Information Statement

Safe Sleep

Using a Dummy or Pacifier

Red Nose recommends six key steps to reduce the risk of sudden unexpected deaths in infancy (SUDI) including SIDS and fatal sleeping accidents:

- Always **place baby on their back to sleep**, not on the tummy or side
- Keep baby's **face and head uncovered**
- Keep baby **smoke free before birth and after**
- Provide a **safe sleeping environment** night and day
- Sleep baby in **their own safe cot in the same room as their parent/adult caregiver** for the first 6–12 months
- **Breastfeed** baby

For the purpose of this information statement the colloquial term 'dummy' is used to include pacifiers, dummies and soothers that are inserted into an infant or child's mouth for the purpose of settling or soothing.

Summary of Evidence

- There is strong evidence that dummies are associated with a reduced risk of sudden infant death when used consistently.
- The mechanisms that provide this protection are not yet understood and pacifier use may possibly be a marker from something else, as yet not identified.
- Dummy use is associated with advantages including a reduced risk of sudden infant death, and effective infant settling.
- However, dummy use is associated with disadvantages including a potential negative impact on breastfeeding, and a higher incidence of respiratory, ear and gastrointestinal infections, accidents and dental malocclusion.
- In some countries, dummy use is promoted as a SIDS risk reduction strategy.
- In other countries, dummy use is not actively discouraged, however is not advocated as a risk reduction strategy.

Recommendations for dummy use

- If parents choose to use a dummy, it is important that they receive evidence based advice, including the advantages and disadvantages of dummy use (American Academy of Pediatrics, 2016; Buccini, Pérez-Escamilla, Paulino LM, Araujo, & Venancio, 2017; Moon & Hauck, 2016; Wild & Komfeld, 2020).
- Breastfeeding mothers are advised to offer a dummy only when breastfeeding has been established, usually after the first 4 to 6 weeks (American Academy of Pediatrics, 2016; Hitchcock, 2017; Horne, Hauck, & Blair, 2013; Moon, 2016).
- Dummies can be offered to bottle-fed infants from birth (American Academy of Pediatrics, 2016).
- If being used, dummies should be offered for all sleep periods (Alm, Wennergren, Möllborg, & Lagercrantz, 2016; Haas, Dowling, & Damato, 2017; Hitchcock, 2017; Moon, 2016).
- Because of the risk of strangulation, pacifiers should not be hung around the infant's neck or attached to infant clothing with a cord or string. Pacifiers that attach to infant clothing should not be used with sleeping infants (American Academy of Pediatrics, 2016).
- Parents who wish to use a dummy should do so only for sleeping periods, and by the end of the first year of life dummy use should be phased out (American Academy of Pediatrics, 2016; Eidelman, 2019; Moon, 2016).

- If the baby refuses the dummy, parents are advised not to force the child to use a dummy (American Academy of Pediatrics, 2016; Hitchcock, 2017; Mitchell, Blair, & L'Hoir, 2006).
- If the dummy falls out of the mouth during sleep, do not to reinsert it (American Academy of Pediatrics, 2016; Horne et al., 2013; Mitchell et al., 2006).
- Dummies should not be coated in anything sweet (American Academy of Pediatrics, 2016).
- Dummies should be cleaned often and replaced regularly (Sexton S. & Natale R., 2009).
- Infants and children with chronic or recurrent otitis media should be restricted in their use of a dummy (American Academy of Pediatrics, 2016; Lubbe & ten Ham-Baloyi, 2017; Rovers et al., 2008).
- Dummies should definitely be discontinued by 2–4 years to reduce the risk of dental malocclusion (Sexton S. & Natale R., 2009).
- Parents may need to be supported with strategies to wean infants and toddlers from dummy use, including activities, rewards, toys, and other objects of affection (Sexton S. & Natale R., 2009).

Evidence

Introduction

Dummies or 'pacifiers' have been used to settle infants for centuries. In 1979, Cozzi and colleague (Cozzi, Albani, & Cardi, 1979) postulated that dummies may protect against Sudden Infant Death Syndrome (SIDS). Evidence to support this hypothesis was first reported by Mitchell and colleagues in 1993 (Mitchell E.A, Taylor B.J, & Ford R.P, 1993).

