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Bed sharing when parents do not smoke: is there a risk of SIDS? An individual level analysis of five major case–control studies

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ABSTRACT

Objective: To resolve uncertainty as to the risk of Sudden Infant Death Syndrome (SIDS) associated with sleeping in bed with your baby if neither parent smokes and the baby is breastfed.

Design: Bed sharing was defined as sleeping with a baby in the parents' bed; room sharing as baby sleeping in the parents' room. Frequency of bed sharing during last sleep was compared between babies who died of SIDS and living control infants. Five large SIDS case–control datasets were combined. Missing data were imputed. Random effects logistic regression controlled for confounding factors.

Setting: Home sleeping arrangements of infants in 19 studies across the UK, Europe and Australasia.

Participants: 1472 SIDS cases, and 4679 controls. Each study effectively included all cases, by standard criteria. Controls were randomly selected normal infants of similar age, time and place.

Results: In the combined dataset, 22.2% of cases and 9.6% of controls were bed sharing, adjusted OR (AOR) for all ages 2.7; 95% CI (1.4 to 5.3). Bed sharing risk decreased with increasing infant age. When neither parent smoked, and the baby was less than 3 months, breastfed and had no other risk factors, the AOR for bed sharing versus room sharing was 5.1 (2.3 to 11.4) and estimated absolute risk for these room sharing infants was very low (0.08 (0.05 to 0.14)/1000 live-births). This increased to 0.23 (0.11 to 0.43)/1000 when bed sharing. Smoking and alcohol use greatly increased bed sharing risk.

Conclusions: Bed sharing for sleep when the parents do not smoke or take alcohol or drugs increases the risk of SIDS. Risks associated with bed sharing are greatly increased when combined with parental smoking, maternal alcohol consumption and/or drug use. A substantial reduction of SIDS rates could be achieved if parents avoided bed sharing.

ARTICLE SUMMARY

Article focus

- Is there a risk of Sudden Infant Death Syndrome (SIDS) due to bed sharing when the baby is breastfed, the parents do not smoke, and the mother does not use alcohol or illegal drugs?
- At what age is it safe to bed share?
- How is the risk of SIDS associated with bed sharing affected by other factors?

Key messages

- When the baby is breastfed and under 3 months, there is a fivefold increase in the risk of SIDS when bed sharing with non-smoking parents and the mother has not taken alcohol or drugs.
- Smoking, alcohol and drugs greatly increase the risk associated with bed sharing.
- A substantial reduction in SIDS rates could be achieved if parents avoided bed sharing.

Strength and limitations of this study

- This is the largest ever analysis of individual records of 1472 SIDS cases and 4679 controls from five major case–control studies.
- Questions on the mother's alcohol use in the last 24 h and illegal drug use were not asked in three of these studies.
- Imputation of missing data enabled a combined analysis of all the data. The analysis gives unbiased, efficient models that describe the data accurately, especially in key areas.

BACKGROUND

Despite the marked reduction in Sudden Infant Death Syndrome (SIDS)[1] following the advice to place babies to sleep on their back (supine),[2] SIDS remains the major cause of infant death in the postneonatal period (28 days through to the first birthday) in high income countries. For instance, in the USA, SIDS remains the leading cause of postneonatal mortality where 2353 babies died from SIDS in 2008, about 0.6/1000 live-births.[3]

Some countries give advice to parents in their 'Reduce the Risks' literature not to bed share with their babies under any

circumstances. For example, the Netherlands advises parents not to bed share for the first 3 months of life[4] based on their own research findings.[5] This is also the case for the USA[6] where the American Academy of Pediatrics Task Force on SIDS cited European[7] and New Zealand[8] data (included in this paper) and made a clear statement advising against bed sharing for sleep. Other countries, notably the UK and Australia, advise only certain groups not to bed share for sleep.[9–12] Bed sharing and the risk of SIDS have become controversial, especially as some, while listing when it should be avoided, highlight the benefits of bed sharing.[13 14]

There is general acceptance that sleeping with a baby is a risk factor for SIDS when sleeping on a sofa in any circumstances or in a bed if the mother smokes and/or has taken alcohol.[15 16] However, authors differ as to whether, in the absence of these risk factors, bed sharing represents a risk.[17–22] Mitchell,[23] in a recent review, suggests that before embarking on further studies, much could be achieved by combining the information from current studies.

However, these risks, specifically for non-smokers when breastfeeding, cannot be quantified directly from published data by standard meta-analysis due to the different ways risks are reported.[5 17 19 24 25] The limited assessment of interactions, for instance between bed sharing and breastfeeding, due to the lack of individual data to analyse was highlighted in the recent meta-analysis of case control studies of SIDS.[26] Therefore, the leading authors of five major recent case–control studies agreed to combine the *individual* data to estimate the risk associated with bed sharing in relation to breastfeeding, smoking, mother's recent alcohol consumption and illegal drug use, after controlling for the other most important risk predictors, namely whether the baby slept in the parents' room or elsewhere, position in which the baby is put to sleep, mother single, mother's age and parity and baby's birth weight. These five datasets included all cases that some might now classify as 'unascertained' or 'asphyxia' because they were found to be bed sharing or sleeping face down.

MATERIAL AND METHODS

Study population

Data from the European case control studies 1992–1996, that is, The European Concerted Action on SIDS, ECAS,[7] the Scottish 1996–2000,[27] the New Zealand 1987–1990,[8] the Irish 1994–2003[28] and the German GeSID 1998–2001[29] datasets were combined. Cases and controls over 1 year of age were excluded. The combined dataset comprised 1472 cases and 4679 normal controls of similar age. For details on how the controls were selected, see online supplementary appendix.

Notes on explanatory variables

The explanatory variables were defined as follows:

- *Bed sharing* was defined as when one or both parents slept with the baby in their bed so that they woke to find the baby dead in bed with them. Controls were bed sharing if the baby was in bed with them when they awoke on the day of interview.
- *Room sharing*—sleeping in the parents' room but not in the parents' bed.
- *Breastfed*—infant was being partially or completely breastfed at the time of death or interview.
- *Bottle fed*—the infant was not breastfed at this time.
- *Parents*—the mother and her current partner.
- *Age*—the infant's age at death or at interview for controls.
- *AOR*—multivariate adjusted OR (AOR). AORs and rates are followed by the 95% CI in parentheses.

