: An International Journal*, 25, 233–236.
- Uhari, M., Mantysari, K., & Niemela, M. (1996). A meta-analytic review of the risk factors for acute otitis media. *Clinical Infectious Disease*, 22, 1079–1083.
- Sacket, D. L., Richardson, W. S., Rosenberg, W., Hayes, R. B., & Haynes, R. B. (2000). *Evidence-based medicine: How to practice and teach EBM*. New York, NY: Churchill Livingstone.
- Sackett, D., Rosenberg, W., Gray, J., Hayes, R., & Richardson, W. (1996). Evidence-based medicine: What it is and what it isn't. *British Medical Journal*, 312, 71–72.
- Sexton, S., & Natale, R. (2009). Risks and benefits of pacifiers. *American Family Physician*, 79, 681–685. Retrieved from www.aafp.org/afp.
- Shah, P. S., Aliwalas, L. L., & Shah, V. S. (2009). Breastfeeding or breastmilk for procedural pain in neonates (review). *Cochrane Database of Systemic Reviews*, 3, 1–43.
- Shotts, L. L., McDaniel, D. M., & Neeley, R. A. (2008). The impact of prolonged pacifier use on speech articulation: A preliminary investigation. *Contemporary Issues in Communication Science and Disorders*, 35, 72–75.
- Smith, L. A., Colson, E. R., Ryban, D., Margolis, A., Colton, T., Lister, G., et al. (2010). Maternal assessment of physician qualification to give advice on AAP-recommended infant sleep practices related to SIDS. *Academic Pediatrics*, 10, 383–388.
- Smith, L. J., & Riordan, J. (2010). Postpartum care. In J. Riordan, & K. Wambach (Eds.), *Breastfeeding and human lactation* (4th ed.) (pp. 253–290). Sudbury, MA: Jones & Bartlett.
- Stevens, B., Yamada, J., & Ohlsson, A. (2010). Sucrose for analgesia in newborn infants undergoing painful procedures (review). *Cochrane Database of Systemic Reviews*, 1, 1–114.
- Stubbs, A. J. M., & Aburn, N. S. (1996). Penetrating eye injury from a rigid infant pacifier. *Australian and New Zealand Journal of Ophthalmology*, 24, 71–73.
- Tomblin, J. B., Hardy, J. C., & Hein, H. A. (1991). Predicting poor-communication status in preschool children using risk factors present at birth. *Journal of Speech and Hearing Research*, 34, 1096–1105.
- Triebenbacher, S. L., & Tegano, D. W. (1993). Children's use of transitional objects during daily separations from significant caregivers. *Perceptual and Motor Skills*, 76, 89–90.
- United States Consumer Product Safety Commission. (2001). *Requirements for pacifiers*, 16C.F.R. Part 1511. Retrieved from <http://search.cpsc.gov/query.html?qt=pacifier&charset=iso-8859-1>.
- United States Consumer Product Safety Commission National Injury Information Clearinghouse. National Electronic Injury Surveillance System (NEISS). *Pacifiers – Calendar Year 1980–2010*. Bethesda, MD.

- United States Consumer Product Safety Commission National Injury Information Clearinghouse. National Electronic Injury Surveillance System (NEISS). *Pacifiers – Calendar Year 1980 – 7/22/11 Reported Incidents*. Bethesda, MD.
- United States Consumer Product Safety Commission National Injury Information Clearinghouse National Electronic Injury Surveillance System (NEISS). *Death Certificate File (not all States reporting during entire period)*. Bethesda, MD.
- VanNorman, R. A. (2001). Why we can't afford to ignore prolonged digit sucking. *Contemporary Pediatrics*, 18, 61–81.
- Ventu, A., Bertolani, P., Francomano, M., Piovano, P., & Ferrari, P. (1999). Do pacifiers cause latex allergy. *Allergy*, 54, 1007.
- Verrestro, A. P., Stefani, F. M., Rodrigues, C. R. M. D., & Wanderley, M. T. (2006). Occlusal and orofacial myofunctional evaluation in children with primary dentition, anterior open bite and pacifier sucking habit. *International Journal of Orofacial Myology*, 32, 7–21.
- Vogel, A., & Mitchell, E. A. (1997). Attitudes to the use of dummies in New Zealand; A qualitative study. *New Zealand Medical Journal*, 110, 395–397.
- Warren, J. J., & Bishara, S. E. (2002). Duration of nutritive and nonnutritive sucking behaviors and their effects on the dental arches in the primary dentition. *American Journal of Orthodontics and Dentofacial Orthopedics*, 121, 347–356.
- Warren, J. J., Levy, S. M., Kirchner, H. L., Nowak, A. J., & Bergus, G. R. (2000). Pacifier use and the occurrence of otitis media in the first year of life. *Pediatric Dentistry*, 23, 103–107.
- Warren, J. J., Levy, S. M., Nowak, A. J., & Shenghui, T. (2000). Non-nutritive sucking behaviors in preschool children: A longitudinal study. *American Academy of Dentistry*, 22, 187–191.
- Wehner, F., Martin, D. D., & Wehner, H. (2004). Asphyxia due to pacifiers—Case report and review of the literature. *Forensic Science International*, 141, 73–75.
- World Health Organization. (2010). *The ten steps to successful breastfeeding*. Baby-friendly USA. Retrieved from <http://www.babyfriendlyusa.org/eng/10steps.html>.
- Zardetto, C. G. D., Rodrigues, C. R. M. D., & Stefani, F. M. (2002). Effects of different pacifiers on the primary dentition and oral myofunctional structures of preschool children. *Pediatric Dentistry*, 24, 552–560.
- Zimmer, S., Barthel, C. R., Ljubicic, R., Bizhang, M., & Raab, W. H. M. (2009). Efficacy of a novel pacifier in the prevention of anterior open bite. *Pediatric Dentistry*, 33, 52–55.