Association between dummy use and sudden infant death

Numerous case-control studies have since been conducted which have allowed the relationship between dummy use and sudden infant death to be investigated (Arnestad, Andersen, & Rognum, 1979; Carpenter, Irgens, & Blair, 2004; Fleming, Blair, Pollard, & Confidential Enquiry into Stillbirths and Deaths in Infancy/Sudden Unexpected Deaths in Infancy Research Team, 1999; Hauck, Herman, & Donovan, 2003; L'Hoir, Engelberts, & van Well, 1999; McGarvey, McDonnell, & Chong, 2003; Tappin, Brooke, & Ecob, 2002).

Physiological and observational studies have also examined possible mechanisms for how dummies may provide this protective effect (Abed, Onetob, Abreua, & Chediaka, 2020; Franco, Chabanski, & Scaillet, 2004; Franco, Scaillet, & Wermenbol, 2000; Hanzer, Zotter, & Sauseng, 2009; Tonkin, Vogel, & Gunn, 2008)

Meta-analyses of available studies (Hauck, Omojokun, & Siadaty, 2005; Mitchell et al., 2006) have consistently reported a reduced risk of sudden infant death (including SIDS) associated with dummy use. Hauck and colleagues (2005) conducted a meta-analysis of seven case-control studies and reported a 61% reduction of SIDS among dummy users compared to a control group, using the last sleep as the reference sleep, based on multivariate odds ratios (OR=0.39, 95% CI: 0.31-0.50). The authors concluded that dummies should be recommended as a potential risk reduction strategy (Hauck et al., 2005) .

A subsequent meta-analysis, using essentially the same studies as Hauck et al (2005), found a 52% reduction in SIDS among dummy users; however reached different conclusions and recommendations for practice (Mitchell et al., 2006). These authors suggested that recommending dummies as a risk reduction strategy was open to debate, highlighting the lack of understanding of a causal mechanism. The authors suggested that dummy use may be a marker for a yet unmeasured variable, and questioned the potential negative impact of dummies on breastfeeding (Mitchell et al., 2006). Callaghan and colleagues (2005) in a systematic review examining dummy use on SIDS, breastfeeding and dental malocclusion, drew similar conclusions (Callaghan et al., 2005) to Mitchell and colleagues (2006) findings that dummies were associated with a reduced risk of SIDS, but may negatively impact breastfeeding. These authors (Callaghan et al., 2005), and others (Blair & Fleming, 2006), have advocated that dummies should not be actively promoted as a specific sudden infant death risk reduction strategy, however should not be discouraged if parents choose to use them.

Findings from subsequent case-control studies (Li, Willinger, & Petitti, 2006; Vennemann, Bajanowski, & Brinkmann, 2009; Vennemann, Findeisen, & Butterfass-Bahloul, 2005) supported a reduced risk of sudden infant death with dummy use, while a case-control study examining infant care practices in high risk populations did not find a significant relationship between sudden infant death and dummy use (Blair, Sidebotham, & Evason-Coombe, 2009).

Further analysis of data (Moon, Yang, Tanabe, Young, & Hauck, 2012) from the Chicago study (conducted between 1993-1996) suggested that dummy use reduced the risk of SIDS by approximately 70% after adjusting for known confounders. Risk was reduced more when mothers were aged ≥20 years, married, non-smokers, had adequate prenatal care and if the baby was ever breastfed. Dummy use also reduced SIDS risk more when the infant was sleeping in the prone/side position compared to supine sleep, bedsharing, or when soft bedding was present.

The authors concluded that dummy use may provide an additional strategy to reduce the risk of SIDS for infants at high risk or in adverse sleep environments (Moon et al., 2012).

Most recently, a 2017 Cochrane Systematic Review concluded there was no controlled trial evidence to support or refute the use of pacifiers to reduce the incidence of SIDS after no studies meeting eligibility criteria to support direct associations were located. The inclusion criteria for the review included published and unpublished controlled trials using random and quasi-random allocations of infants born at term and at preterm (less than 37weeks' gestation) or with low birth weight(< 2500 g) (Psaila, Foster, Pulbrook, & Jeffery, 2017).