All datasets enabled the identification of cases found sleeping in the parents' room or elsewhere and whether or not they were bed sharing, together with comparable control data. Cases and controls cosleeping on a sofa or elsewhere were included but grouped with those not bed sharing and not sleeping in the parents' room. Whether or not the mother or partner smoked, together with the infant's age, sex, race, birth weight, mother's age, parity, whether single or with a partner, and position the infant was last placed to sleep and how the baby was being fed at the time of death/interview were available for all datasets. In addition, data on the mother's alcohol consumption in the last 24 h and mother's illegal drug use after birth were available in two datasets. In total, all the variables shown in table 1, together with age at the time of death or interview, and study[i] were used in the analyses.

Statistical analysis

All variables, other than case or control, age and study, included some missing data. Missing data were imputed as described in the online supplementary appendix. ORs were calculated by logit regression. Univariate analyses were adjusted for age and study because controls were on average 3 weeks older than cases, and the number of controls per case varied between studies. For multivariate AORs, a multilevel logit regression model was used with 'bed sharing' random across studies. The fraction of bed sharing deaths *attributable* to bed sharing, that is the fraction of bed sharing deaths that would not have occurred had the babies not been bed sharing but placed supine on a cot in the parents' room, all other things being unchanged, was computed as described by Bruzzi *et al*[30] Death rates were computed using the same multivariate model by omitting the trend of bed sharing with age. Rates are given for all infants computed by a weighted combination of the rates for boys and girls. The base rate for girls was the SIDS rate when none of the model risk

[i]The ECAS data set comprises a set of 20 studies, five of which were excluded due to absence of data on feeding or unwillingness to participate.

Table 1 The number and percent of cases and controls for each factor, percent missing data, univariate ORs and CIs based on complete data. Also, univariate ORs and multivariate AORs and CIs based on the imputed data sets.

	Cases		Controls		Percentage of missing records	Complete records Single factor		Complete and imputed data Single factor		Selected multivariate	
Variable	**No**	**%**	**No**	**%**		**OR**	**95% CI**	**OR***	**95% CI**	**AOR‡**	**95% CI**
Bed sharing					0.9						
No	1131	77.8	4192	90.4		1	2.2 to 3.1	1	–	1	–
Yes	323	22.2	446	9.6		2.6		2.6	2.2 to 3.1	2.7‡	1.4 to 5.3
Feeding					0.8						
Breast	504	34.9	2491	53.5		1	–	1	–	1	–
Bottle	940	65.1	2168	46.5		2.9	2.5 to 3.3	2.9	2.5 to 3.3	1.5	1.2 to 1.8
Position last left					1.6						
Back all ages	377	26.5	1972	42.6		1	–	1	–	1	–
Side	438	30.8	1869	40.3		1.6	1.3 to 1.8	1.6	1.3 to 1.9	1.5†	1.2 to 2.1
Front	607	42.7	791	17.1		7.8	6.4 to 9.5	7.9	6.5 to 9.6	10.5†	7.5 to 14.6
Parental smoking					2.9						
Neither	314	22.4	2285	50.0		1	–	1	–	1	–
Partner only	194	13.8	1083	23.7		1.4	1.1 to 1.7	1.4	1.1 to 1.7	1.1*	0.8 to 1.4
Mother only	194	13.8	427	9.4		3.7	3.0 to 4.6	3.8	3.1 to 4.7	1.5*	1.2 to 2.1
Both	703	50.0	774	16.9		7.4	6.2 to 8.7	7.3	6.2 to 8.6	2.9*	2.3 to 3.6
Mother took 2 unit or more of alcohol in last 24 h					61.3						
No	478	81.0	1694	94.5		1	–	1	–	1	–
Yes	112	19.0	99	5.5		5.1	3.7 to 7.0	6.5	4.6 to 9.3	4.8*	2.6 to 8.9
Mother used illegal drugs after birth					60.5						
None	582	96.5	1825	99.8		1	–	1	–	1	–
Any	21	3.5	3	0.2		19.2	5.4 to 68.3	30.7	8.8 to 106.8	11.5*	2.2 to 59.5
Sex					0.3						
Unmatched studies:											
Female	351	39.5	1401	49.3		1	–	1	–	1	–
Male	538	60.5	1442	50.7		1.5	1.3 to 1.8	1.5	1.3 to 1.7	1.6	1.3 to 1.9
Matched studies:											
Female	217	37.6	683	37.5		1	–	1	–	1	–
Male	360	62.4	1141	62.5		1.0	0.8 to 1.2	1.0	0.8 to 1.2	0.8	0.6 to 1.1
Race					0.3						
White	1181	81.1	4242	90.7		1	–	1	–	1	–
Non-white	276	18.9	434	9.3		3.0	2.5 to 3.6	3.0	2.5 to 3.6	1.5	1.1 to 1.9

Continued

Table 1 Continued

Variable	Cases No	Cases %	Controls No	Controls %	Percentage of missing records	Complete records Single factor OR	Complete records Single factor 95% CI	Complete and imputed data Single factor OR*	Complete and imputed data Single factor 95% CI	Complete and imputed data Selected multivariate AOR‡	Complete and imputed data Selected multivariate 95% CI
Birth Weight group:					2.3						
3500 g or more	415	28.9	2293	50.1		1	–	1	–	1	–
2500 to 3499 g	760	52.8	2092	45.8		2.0	1.7 to 2.3	2.0	1.7 to 2.3	1.7	1.4 to 2.0
2000 to 2499 g	144	10.0	127	2.8		6.3	4.8 to 8.2	6.4	4.9 to 8.3	4.2	2.9 to 6.0
under 2000 g	120	8.3	59	1.3		13.5	9.6 to 18.9	13.8	9.8 to 19.4	9.6	6.2 to 14.7
Mother's age in years					0.6						
Over 30	326	22.4	1921	41.2		1	–	1	–	1	–
26 to 30	419	28.8	1552	33.3		1.8	1.5 to 2.1	1.8	1.5 to 2.1	1.9	1.5 to 2.3
21 to 25	434	29.9	910	19.5		3.3	2.8 to 3.9	3.3	2.8 to 3.9	3.0	2.4 to 3.8
19 to 20	162	11.1	169	3.6		6.8	5.2 to 8.8	6.8	5.3 to 8.8	7.7	5.2 to 11.4
18 under	113	7.8	111	2.4		7.1	5.3 to 9.6	7.2	5.3 to 9.7	9.1	5.9 to 14.1
Number of live births including the present one:					0.8						
1	407	28.1	1836	39.4		1	–	1	–	1	–
2	491	33.9	1566	33.7		1.4	1.2 to 1.7	1.4	1.2 to 1.7	2.3	1.9 to 2.9
3	280	19.3	748	16.1		1.8	1.5 to 2.2	1.9	1.5 to 2.2	3.8	2.9 to 4.9
4	149	10.3	304	6.5		2.6	2.1 to 3.3	2.6	2.1 to 3.3	5.2	3.7 to 7.4
5 or more	122	8.4	200	4.3		3.5	2.7 to 4.5	3.5	2.7 to 4.6	7.7	5.3 to 11.3
Mother's marital status:					0.2						
Married or with partner	996	68.1	4049	86.6		1	–	1	–	1	–
Single	467	31.9	628	13.4		4.0	3.4 to 4.7	4.0	3.4 to 4.7	1.9	1.5 to 2.4
Where slept last					1.4						
Parents' room	817	56.9	2806	60.6		1	–	1	–	1	–
Elsewhere	617	43.1	1823	39.4		1.3	1.1 to 1.5	1.3	1.2 to 1.5	2.4	2.0 to 2.9

