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**What is known about this topic:**

Pacifier use can reduce the risk of Sudden infant death syndrome.

Emergency department (ED) visits may represent teachable moments where educational interventions are particularly effective.

**What this study adds:**

Parents were much less aware of the pacifier recommendation than other SIDS prevention recommendations.

An ED educational intervention was associated with an increase in pacifier use (NNT3) but was labor intensive.

**Title:** Using a pacifier to decrease sudden infant death syndrome: An emergency department educational intervention.

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**KEYWORDS:** Sudden infant death syndrome; pacifier; emergency department; parental education;

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## ABSTRACT

**Background:** Pacifier use decreases the risk of sudden infant death syndrome (SIDS).

An emergency department (ED) visit may provide an opportunistic ‘teachable moment’ for parents.

**Objectives:** To test the hypotheses (1) that caregivers were less familiar with the role of pacifiers in sudden infant death (SIDS) prevention than other recommendations, and (2) that an ED educational intervention would increase pacifier use in infants younger than six months, and (3) that otitis media would not occur more frequently in pacifier users.

**Methods:** An intervention-group-only longitudinal study in a county hospital ED. We measured pacifier use infants and baseline knowledge of SIDS prevention recommendations in caregivers. We followed up three months later to determine pacifier use, and 12 months later to determine episodes of otitis media.

**Results:** We analyzed data for 780 infants. Parents knew of advice against co-sleeping in 469/780 (60%), smoking in 660/776 (85%), and prone sleeping in 613/780 (79%). Only 268/777 (35%) knew the recommendation to offer a pacifier at bedtime. At enrollment 449/780 (58%) did not use a pacifier. Of 210/338 infants aged less than 6 months followed up 41/112 (37%) non-users had started using a pacifier at bedtime (NNT 3). Over the same period, 37/98 (38%) users had discontinued their pacifier. Otitis media did not differ between users and non-users at 12 months.

**Conclusion:** Caregiver knowledge of the role of pacifiers in SIDS prevention was less than for other recommendations. Our educational intervention appeared to increase pacifier use. Pacifier use was not associated with increased otitis media.



## INTRODUCTION

In 2005 the American Academy of Pediatrics recommended that caregivers should offer infants between one and six months of age a pacifier (dummy, soother, binky) when sleeping. The recommendation was based on studies(De-Kun et al. 2005, Fleming et al. 1999, Arnestad et al. 1997, Fleming et al. 1996, Hauck et al. 2003) showing pacifier use is associated with decreased risk of sudden infant death syndrome (SIDS). Pacifier use also mitigates the SIDS risk associated with soft bedding and prone sleeping position.(Task Force on Sudden Infant Death 2005) Our clinical experience suggested that relatively few parents knew the role of pacifiers in SIDS prevention; on the contrary they feared pacifiers increased ear infections.

Alcohol abuse and injury prevention research suggest that emergency department (ED) visits represent 'teachable moments' during which educational interventions may be disproportionately effective.(Johnson et al. 2007, Williams et al. 2005) In this case, a potentially effective intervention in the ED could be to recommend offering a pacifier at bed time. Although a randomized controlled trial would be ideal, we felt it unethical to randomize some infants' parents to receive knowledge that could prevent SIDS while withholding it from others.

Instead, we performed an intervention only trial in which we associated new pacifier use with (but could not attribute it to) our intervention and controlled for other variables. We conceptualized the conversion of non-user to user as a combination of infant and family

factors, our intervention, overall community knowledge (which could vary with time), and knowledge dissemination as a direct result of the intervention.

We hypothesized (1) that infant caregivers were less familiar with the role of pacifiers in SIDS prevention than other recommendations, (2) that an ED educational intervention would increase pacifier use in infants younger than six months, and (3) that otitis media would not occur more frequently in infants using pacifiers.

## **METHODS**

### **Design**

We conducted a longitudinal study of an educational intervention between 11/26/2008 and 8/1/2011 including a 12 month period of follow up without additional patient accrual.