Additional advantages of dummy use

Non-nutritive sucking using sucrose and dummies have been shown to help reduce infant responses to painful procedures, as measured by a reduction in crying (Blass & Hoffmeyer, 1991; Carbajal, Chauvet, Couderc, & Olivier-Martin, 1999). Studies in preterm infants have also shown that non-nutritive sucking using dummies has been associated with a reduced length of hospital stay for preterm infants (Pinelli & Symington, 2000; Pinelli & Symington, 2005).

Potential Causal Mechanisms Hypotheses

Although epidemiological studies have provided observational studies that support dummy use to be protective for SIDS, the physiological mechanisms responsible for this protection remain uncertain.

The mechanism by which dummies might reduce the risk of SIDS, or by their absence increase the risk, is not fully understood. Several mechanisms have been suggested (Abed et al., 2020; Horne, 2018; Mitchell et al., 2006)

These proposed hypotheses include avoidance of the prone sleeping position (Hauck et al., 2005; Moon et al., 2012), protection of the oropharyngeal airway as sucking on a dummy keeps the tongue forward maintaining upper airway patency (Abed et al., 2020; Cozzi, Morini, Tozzi, Bonci, & Cozzi, 2002; Ponti & Leduc, 2003), reduction of gastro- oesophageal reflux through non-nutrient sucking (Mitchell

E.A et al., 1993), and lowering the arousal threshold (Franco, Chabanski, & Scaillet, 2004). An infant who is soothed by a dummy may not move as often during sleep, thus limiting the chance of becoming covered by blankets (Ponti & Leduc, 2003). It has also been suggested that the bulky handle of the dummy may prevent accidental hypoxia as a result of an infant's face being buried in soft bedding (Li et al., 2006). Sucking on a dummy may also enhance development of neural pathways that control patency of the upper airway (Li et al., 2006; Marter & Agruss, 2007).

Horne (2018) conducted a review into the protective factor of dummy use and prevention of SIDS which suggested that a likely mechanism for this is increased heart rate variability which has been demonstrated during sucking periods (Franco, Chabanski, Scaillet, Grosswasser, & Kahn, 2004; Yiallourou et al., 2014).

However dummy sucking has also been shown to have no effect on heart rate, heart rate variability, respiratory frequency or oxygen saturation in term infants (Hanzer et al., 2010; Lappi et al., 2007), although dummy suckling has shown an increase in blood pressure in quietly awake or sleeping term infants (Hanzer et al., 2010; Yiallourou et al., 2014).

Dummies usually fall out within the first 30 minutes of sleep. The beneficial effect might not be a result of the presence of a dummy at a specific time, which may also help to explain the apparent protective effect of usual dummy use versus the presence or not of a dummy on the night the infant died. Dummy use may also be a marker for some protective factors that have eluded measurement (Mitchell et al., 2006).

An Irish study reported that infants are at increased risk for SIDS if they habitually used a dummy but did not use it for the last sleep (McGarvey et al., 2003), and the British CESDI study reported a similar finding, but in multivariate analysis the association did not reach statistical significance (Fleming et al., 1999). This study also suggested that thumb sucking behaviours may be protective (Fleming et al., 1999). These findings imply one of several possibilities: that dummies have to be used consistently for all sleep periods; or that the absence of a dummy is a marker for an as yet unmeasured disruption in routine.

Recent studies have also shown that in countries which have shown a reduction in prevalence of dummy use, rates of sudden infant death have also decreased (Blair et al., 2009). This finding suggests that the decreased incidence of SIDS cannot be attributed to dummy use alone.

Potential Disadvantages of Dummy Use

The potential disadvantages of using dummies must also be considered. Given the many benefits of breastfeeding, an issue of consideration is that dummy use may negatively impact the establishment, frequency and duration of breastfeeding. Several studies have demonstrated a significant relationship between frequent and continuous dummy use and reduction in breastfeeding (Callaghan et al., 2005; Howard, Howard, & Lanphear, 2003; Moimaz et al., 2012), although it is unclear whether the relationship is causal or if dummy use is a marker for reduced motivation to breastfeed (Callaghan et al., 2005; Mitchell et al., 2006).