‡Multivariate AORs including AOR for bed sharing pooled for all ages up to 1 year.
†Multivariate AOR when baby in a cot in parent's room & age is 3 months or less.
The corresponding AOR's when baby is over 3 m are 1.4 (1.1 to 1.8) & 7.7 (5.9 to 10.2) respectively.
*Multivariate AOR when baby in a cot in parents' room.
AOR, Adjusted OR.

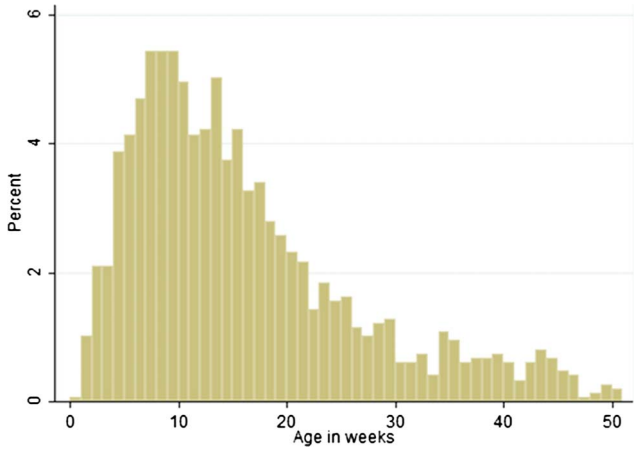

Figure 1 The age distribution of the cases in the combined study.

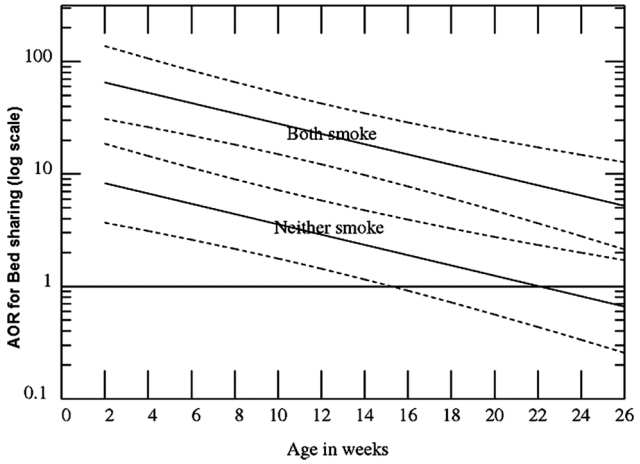

Figure 2 Adjusted ORs (AORs; log scale) for Sudden Infant Death Syndrome by age for bed sharing breast-fed infants, when neither parent smokes and both smoke versus comparable infants sleeping supine in the parents' room. AORs are also adjusted for feeding, sleeping position when last left, where last slept, sex, race, and birth weight, mother's age, parity, marital status, alcohol and drug use.

factors were present. To obtain average AOR for infants <3 months and for infants aged 3 months or more, a logistic form of the rates model confined to records under 3 months and 3 months or more was fitted.

Full details of the statistical methods are given in the online supplementary appendix.

RESULTS

The age distribution of the 1472 cases is shown in figure 1. The peak incidence rate is between 7 and 10 weeks.

Univariate and multivariate analyses

The data for each variable are tabulated for cases and controls in table 1 together with the percentage of missing data and the single factor ORs adjusted for age and study, together with the corresponding OR derived from analysis of the imputed datasets. Corresponding multivariate adjusted AORs from the overall rates model are also reported. For variables that interact with bed sharing, and consequently age, AORs reported in table 1 are those for infants room sharing but not bed sharing.

Feeding

Table 1 shows that bottle feeding increases the risk of SIDS. When analysed as a single factor, the OR for bottle feeding is 2.9 (2.5 to 3.3); however, the multivariate AOR is 1.5 (1.2 to 1.8).

Multivariate analyses for interactions between age, bed sharing and other variables

The baseline in the multivariate analysis is a breast-fed baby placed on his/her back to sleep on a cot in the parents' room neither of whom smokes nor has any other risk factors.

Bed sharing

The log-linear downward trend in the OR for bed sharing in the first 6 months of life is shown in figure 2, when neither parent smoked and when both smoked. These values are predicted by the overall model of the whole dataset. Checks show that the predicted risks closely fit the data, especially when neither parent smoked and the mother had taken neither alcohol nor drugs and the baby was breastfed and bed sharing (see online supplementary appendix).

The analysis showed that *only* the position last left, parental smoking, maternal alcohol consumption in the last 24 h and illegal drug use interact with bed sharing, and consequently the associated risks when bed sharing also decline with increasing age. Table 2 summarises the adjusted AORs for each of these factors, first when room sharing and second when bed sharing at 2, 10 and 20 weeks of age. Three ages are used to illustrate the reduction in risks associated with bed sharing, as the baby gets older. Table 2 confirms that the OR for bed sharing is 8.3 (3.7–18.6) at 2 weeks, and figure 2 shows that bed sharing is a significant risk factor for the first 15 weeks of life in the absence of smoking, alcohol, drugs and all other risk factors.

Position last left

When sleeping in a cot, there is a significant risk associated with placing the baby on its side and a substantial risk when it is placed prone. In contrast, when bed sharing, being placed on the side is not associated with an increased risk and analysis shows that when the baby is placed prone, there is little and no significant increase in risk for the first 3 months, table 2.