### **Setting**

The study site was a teaching county hospital with emergency medicine, family practice and OBGYN residencies serving a mixed rural, suburban and urban population.

### **Subjects**

#### **Inclusion criteria**

All infants younger than 12 months of age and their primary caregivers were eligible.

Research assistants (RA) worked four or eight hour shifts including nights, weekends and holidays. Because of potentially non-random gaps in RA coverage we considered our sampling to be convenience rather than consecutive.

## Exclusion Criteria

Subjects were excluded for refusal of consent, being in foster care or custody.

## The intervention

The survey and educational intervention were administered by an RA or investigator. The initial survey inquired about pacifier use, parental knowledge of SIDS prevention strategies, household characteristics, and other demographic characteristics. The key SIDS-prevention strategies inquired after were: (a) infants should not sleep in the same bed as their parents; (b) infants should sleep on their back, not prone; (c) stuffed toys, comforters, blankets etc. should not be in the crib; (d) parents should not smoke; and (e) infants between one and six months of age should be offered a pacifier when being put down to sleep.

This baseline survey was conducted face to face with the primary caregiver and is included as **Appendix 1**. Prior to implementation, we tested pilot versions to reduce ambiguity.

The educational intervention consisted of the RA discussing SIDS prevention with the parents by explaining the contents of a printed color one-page brochure. Spanish speakers or a telephone translation service was used for Spanish speaking caregivers. This brochure is shown in **Appendix 2**. After the intervention, the brochure was given to the parents.



Follow-up telephone calls were made at three and 12 months after enrollment. Five attempts at telephone contact were made on different days and at different times for each subject at each time point. If follow-up failed we checked the coroner's records for vital status. Spanish and English speaking RAs made the follow-up calls. During the three-month follow-up telephone-call, we questioned caregivers about pacifier use and about how many other people they had told of the intervention. At 12-months follow-up, we inquired about the number of episodes of otitis media with which the child had been diagnosed.

RAs were trained with two hours of didactic lectures about SIDS and SIDS prevention. They were also trained in study enrollment procedures using scripts, role play sessions, and by observation of a study investigator. RA training was repeated and reinforced regularly during the study.

The initial survey was collected with pen and paper and keyed into a customized Filemaker-pro database (Filemaker Inc, Santa Clara, CA) by RAs. The investigators reviewed all cases for data entry errors. Follow-up data was entered directly into the database during the telephone call.

### **Statistical methods**

We expected that conversion from pacifier non-user to user between one and six months of age would be a function (a) infant, caregiver and household characteristics, (b) overall community knowledge of the role of pacifiers which could vary with time (a secular

trend), (c) knowledge spread among caregivers as a direct result of the intervention and (d) our intervention. We could not directly measure the effect of our intervention without withholding it. We therefore adjusted for the other factors and associated the remaining effect with our intervention.

We grouped variables within the categories ‘infant characteristics’, ‘caregiver characteristics’ and ‘household characteristics’. We modeled the variables pacifier use in the hospital, NICU stay, and primary care provider, within the infant category. Within the caregiver category we modeled primary caregiver, self described race/ethnicity, caregiver age, and recollection of prior clinic and discharge education. Within the household category we considered medical insurance type, number of bedrooms, number of siblings, and their interactions. This preliminary analysis informed variable selection for our overall models. We ultimately retained only those with a  $p$ -value of  $\leq 0.05$ .

We addressed community knowledge by measuring awareness of the role of pacifiers in SIDS prevention in infants up to 12 months of age and comparing the baseline knowledge of newly enrolled caregivers in each four month period of recruitment for each recommendation.

We addressed physical proximity by creating two proximity measures defined as the number of prior participants living within five and 20 minutes driving time. Times were calculated using Google maps.(Ozimek and Miles 2011) We addressed the effect of social proximity, rather than social proximity itself, by asking caregivers at follow-up with how many other people had shared the pacifier recommendations.