An updated Cochrane review by Jaafar and colleagues (2016) assessed the effect of restricted versus unrestricted pacifier use in healthy full-term infants on established breastfeeding. The meta-analysis of two combined studies which involved 1302 infants, found no significant effects of pacifier use on the prevalence or duration of exclusive and partial breastfeeding at three months and at four months of age (Jaafar, Ho, Jahanfar, & Angolkar, 2016).

A 2009 systematic review of 29 studies also examined the association between dummies and breastfeeding.

These studies included four randomised controlled trials (RCTs), 20 cohort studies, and five cross-sectional studies (O'Connor, Tanabe, & Siadaty, 2009). None of the RCTs found a significant difference in breastfeeding outcomes with the dummy/dummy-related intervention, while all of the observational studies reported either a significantly shortened duration or exclusivity of breastfeeding with dummy use (n=17 studies), or a trend in the same direction (n=8 studies). A further review, that included several RCTs, recommended that as dummy use may be associated with early weaning from the breast or may be a marker of breastfeeding difficulties, it should be avoided until breastfeeding is well established (Sexton S. & Natale R., 2009).

Zimmerman and Thompson (2015) conducted a review of 14 studies which examined evidence that supported or refuted nipple confusion for babies using bottles or pacifiers. The authors concluded that the majority of evidence suggested presence of nipple confusion related to bottles usage with little evidence to support nipple confusion with regards to pacifier use; and highlighted the difficulty in ascertaining causality; namely determining if bottle/pacifier nipples caused infants to refuse the breast or whether this was a marker for breastfeeding difficulties or maternal/infant characteristics (Zimmerman and Thompson, 2015).

A recently published randomised control trial (Hermanson 2020) investigated whether a recommendation of early pacifier use affects the proportion of breast-feeding at six months compared to a recommendation to avoid pacifier use during the first two weeks of life. A total of 209 primiparous mothers and their term infants were randomly assigned to an intervention group or a control group. The primary outcome was the proportion of breastfeeding at six months. Secondary outcomes were the proportions

of breastfeeding and breastfeeding problems at two and four months. Early versus late recommendation of pacifier introduction did not affect the proportion of breastfeeding at six months (Hermanson & Lindh Åstrand, 2020).

Few studies have examined the effect of thumb or digit sucking on breastfeeding outcomes. Aarts and colleagues (1999) conducted a prospective, longitudinal study of 506 mother infant pairs, examining thumb sucking and dummy use on breastfeeding patterns in exclusively breastfed infants. Dummy use was associated with fewer feeds and shorter suckling duration per 24 hours, shorter duration of exclusive breastfeeding, and shorter total breastfeeding duration compared with no dummy use. These associations were not found for thumb sucking.

Dummy use has also been associated with a significantly higher risk of infections including otitis media (Joanna Briggs Institute, 2006; Niemelä, Pihakari, Pokka, & Uhari, 2000; Rovers et al., 2008), wheezing, earache, diarrhoea/ gastroenteritis (Marter & Agruss, 2007; Mitchell et al., 2006; North, Fleming, & Golding, 1999), and oral yeast infection (Mattos-Graner, de Moraes, Rontani, & Birman, 2001). The American Academy of Pediatrics strongly recommends weaning children from dummies in the second six months of life to prevent otitis media (American Academy of Pediatrics, 2016). Infants and children with chronic or recurrent otitis media should be restricted in their use of a dummy (Ponti & Leduc, 2003; Rovers et al., 2008).

Other potential disadvantages include accidents (airway obstruction) (Simkiss, Sheppard, & Pal, 1998), strangulation by the cord (American Academy of Pediatrics, 2016), eye injuries, and dental malocclusion (Callaghan et al., 2005; Larsson, 1994; Mitchell et al., 2006).

A meta-analysis examining dummy use and malocclusion concluded that a longer duration of dummy use was associated with increased incidence of malocclusion (Poyak et al 2006). This review found adverse dental effects can be evident after two years of age, with the most significant malocclusions experienced by children who continued dummy sucking habits beyond 48 months of age.