Parental smoking

Table 2 also highlights the strength of the very significant interaction between smoking and bed sharing. Infants who bed share at 2 weeks of age and whose

Table 2 The AORs for avoidable factors that interact with bed sharing, adjusted for all other factors. Therefore, they relate to the baseline corresponding to babies of non-smoking mothers who do not use drugs, and taking <2 units of alcohol in the last 24 hours, having a non-smoking partner, and no other risk factors

	Room sharing		Bed sharing					
			At 2 weeks		At 10 weeks		At 20 weeks	
Factor	AOR	95% CI	AOR	95% CI	AOR	95% CI	AOR	95% CI
Position last left								
Back	1.0	—					1.2	0.6 to 2.8
Side	1.8*	1.3 to 2.4	8.3	3.7 to 18.6	3.6	1.8 to 7.2	0.8	0.3 to 2.0
Front	12.0*	8.6 to 16.8					5.3	1.8 to 16.0
Parental smoking								
None	1.0	—	8.3	3.7 to 18.6	3.6	1.8 to 7.2	1.2	0.6 to 2.8
Partner	1.1	0.8 to 1.4	17.6	8.1 to 38.5	7.6	3.8 to 15.1	2.6	1.2 to 6.0
Mother	1.5	1.2 to 2.1	47.5	18.9 to 118.9	20.4	8.9 to 47.7	7.1	2.8 to 18.0
Both	2.9	2.3 to 3.6	64.9	30.8 to 136.9	28.0	15.0 to 52.3	9.7	4.7 to 20.2
Mother's alcohol								
2+ vs <2 units or none	4.7	2.6 to 8.7	89.7	25.3 to 317.7	38.6	12.6 to 117.8	13.5	4.6 to 39.4
Mother illegal drug user								
Yes vs no	11.4	2.2 to 57.8 1		Inestimably large				

*After 3 months, the AOR for put down on side is 1.4 (1.1 to 1.8) and front 7.7 (5.8 to 10.1) when room sharing.
Note: For the first 3 months when bed sharing, risk is not affected by the position put down. All AORs are adjusted for other factors in the table and bottle feeding, sex, whether matched or unmatched, race, birth weight group, mother's age group, number of live births (grouped), mother single and where slept.
AOR, Adjusted OR.

parents both smoke are at 65-fold increased risk of SIDS compared with infants room sharing with parents who do not smoke. There is a 'dose response' effect, univariately, when room sharing, and when bed sharing at 2, 10 and 20 weeks related to whether just the partner smokes, just the mother smokes or both smoke. However, when the parents do not sleep with the infant, the risks associated with parental smoking are comparatively small.

Alcohol and drugs

Table 2 also shows the AORs associated with the mother having had 2 or more units of alcohol in the last 24 h. If the baby does not bed share, having 2 or more units increases the risk nearly fivefold in contrast to a very substantial increase in risk when bed sharing, especially in the first weeks of life (AOR at 2 weeks of age=89.7). The use of any illegal drugs by the mother, including cannabis, increases the risk 11-fold even when the baby is room sharing. The risks associated with a drug using mother bed sharing are unquantifiably large.

Average ORs for the first 3 months and after

In view of the trends in the AORs associated with bed sharing and age, table 3 tabulates the average under and over 3 months AORs for two key factors, smoking and alcohol, when room sharing and bed sharing. These

Table 3 Average AORs for smoking and maternal alcohol when room sharing and bed sharing with the multiplicative increase in risk due to bed sharing, for infants aged under 3 months and 3 months up to a year

Age group	Risk factors		Room sharing		Bed sharing		Increase when bed sharing	
	Smoking	Alcohol	AOR	95% CI	AOR	95% CI	Multiplier	95% CI
<3 month	No	No	1	–	5.1	2.3 to 11.4	5.1	2.3 to 11.4
	Partner	No	0.7	0.5 to 1.1	7.8	3.6 to 17.2	11.2	5.0 to 25.1
	Mother	No	1.3	0.8 to 2.2	20.3	7.4 to 56.4	15.2	5.3 to 43.4
	Both	No	2.9	2.0 to 4.2	21.6	11.1 to 42.3	7.5	3.9 to 14.6
	Both	Yes	13.7	5.5 to 34.4	151.0	50.2 to 448.4	10.8	3.0 to 39.2
3 months and over	No	No	1	_	1.0	0.3 to 3.1	1.0	0.3 to 3.1
	Partner	No	1.2	0.9 to 1.7	3.0	1.2 to 7.5	2.5	1.0 to 6.3
	Mother	No	1.7	1.2 to 2.4	6.1	1.7 to 22.6	3.6*	0.9 to 13.9
	Both	No	3.0	2.3 to 4.0	13.7	6.1 to 31.0	4.6	2.0 to 10.3
	Both	Yes	15.7	8.1 to 30.4	243.8	76.1 to 781.4	15.6	4.2 to 57.4

*This multiplier is significant at p=0.062.
The AORs are adjusted for all other factors in the table, any drug use by the mother since birth, bottle feeding, sex, whether matched or unmatched, race, birth weight group, mother's age group, number of live births (grouped), mother single and where slept.
AOR, Adjusted OR.

adjusted ORs apply when no other risk factors are present and the baseline risk group is breast-fed baby girls placed on their back for sleep by the bed of non-smoking parents having no other risk factors. Table 3 shows that if this group with a baseline risk bed share, their average risk for the first 3 months, AOR is 5.1 (2.3 to 11.4). After the infant is 3 months old, the corresponding average AOR is 1.0 (0.3 to 3.0).

The multipliers shown in the last column show the ratio of the AORs when bed sharing to the corresponding AOR when room sharing. Insofar as these multipliers are >5.1 for the under 3 months, and >1 after that age, they show that the interaction, first of smoking and then of parental smoking plus maternal alcohol with bed sharing, greatly enhances the risk associated with bed sharing. The data are too sparse to give meaningful AORs when the mother is a drug user. It will also be noted that the second largest increase in risk associated with bed sharing occurs when the baby is under 3 months and the mother smoked.

Calculation of AORs for other risk groups

Because AORs multiply in the absence of interaction, tables 1–3 enable approximate[ii] AORs to be calculated for almost all other risk groups. Thus, at 2 weeks, if the baby is not breastfed but bottle fed, table 1 shows that the AOR is multiplied by 1.5; if the baby's birth weight is between 2000 and 2499 g, the AOR is scaled up by 4.2, and so on. Thus, at 2 weeks, for a bottle-fed baby boy with birth weight 2140 g who bed shares with a cohabiting 21-year-old mother with one previous child and both parents smoke, the

$$\begin{aligned}\text{AOR} &= 64.9\,(\text{table 2: both smoke})\\ &\times 1.5\,(\text{table 1: bottle fed})\\ &\times 1.6\,(\text{table 1: male})\\ &\times 4.2\,(\text{table 1: birth weight})\\ &\times 3.0\,(\text{table 1: mother's age})\\ &\times 2.3\,(\text{table 1: 1 previous child})\\ &= 4514 \text{ when compared with babies with no risk factors.}\end{aligned}$$

Using table 2, if we replace 65.1 with 2.9, we find that this alarming figure drops to 202 for parents who did not bed share. By changing the first AOR from 65.1 to 21.8, we find the average AOR for this child for the first 3 months to be approximately 1516, again reducing to an average of 202 if the baby did not bed share but is placed supine for sleep on a cot in the parents' room.