SIDS by definition occurs up to 12 months of age. We included infants up to 12 months of age because we were assessing knowledge of recommendations to prevent SIDS. Because the pacifier recommendation applies only up to six months of age we limited intervention effect estimates to infants aged less than six months. We included all infants when estimating the effect of pacifier use on the incidence of otitis media.

We calculated the efficacy of the intervention as the proportion of non-users who became users and who were younger than six months old at first follow up. We performed an intention to treat analysis for those successfully followed up, but who because of delays in successfully contacting the caregiver, were actually over six months of age at follow up and a treatment received analysis including those only who were actually under 6 months of age at this follow-up. We used published estimates of the numbers needed to treat (pacifier use) (NNT) to prevent one death from SIDS to estimate of the number of infants whose caregivers would need to be educated to prevent one death from SIDS.(Hauck et al. 2003) We compared the prevalence of parent-reported diagnoses of otitis media, and recurrent otitis media (defined as three or more episodes) between pacifier users and never-users with Fisher's exact test.

We managed and analyzed study data using Stata 12 (Statacorp LLP, College Station TX). Kern Medical Center's institutional review board approved the study. Written informed consent was obtained from the available adult with nearest next of kin.

## RESULTS

We enrolled 799 infants. Nineteen patients were excluded for repeated enrollment. One infant died of SIDS and one of pneumonia. Both were pacifier users at baseline. The primary caregiver was usually the mother or grandmother. The median age of mothers (who were sole caregivers) was 24 (IQR 10); grandmothers were in their 40s-50s (median and mean 50 IQR14). Sample characteristics and baseline pacifier use are detailed in

**Table 1.**

### **Baseline knowledge of SIDS prevention recommendations**

Caregiver knowledge of recommendations is in **Table 2**. Pacifier use was the least well known recommendation. African-Americans had consistently poorer baseline knowledge of the recommendations but made up only 8% of the sample.

### **Pacifier use**

At baseline 331/780 (42%) used a pacifier. Among infants aged less than three and 3-6 months pacifier use was 166/338 (49%) and 71/171 (42%) respectively. Pacifier use was more frequent among younger infants of younger mothers and among those who been given a pacifier in the hospital. Factors associated with baseline pacifier use are shown in **Table 3**. Parents also indicated that advice given personally by a physician was highly influential. We found no effect for social or physical proximity and no evidence of a secular trend.

### **Effect of the intervention**

We completed three-month follow-up in 496/780 (64%) patients. Twelve month follow-up was successful in 391/780 (50%) infants. Overall pacifier use at three-month follow up was 192/496 (39%); this comprised younger infants starting and older infants discontinuing pacifier use (**Figure 1**).

#### Intention to treat analysis

Three month follow-up was successful in 210/338 infants who were aged less than three months at enrollment (i.e. aged less than 6 months at follow-up). We contacted 112 /172 (65%) of previous non users and 98/166 (59%) baseline pacifier users. Of the non users 41 (37%) had started using a pacifier at bedtime. Over the same time period, 37/98 (38%) users younger than three months had discontinued their pacifier.

#### Treatment received analysis

Sixty-two infants who were expected to be less than six months of age at three-month follow up were in fact older than six months because of delays in successfully completing follow up. Excluding these infants at three-month follow up; 70/148 (47%) were pacifier users at enrollment. Following the intervention 33/78 (42%) of non users has started using a pacifier and 20/70 (29%) had discontinued pacifier use.

Assuming that none of the non-users would have spontaneously become users without the intervention, and ignoring any reduction in early pacifier discontinuation attributable to the intervention, we estimate the number of non-pacifier-using infants needed to treat (educate caregiver for infants aged <3 months) to gain an additional user is 3, (95% CI 2,

4). The NNT for pacifier use to prevent one case of SIDS was 2,733, yielding an NNT (educational intervention) to prevent one SIDS case of 8,199.(Hauck et al. 2003)

Only infant age was significantly associated with starting pacifier use after the intervention OR 0.77 (95% CI 0.63, 0.94). Participants reported telling a total of 947(median 1, IQR 3), other individuals about the pacifier recommendation. The number of people told by prior participants did not affect any outcome. We were able to calculate physical proximity for 281,250 participant dyads. We found no effect for secular trend or physical or social proximity on pacifier uptake or discontinuation rates. Increasing age was not associated with change in sleeping position.