Current Recommendations

Debate continues over dummy use as a strategy to reduce the risk of sudden infant death. Following a review of

the evidence, the International Society for the Study and Prevention of Infant Death (ISPID) was unable to provide a definitive recommendation regarding the use of dummies as a specific SIDS risk reduction strategy (American Academy of Pediatrics, 2016; Horne et al., 2013). Differences in recommendations made by different countries, agencies and researchers have been acknowledged.

Some countries, such as the United States and the Netherlands (American Academy of Pediatrics, 2016; Hauck et al., 2005)), have actively encouraged dummy use as a risk reduction strategy for SUDI, while others, including Australia and New Zealand, have followed a more conservative approach (Mitchell et al 2012). This approach advocates that while it is appropriate to not

actively discourage the use of dummies, in consideration of the significant disadvantages of dummy use, there is insufficient evidence to actively encourage dummy use as a risk reduction strategy (American Academy of Pediatrics, 2016; Callaghan et al., 2005; Horne et al., 2013; Mitchell et al., 2006) at the present time.

There is however international consensus that dummy use is associated with several advantages and disadvantages that should be considered by parents in order for them to make informed choices about the use of dummies for their own infants (American Academy of Pediatrics, 2016; Horne et al., 2013).

The physiology of infant dummy use, non-use among routine users, and infant thumb-sucking deserves further research investigation (Mitchell, Freemantle, Young, & Byard, 2012).

Recommendations for dummy use

- If parents choose to use a dummy for their baby, evidence-based advice needs to be provided, including the advantages and disadvantages of dummy use (Buccini et al., 2017; Wild & Komfeld, 2020).
- Breastfeeding mothers are advised to offer a dummy only when breastfeeding has been established, usually after the first 4-6 weeks (American Academy of Pediatrics, 2016; Hitchcock, 2017; Moon, 2016).
- Dummies can be offered to bottle-fed infants from birth (American Academy of Pediatrics, 2016).
- If being used, dummies should be offered for all sleep periods. (Alm et al., 2016; Haas et al., 2017; Hitchcock, 2017; Moon, 2016).
- Due to the risk of strangulation, pacifiers should not be hung around the infant's neck or attached to infant clothing on a cord or string. Pacifiers that attach to infant clothing should be removed when the infant is placed to sleep or is not being observed (American Academy of Pediatrics, 2016).
- Parents who wish to use a dummy should do so only for sleeping periods and by the end of the first year of life dummy use should be phased out (American Academy of Pediatrics, 2016; Eidelman, 2019; Moon, 2016).
- If the baby refuses the dummy, parents are advised not to force the child to use a dummy (American Academy of Pediatrics, 2016; Hitchcock, 2017).
- If the dummy falls out of the mouth during sleep, do not to reinsert it (American Academy of Pediatrics, 2016).
- Dummies should not be coated in anything sweet (American Academy of Pediatrics, 2016).
- Dummies should be cleaned often and replaced regularly (Sexton S. & Natale R., 2009).
- Dummies should be discontinued between 6 months and 12 months to reduce the risk of otitis media and dental malocclusion (Lubbe & ten Ham-Baloyi, 2017; Rovers et al., 2008; Sexton S. & Natale R., 2009).
- Parents may need to be supported with strategies to wean infants and toddlers from dummy use, including activities, reward, toys, and other objects of affection (Sexton S. & Natale R., 2009).

When to avoid the dummy

If you observe any of the following problems, it is recommended to reduce or discontinue dummy use, at least until the problem is resolved:

- Baby's frequency or duration of feeds is reduced by use of the dummy (newborns should be nursing around 8 to 12 times a day).
- Baby is having breastfeeding difficulties (eg with latch to the breast) or problems with weight gain (in which case baby needs to nurse as often as possible).
- Mother is having problems with sore nipples or milk supply problems (need to put baby to breast, not dummy, at every opportunity in order to increase milk supply).
- Increased incidence of infection: mother and/or baby have thrush, particularly if repeated episodes or infection is difficult to clear.
- Baby is having repeated ear infections.

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