These alarming AORs show how the effect of multiple risk factors builds up, and indicates that infants with multiple risk factors are likely to be at a far greater risk than is generally supposed.

[ii]The AORs obtained as described here will not be precise but will be well within the CI for the best estimates, see online supplementary appendix.

Fraction of deaths while bed sharing attributable to bed sharing

In this combined dataset, 22% (n=323) of the deaths occurred while bed sharing; 66% (n = 212) of these were under the age of 3 months. Overall, 87.7% (86.3% to 89.2%) were attributable to bed sharing, assuming that they would otherwise have been placed on their back on a cot in the parents' room. This rises to 89.5% (88.8% to 90.3%) for bed sharing deaths under 3 months of age.

Comparison of SIDS rates

To get an overview of the absolute risks and increases in risk associated with bed sharing, SIDS death rates for infants (ie, ages 0 up to 1 year) when room sharing or bed sharing are estimated and tabulated in table 4 for six combinations of risk factors. In addition, table 4 also shows the ratio of SIDS rates for bed sharing compared with room sharing. These SIDS rates have been calculated by assuming that the population SIDS rate is 0.5/1000 live births and apply to a typical cohabiting white mother aged 26–30 having a second normal weight baby with birth weight between 2.5 and 3.5 kg—the most common situation of a mother completing her family.

Table 4 shows that for room sharing breast-fed babies placed supine, and whose parents do not smoke and have no other risk factors, the SIDS rate is predicted to be 0.08 (0.05 to 0.14)/1000 live-births. This rate is predicted to increase by 2.7 times (1.4 to 5.3) to 0.23 (0.11 to 0.49)/1000 when bed sharing. For all combinations of risk factors, the predicted increases in risk associated with bed sharing are statistically significant. These rates may be scaled up or down depending on the population SIDS rate, and other factors present; see online supplementary appendix for details. For example, from tables 1 and 4, we find that a 2.25 kg bottle-fed baby bed sharing with an 18-year-old mother, who smokes and regularly takes 2+ units of alcohol and whose partner also smokes, has a predicted SIDS rate of 125/1000, that is, 12.5% (see online supplementary table b) in online supplementary appendix.

DISCUSSION

Mitchell[21] recently reviewed the risks and benefits of bed sharing; he concluded that the postulated benefits and guidelines for bed sharing safely are not evidence based. He also found that there is only one small group with *no* increased risk of SIDS when bed sharing, namely breast-fed infants over 3 months whose parents do not smoke, and whose mother does not take 2 or more units of alcohol or drugs and does not cosleep on a sofa. Mitchell urged that parents had a right to know the risks they are exposing their infants to when bed sharing, but was unable to quantify these risks.

This study combines five major SIDS case–control studies. It includes 1472 cases and 4679 controls, making it the largest study of SIDS risk factors with individual level data. By combining individual data, this design

Table 4 Predicted SIDS Infant death rates for normal women*

	Risk factors present			Room sharing		Bed sharing		Ratio of rates	
Group number	Feeding	smoking	Alcohol	Rate/1000	95% CI	Rate/1000	95% CI	Ratio	95% CI
Minimum risk	Br	No	No	0.08	0.05 to 0.14	0.23	0.11 to 0.49	2.7	1.4 to 5.3
1	Bot	No	No	0.13	0.08 to 0.21	0.34	0.16 to 0.73	2.7	1.4 to 5.3
2	Br	Partner	No	0.09	0.05 to 0.16	0.52	0.25 to 1.08	5.6	2.9 to 10.8
3	Br	Mother	No	0.13	0.08 to 0.23	1.27	0.54 to 3.00	9.7	4.4 to 21.7
4	Br	Both	No	0.24	0.15 to 0.41	1.88	0.94 to 3.73	7.7	4.3 to 13.8
5	Bot	Both	Yes	1.77	0.87 to 3.48	27.5	10.4 to 68.4	15.6	5.7 to 41.5

*Predicted SIDS mortality rates for a cohabiting, white mother age 26 to 30, having a second normal weight baby with birth weight between 2.5 and 3.5 kg and having no other risk factors, that is mother is not a drug user, has a partner and room shares.
Bot, bottle; Br, breast; SIDS, Sudden Infant Death Syndrome.

allows the interaction of risk factors such as breastfeeding, infant age and smoking to be examined in relation to bed sharing and SIDS. Accordingly, it is able to examine the interplay of the risk factors related to bed sharing in depth as never before. Our findings confirm Mitchell's conclusions and *quantify* the relative risks and predicted SIDS rates associated with bed sharing in a variety of circumstances.

It has been suggested that we should have taken into account the partner's alcohol consumption in the last 24 h and his drug use. We did not include the former factor because, in the analysis of the ECAS study, it was found that the partner's consumption of alcohol was correlated with that of the mother and did not add further to the risk of SIDS.[7] To check on this possibility, we have gone back to the original records for the key subgroup, namely babies <3 months who were breastfed and whose parents did not smoke and whose mother took less than 2 units of alcohol in the last 24 h and did not use drugs, who either bed shared or room shared. We find that in both the bed sharing and room sharing groups, the control partners had taken slightly *more* alcohol in the last 24 h than the partners of cases. Consequently, if we adjusted for this factor, it would increase the OR for bed sharing. We also note that the subgroup OR based on the complete data is 5.6 (1.6 to 20.3), which is almost identical to the adjusted AOR for this group 5.1 (2.3 to 11.4: table 3).

To respond to the criticism that the missing data in relation to alcohol and drug use in three of the five datasets make any attempt to exclude the contribution of these factors to the risks associated with bed sharing completely unreliable, we have gone back to the original records for bed sharing cases in the key subgroup. Most of these records include pertinent questions on alcohol use, but not maternal use, in the last 24 h. This enabled us to establish that neither alcohol nor drug use contributed in any way to any of these deaths.