One year follow-up was successful in 391/780 (50%) infants. Parents reported 156 episodes of otitis media in 391 infants (40%) with 35 (9%) having three or more infections and eight parents reporting six or more episodes. Overall, the prevalence of parent-reported otitis media in ‘never-users’ was indistinguishable from pacifier users. (Fishers exact test  $p= 0.808$ ). Among never-users there were 18/156 infants with recurrent (three or more episodes of) otitis media compared with 17/112 among any time pacifier users (Fishers exact test  $p= 0.471$ ).

## DISCUSSION

Parental knowledge of the role of pacifiers in SIDS reduction was much less than for other SIDS prevention recommendations. Our educational intervention appeared to

increase pacifier use. We did not see an association between parent-reported otitis media and pacifier use.

Our subjects' knowledge of other parenting practices known to reduce SIDS was at least as good as that reported elsewhere among professional child minders and parents.(Moon and Oden 2003, Moon et al. 2010) Perhaps it is unsurprising parental knowledge of the role of pacifiers was less than for the other recommendations because the same is true of health care providers.(Moon et al. 2007, Eron et al. 2011) The better known recommendations substantially predate the recommendation to use a pacifier. Unlike recommendations against smoking and non-supine sleeping positions; the pacifier recommendation has been controversial.(Fleming et al. 2006) Recommendations to use a pacifier compete with some mothers' and dentists' fears that pacifiers will harm infants' developing mandibles,(Pansy et al. 2008, Vazquez-Nava et al. 2006, Warren et al. 2005) impair breast feeding,(Howard et al. 2003, Scott et al. 2006) or increase otitis media.(Uhari et al. 1996)

Educational interventions addressing bed sharing, smoking, and sleeping position have been shown to be effective in changing parental behavior,(Rasinski et al. 2003, Gibson et al. 2000, Moon et al. 2004) and epidemiological studies show community-wide education decreases SIDS deaths.(Davidson-Rada et al. 1995, Kiechl-Kohlendorfer et al. 2001) The effect size of our intervention on pacifier use was comparable to that of other educational interventions designed to decrease prone sleeping and bed sharing.(Moon et al. 2004) This is encouraging because the change in behavior occurred in the absence of the

expansive multi-pronged approach of other successful SIDS prevention interventions.(Davidson-Rada et al. 1995)

Implementing an intervention such as ours is not a trivial exercise. The very high NNT to prevent one SIDS case reflects the rarity of SIDS. Consistent with studies of the 'Back to Sleep' campaign, we found that parents especially value physicians' advice in this regard and further study to determine the efficacy and costs of such an approach is warranted.(Willinger et al. 2000) We speculate that individual emergency physicians discussing SIDS prevention strategies, and specifically discussing the role for pacifiers during the history taking, would incur minimal marginal cost and would be much more efficient. This does not detract from the role of primary care providers in instructing parents regarding SIDS prevention strategies.

#### Limitations

This study has limitations. We assumed new pacifier use was a result of our intervention and discounted delayed pacifier discontinuance that might have resulted from our intervention. This assumes that parents would not discontinue pacifier use as a result of our intervention. We feel that this is a reasonable assumption. The ideal approach would be to randomize parents to receive this SIDS risk reduction information or not. Even if one were to argue for using 'usual care' (i.e. information withheld) as controls consent would still be needed to conduct the initial and follow-up surveys. Parents might inquire why pacifier use was being asked after; and would likely be unimpressed if they were being assigned 'usual care'. It is difficult to conceive how a study design that withheld such information could ever be ethical.