Also, as discussed in more detail in the online supplementary appendix, because missing data are primarily determined by the study; by including a 'study' when modelling the subset of complete data and modelling the imputed data, the results of both will be essentially unbiased. In this setting, multiple imputations are expected primarily to recover information by including the partially observed records in the analysis, which is what we found. Consequently, we can be confident of our estimate of the adjusted effect of bed sharing from the imputed data.

Importantly, the combined data have enabled the demonstration of increased relative risk associated with bed sharing when the baby is breastfed and neither parent smokes and no other risk factors are present (see figure 2 and table 2). The average risk is in the first 3 months and is 5.1 (2.3 to 11.4) times greater than if the baby is put to sleep supine on a cot in the parents' room (table 3). This increased risk is unlikely to be due to *chance* (p=0.000059). *Bias* could occur because these estimates are based on models fitted to all the data or to all the data relating to infants under 3 months of age. Moreover, checks show that the models accurately describe the data, especially those relating to cases whose only risk factor is bed sharing; see online supplementary appendix. Bias is also possible due to the selection of the studies. However, the present study incorporates far more data than were included in Vennemann *et al*'s[26] recent meta-analysis of the ORs for bed sharing in infants of non-smoking mothers. The meta-analysis produced summary ORs that were very similar to those reported in this study. Furthermore, our findings are very unlikely to be due to *confounding* since the AORs are adjusted for all the major SIDS risk factors. Although the partner's consumption of alcohol is not included in the dataset, it was found in the ECAS study that this factor was correlated with mother's alcohol consumption (r=0.52) and, after taking account of the mother's alcohol consumption, it did not add further to the prediction of risk.[7]

Mitchell's[21] review of the mechanisms by which bed sharing might cause SIDS shows that a causal pathway is not unreasonable. Box 1 reviews the evidence that the association of bed sharing, when mothers do not smoke, have not taken alcohol or use drugs, with SIDS is causal by Bradford Hill's criteria.[31] Clearly, bed sharing in the white European context can be a causal factor for SIDS, especially in the first 3 months in the absence of other factors. It has been argued that because the risk of bed

Box 1 Assessment of bed sharing, in the absence of parental smoking alcohol and maternal drug use, as a causal risk for SIDS by Bradford Hill's criteria[31]

Strength of association
- Adjusted Odds Ratio (AOR) for bed sharing=2.7 (95% CI 1.4 to 5.3), p=0.0027, for breastfed infants with no other risk factors. AOR for the first 3 months of life=5.1 (2.3 to 11.4), p=0.00006. These AORs are moderately strong.

Consistent
- Of more than 12 published studies, all but two small ones show, after multivariate adjustment, increased risk of SIDS associated with bed sharing, some combined with sofa sharing.[26]

SPECIFIC × (not an essential criterion)
- Smoking, alcohol and drug use all have greatly increased risk when bed sharing
- Bed sharing is associated with other causes of death, eg, Suffocation.
- SIDS can occur in the absence of bed sharing.

Temporally correct
- Bed sharing always precedes SIDS.

Dose response
- New Zealand study showed risk increased with duration of bed sharing.[32] Not otherwise investigated.

Biologically plausible
- Bed sharing risk is greatest to youngest infants who are most vulnerable.

Coherence
- The proposition that bed sharing is causally related to SIDS is coherent with theories that respiratory obstruction, re-breathing expired gases, and thermal stress (or overheating), which may also give rise to the release of lethal toxins,[33] are all mechanisms leading to SIDS, in the absence of smoking, alcohol or drugs. Infants placed prone are exposed to similar hazards.

Direct experimental evidence ×
- Not ethically possible.

Analogy
- Overlying is a serious cause of mortality in piglets. Sows are normally separated by a bar from piglets to prevent them being crushed when she turns over, but allowing her piglets to feed.

sharing is greatly increased by parental smoking, alcohol and/or drugs, it is the way we bed share rather than bed sharing itself that is important. Parental smoking greatly enhances the risk of SIDS associated with bed sharing, but in what way their pattern of bed sharing differs from that of non-smokers is not obvious. Although breastfeeding is lower among smokers than non-smokers, 46% of cases of bed sharing smokers were breastfeeding and 61% of controls. These figures are lower than for non-smokers, 62% and 73%, respectively, but these differences do not demonstrate that parental smoking results in a different way of bed sharing. For non-smokers and smokers alike, sleeping in a 'western style' bed with a baby carries a risk of SIDS. Why the risk is so greatly enhanced by parental smoking is not known.

Recently, there has been a tendency to record unexplained bed sharing infant deaths as due to 'suffocation-bed' (ICD code E913/W75)[34 35] or 'undetermined', rather than SIDS when the baby was bed sharing and may have suffocated.[36] However, an investigation into deaths certified as SIDS and unascertained by the UK Office of National Statistics found that many of their characteristics were very similar,[37] and now ONS reports these deaths together as unexplained deaths in infancy.[38] In 2004, Limerick and Bacon,[39] in a study of terminology used by pathologists in reporting SIDS, found that when giving the cause of death of an infant found unexpectedly dead while bed sharing, only 1 in 70 said asphyxia. The selection of cases in our studies includes all such deaths. Certifying such deaths under headings other than SIDS does nothing to minimise the tragedy.

Other new findings

The risk of SIDS for an average family with no known modifiable risk factors—table 4 baseline (breast-fed, non-smoking, non-drinking parents who are room sharing and not bed sharing)–was 0.08/1000 live-births. This is the level of SIDS that might be achieved if all known modifiable risk factors were removed. Such a SIDS level may be deemed intrinsic (possibly genetic) and not directly amenable to behaviour modification. This rate is consistent with countries reporting low SIDS rates. National surveys in the Netherlands show that, following an active campaign to discourage bed sharing,[4] bed sharing rates have fallen from 13% in 1999, to 10% in 2005, to 1.5% always bed sharing and 3.1% sometimes bed sharing in 2011 (M L'Hoir, Personal communication Apr, 2012). During the same period, as part of a general downward trend in SIDS mortality,[40] SIDS rates have fallen by 25% from 0.12 in 2000 to 0.09/1000 in 2010.[41 42] At the same time, the percentage of infants being breastfed at 3 months of age has risen from 45% to 52%, and at 6 months from 24% to 32%,[43] confirming that promotion of bed sharing is not necessary to achieve high rates of prolonged breastfeeding.

A recent study commissioned by UNICEF[44] suggests that the promotion of breastfeeding and support of breastfeeding mothers in the UK would reduce the burden of disease on the National Health Service and could thereby be cost-effective. However, if bed sharing is promoted as a means of encouraging breastfeeding, it is likely to increase the number of SIDS because AOR for bed sharing, 2.7, is nearly double that for bottle feeding, 1.5. Consequently, such an approach would be likely to *increase* the number of SIDS cases. If SIDS deaths are costed at more than £1.5 million each, as in the UNICEF report, the costs resulting from any increase in bed sharing would far outweigh any benefits from the increased breastfeeding rates, quite apart from the disastrous consequences for families associated

with the loss of a child. To reap the benefit of increasing the breastfeeding duration and rates, the Dutch recommendations should be followed, namely: 'To achieve maximal security for the baby and optimal availability of breastfeeding, mothers are advised to take the baby of less than 4 months of age into their bed for feeding during the night, but afterwards to place the baby on its back into his own crib, placed adjacent to the parents' bed in the parents' bedroom'.[5]

Thus, we do not suggest that babies should not be brought into the parent's bed for comfort and feeding. This has been investigated in previous studies and has not been found to be a risk factor, provided the infant is returned to his or her own cot.[45 46] This study is concerned with the risks associated with *sleeping* with a baby in bed. Tables 3 and 4 of this report are designed to enable an informed choice to be made by parents as to whether the risks associated with bed sharing outweigh the postulated benefits. However, our models predict that 88% of the deaths that occurred while bed sharing would probably not have occurred had the baby been placed on its back in a cot by the parents' bed. Even for the very low-risk breastfed babies under 3 months of age, with no risk factors other than that they slept in their parents' bed, the model predicts that 81% (78.9% to 82%) of the deaths could have been readily prevented in this way. One has to ask whether it is worth taking the risk, however small, of losing a baby, when it can be so easily avoided.

Previous epidemiological studies have shown that being placed on the front, prone, for sleep was a risk factor for SIDS and fulfilled similar criteria as a causal risk for SIDS; in the 1970s, OR was 2.9 (1.2 to 7.5) and in 1986 from five pooled case–control studies, OR was 3.0 (1.7 to 5.3).[2] A campaign to reduce prone sleeping effectively halved the number of SIDS cases worldwide between 1990 and 2000, saving thousands of babies in the developed world. Delay in implementing an effective 'back to sleep' campaign is estimated to have resulted in the deaths of 10 000 infants in the UK alone.[2]

Recent case studies indicate that now 50% or more of SIDS cases[18 47] occur while bed sharing in contrast to 22% in this study, table 1. In the UK, possibly due to the pro bed sharing lobby[14] in the 10 years between the two studies by Blair and colleagues,[46 18] the percentage of cases bed sharing (excluding sofa sharing) doubled and the percentage of controls bed sharing increased by 50% from 14.5% to 21.8%. Meanwhile, the crude unadjusted OR for bed sharing only changed from 2.0 to 2.2. (An adjusted OR for bed sharing is not reported for the latter study.) Our analysis estimates that 88% of bed sharing deaths are attributable to bed sharing, that is, would not have occurred had the baby not been bed sharing. The stability of the crude OR for bed sharing despite the increase in the prevalence of bed sharing suggests that our estimate of attributable risk may reasonably be applied currently. Consequently, our analysis suggests that about 90% of bed sharing SIDS deaths would not occur in the absence of bed sharing.

The current messages saying that bed sharing is dangerous only if you or your partner are smokers, have been drinking alcohol or taking drugs that make you drowsy, are very tired or the baby is premature or of low-birth weight, are not effective because many of the bed sharing deaths involve these factors. Our findings suggest that professionals and the literature should take a more definite stand against bed sharing, especially for babies under 3 months. If parents were made aware of the risks of sleeping with their baby, and room sharing were promoted, as 'Back to Sleep' was promoted 20 years ago, a substantial further reduction in SIDS rates could be achieved.

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Contributors The first five authors played a major role in the design and analysis of their studies, and submitted data for this combined analysis. JRC and MS were responsible for imputing missing data. RGC combined and analysed the data and drafted the report. EAM advised on the analysis. All authors commented on drafts and have seen and approved the paper as submitted.

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Data sharing statement The original case–control datasets and the imputed data can only be made available to other research workers in this field, with the explicit permission of the person responsible for each dataset.

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Appendix: Selection of controls and Statistical methods

Selection of controls

ECAS dataset
For three studies, regional coordinators selected 6 live controls of the same gender and born at the same maternity ward 14 days subsequent to the index case. A delay period of 14 days was expected to assure that controls had an age similar to the SIDS baby when parents completed the questionnaire. Parents of the first four of these selected infants were invited to participate. If a family was unwilling to participate, another family among the two families of the remaining infants was invited.

For the other 12 studies included in this dataset it was intended that at least two live controls were obtained for each case. Almost all cases in these studies had 2 controls; all had one. These controls were selected from a list of births in the area and born within one week before or after the case. Controls were not matched for any other characteristic. Initially four controls were selected to be used as replacements if necessary.

GsSIDS dataset
For each case, 10 controls were selected that were matched for region, age, gender, and reference sleep. The control infants were recruited through the same or neighbouring local birth registration office where the case was registered. Control infants had been born 4–6 weeks after the case infant, so that by the time the interviews were done they had the same age as the index case (±2 weeks). From the control families who agreed, the three infants closest in age to the index case were selected. A total of 2702 controls were contacted; 58.7% agreed to participate.

Irish dataset
For every case notified to the SIDS register, four controls were selected randomly from the birth register and matched for date of birth and geographical location (same community care area as the index case). If an insufficient number of infants were born in the same community care area on a particular date, then a list of infants born on the two days either side of that date was also used. All families were invited by letter to participate in a standardized home interview. Where no response was obtained from controls families within one week, an additional four letters were sent, after which no further attempt at recruitment/replacement of controls was made. Information was collected on socio-demographics, pregnancy, the infant/child's medical history, the home environment, parenting practices and details of the last 48 hours, and last sleep period with a corresponding reference sleep period used for controls. An average of three controls per case were recruited; in the final dataset, the proportion of cases that had 4 completed control questionnaires was 33%, 3 control questionnaires = 22%, 2 controls = 20%, 1=11%, 6% had >4controls and 7% of cases had no corresponding control data.

New Zealand dataset
Controls were randomly selected from all births, except home births (less than 1%) in the participating regions. Controls had to be born and domiciled in the study region.

The following method was used to select controls:

(a) A date of interview (nominated date) was randomly selected.
(b) The control was then randomly allocated an age and date at interview.