We standardized the time to follow-up rather than choosing to follow-up when the child was aged six months. This facilitated assessment of the intervention but was less patient centered. We relied on caregiver reporting and recall of outcomes. Because we used only a single site, external validity is unproven. Nonetheless our finding that parental knowledge of other SIDS recommendations was similar to that reported by other investigators supports the external validity of our findings.(Gibson et al. 2000) Our study was powered to demonstrate increased pacifier adoption not a decreased SIDS rate. We did not measure changes in the adoption of other recommendations. Collecting this additional comparative data would have lengthened the interview process and potentially decreased subject cooperation. We also had difficulty completing follow-up, a common difficulty in patient populations like ours. We had to rely on a simple pamphlet without the benefit of language optimization which could have increased efficacy.(Buller et al. 2000)

## **CONCLUSION**

Parental knowledge of the role of pacifiers in SIDS prevention was modest and much less than for other recommendations. Our targeted ED-based educational intervention was labor intensive but appeared successful in increasing pacifier use. Pacifier use was not associated with increased otitis media.

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**Competing interests**

There are no competing interests for any author.

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**Table 1.**

		<b>Number</b>	<b>(%)</b>	<b>Median</b>	<b>IQR</b>
<b>Age</b>	Total sample (in months)	780		3.9	6.28
<b>Primary Caregiver</b>					
	Mother Alone	608	78		
	Mother & Father	29	4		
	Grandmother Alone	15	2		
	Grandmother & Mother	90	11		
	Other	38	5		
	Father alone	0	0		
<b>Insurance</b>					
	Medi-Cal	656	84		
	Private	22	3		
	Uninsured	32	4		
	Declined to answer	70	9		
<b>Pacifier use</b>					
	<b>(Younger 6 months at enrollment)</b>	509	65		
	Uses Pacifier when sleeping				
	Never	271	53		
	Sometimes	166	33		
	Usually	30	6		
	Always	42	8		

**Table 1.** Description of infants, caregivers and their households. Description of infants, caregivers and their households. Medi-Cal is Medic-Aid in California.



**Table 2**

Baseline knowledge of recommendations by primary caregivers.

Recommendation	Overall		First Child		≥3 children		Carer ≤35 y		Carer >35y	
	n	(%)	n	(%)	n	(%)	n	%	n	%
Not to sleep in same bed as an adult	469/780	60	116/185	63	124/214	58	339/660	59	80/119	67
Infant to sleep on his back	613/780	79	143/185	77	166/214	78	518/661	78	95/119	80
No blankets, stuffed toys	589/776	76	136/184	74	158/213	74	500/657	76	89/119	75
Caregivers should not smoke	660/776	85	166/183	91	178/213	84	566/657	86	96/119	81
Offer infant pacifier to sleep	268/777	35	64/184	35	76/213	36	223/658	34	45/119	38



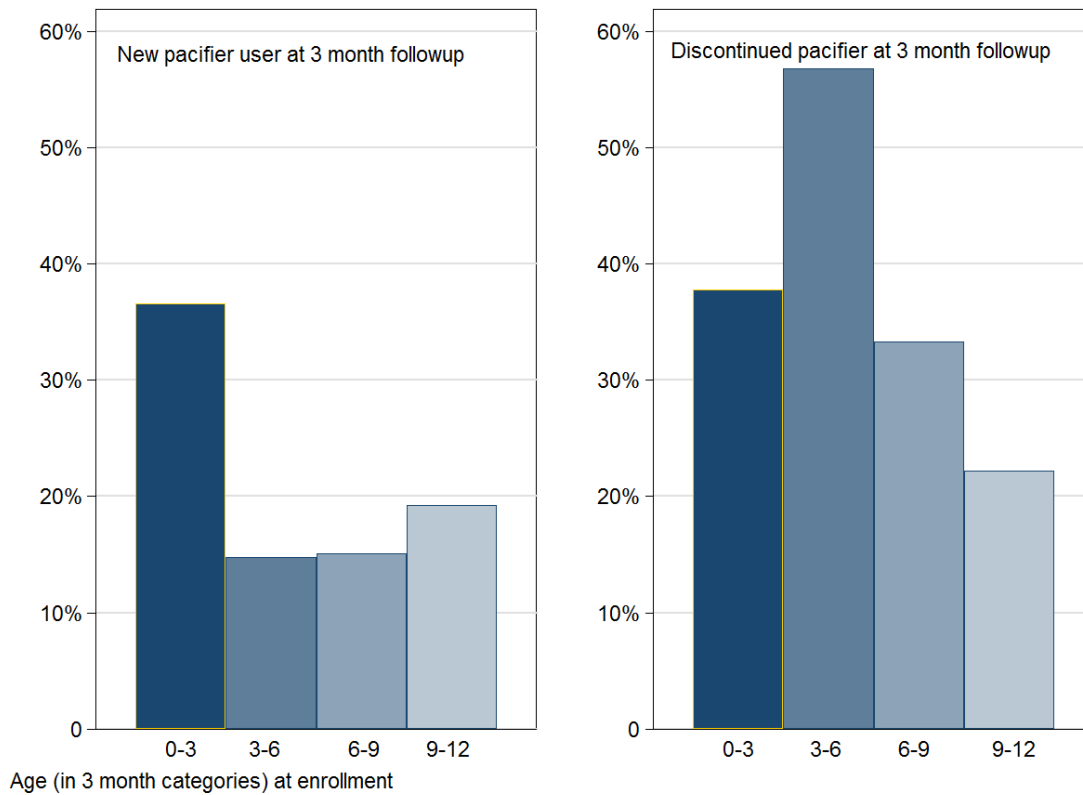


**Table 3**

<b>Variable</b>	<b>Odds Ratio (95% CI)</b>
Infants' age (per month)	0.906 (95% CI 0.866 - 0.947)**
Caregivers' age (per year)	0.970 (95% CI 0.950 - 0.990)**
Ratio of bedrooms to children	1.282 (95% CI 1.076 - 1.529)**
Given pacifier in the hospital	1.754 (95% CI 1.282 - 2.399)**
Knew pacifier recommendation	1.390 (95% CI 1.006 - 1.920)*

Factors associated with pacifier use at enrollment \*p<0.05 \*\*p<0.01. CI, confidence interval.  
Ratio of bedrooms to children includes primary caregiver's bedroom

**Figure 1.** Pacifier uptake and discontinuance at 3-month follow up by age group at enrollment (in months).



**Appendix 1**  
**Survey instrument**  
**Appendix 2**  
**.pdf of the brochure**

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**Appendix 3** Baseline parenting practices of the primary caregiver and other variables.

<b>Infant sleeps with pacifier</b>	<b>Never (%)</b>	<b>Sometimes (%)</b>	<b>Usually (%)</b>	<b>Always (%)</b>
Caregiver knew recommendation to offer pacifier at bedtime	143/266 (54)	75/266 (28)	13/266 (5)	35/266 (13)
Caregiver did not know to offer pacifier at bedtime	305/507 (60)	129/507 (25)	28/507 (5)	45/507 (9)
Recalled discharge counseling	185/329 (56)	92/329 (28)	17/329 (5)	35/329 (11)
Did not recall discharge counseling	250/421 (59)	110/421 (26)	22/421 (5)	39/421 (9)
Recalled clinic SIDS counseling	301/521 (58)	145/521 (28)	26/521 (5)	49/521 (9)
Did not recall clinic SIDS counseling	141/241 (59)	57/241 (24)	14/241 (6)	29/241 (12)
Three or more children	145/213 (68)	52/213 (24)	6/213 (3)	10/213 (5)
Less than three children	304/563 (54)	154/563 (27)	35/563 (6)	70/563 (12)