(c) Births by day of the week vary considerably, probably because of induction of labour. The day of birth was adjusted to fit this distribution.
(d) An obstetric hospital was randomly chosen in proportion to the number of births over the previous year.
(e) In hospitals with more than one birth on the selected day random numbers were used to select a particular infant from among those born on the nominated day. For obstetric hospitals where there were no deliveries, a random direction indicator was used to indicate whether to go forwards or backwards in time to select the infant.

Thus, the controls were a representative sample of all live births in the study regions.

For questions on infant care practice that particularly related to the period of sleep prior to the death in the cases, parents of controls were given a nominated time of day which was randomly allocated to ensure that the distribution of this time among controls was similar to the estimated distribution of the time of death of the cases. If the infant was not asleep at the nominated time of day the direction indicator was used to select either the previous or subsequent sleep.

Scottish dataset

We identified babies born immediately before and after the index case in the same maternity unit to act as controls (2 controls for each index case). Controls were therefore matched for age, season, and maternity unit. If no contact could be made with the baby born immediately before the index case (or immediately after), then the baby born immediately before that first attempted control (or immediately after) was also attempted. If neither of the 2 babies born before or 2 babies born after could be contacted and a visit completed within 28 days of the index infant's death then no further attempts were made to contact other baby's parents to act as controls for the index case.

Statistical methods

Missing data

Preliminary analysis, together with the study context, showed that missing values were most plausibly missing at random dependent on study. Therefore, since we include study indicators as covariates, a complete records analysis will give unbiased if somewhat inefficient inference[A1]. To include the information from studies in which alcohol and drug use data were not observed, we used multiple imputation (under the missing at random assumption) to impute missing data. We used the REALCOM-IMPUTE software[A2] with a single level imputation model because alcohol and drug data were too sparse, among the studies in which they were recorded, to obtain convergence for a multilevel imputation model. Missing data were imputed for cases and controls separately. Ten imputed data sets were computed. Using STATA 12[A3] the substantive multilevel model was fitted to each in turn. Convergence was not achieved for one because the likelihood was flat in the region of the maximum; the results for the remaining 9 were combined for inference using Rubin's rules[A4].

Analysis showed that the between imputation variation across the 9 imputed data sets was small relative to the within imputation variance, so 9 imputations were sufficient.

Reliability of results based on observed and imputed data

First, define the *key sub group* as babies < 3 months who were breast fed whose parents did not smoke and whose mother took less than 2 units of alcohol in the last 24 hours and was not a drug user, who either bed shared or room shared. We have data on both maternal and paternal alcohol consumption in the last 24 hours and drug use after birth for two datasets, and for the key subgroup of cases and controls, we have extracted the paternal data from the original records. The unadjusted OR for bed sharing in this group is 5.6 (1.6– 20.3), p = 0.009. And for this group, in both the bed sharing and room sharing groups the control partners had taken slightly *more* alcohol in the last 24 hours than the cases' partners. Consequently, after adjusting for partner's alcohol consumption in the last 24 hours, the OR is 7.7 (1.8 – 32.3), although the OR for partner's alcohol is not significant; OR = 0.73 (0.41 – 1.27), p =0.265.

For cases, belonging to the key subgroup in the three studies for which maternal alcohol use in the last 24 hours was not available , we have checked the original records, most of which include pertinent questions about alcohol use, and ensured that alcohol and drugs were not contributory factors in any.

Second, the prevalence of alcohol and drug use among mothers varies considerably across the studies where the information was collected. For controls, the prevalence of mother having more than 2 units of alcohol in the last twenty four hours (henceforth 'mother using alcohol') ranged from 0 to 9%, and the prevalence of mother using any illegal drug (henceforth 'mother using drugs') ranged from 0 to 0.6%. For cases the corresponding percentages range from 0 to 39% and 0 to 3% respectively. Consequently the ORs for mother using alcohol vary significantly across the studies. However, there is no evidence that the three-way interaction of mother using alcohol, bed sharing and study is significant, p = 0.429. Therefore, the relationship between bed sharing and study does not vary by mother using alcohol. In consequence, the OR for bed sharing is not affected by varying prevalence of mother using alcohol across the studies. For mother using drugs the data are too sparse for the analogous three-way interaction to be tested. However, it seems unlikely it would be significant. In consequence, the OR for bed sharing is not affected by varying prevalence of mother using drugs across the studies.

Third, because the alcohol and drug data are plausibly missing at random, MAR, dependent on study, which is included as an indicator variable in both the substantive model and the imputation model, theory suggests that the point estimates in the complete records analysis should be unbiased,[A5] and within sampling variation of those obtained after multiple imputation. The advantage of multiple imputation here is thus the recovery of information, primarily through the inclusion of the partially observed data from the three studies in which alcohol and drug use were not collected, c.f., Carpenter and Kenwood, p 220.[A5] The results are in line with this, as shown in Table 1, columns 8-11. Also as reported above the OR for the key subgroup is 5.6 (1.6– 20.3). The number of observations in this subgroup are too small to attempt adjustment for other factors like maternal age parity and birth weight. Compare this subgroup OR with the fully adjusted AOR of 5.1 ((2.3 – 11.4) for breast fed babies < 3 month, whose parents do not smoke and whose mother did not take two units alcohol or more in the last 24 hours alcohol. or use drugs. This AOR is also adjusted for all the other factors in the model, see Table 3. The narrower CI results from the recovery of the partially observed data.

Calculation of univariate and multivariate odds ratios

Odds ratios were calculated by logit regression. Univariate analyses were adjusted for age and study because controls were on average 3 weeks older than cases, and the number of controls varied between studies. For multivariate AORs, multilevel logit regression model was fitted with 'bed sharing' random across studies; this was done to take account of a significant interaction of bed sharing with studies. Some other AORs showed significant interaction with studies; however, it was found that these were due to significant deviations in one or at most two studies. When parameters were added to the overall model, to account for these interactions, they had little effect on the main parameters, and only slightly *increased* the estimate of risk associated with bed sharing. The additional parameters were therefore dropped in the final model and these interactions ignored.

The trend in the ln(OR) for bed sharing with age was best represented by a linear downward trend on the logit scale, for the first six months followed by a constant term thereafter. In all four models were used for the analysis:

Model 1. A multilevel logit model of the whole data, including the interaction of age and bed sharing, modelled by the linear trend,

Model 2. To obtain rates applicable to all ages, the same model, excluding the age×bedsharing interaction was fitted, thereby obtaining average AOR for the year.

Models 3 & 4. To obtain average AORs for the first three months and later, a logistic forms of the rates model was fitted to records of infants under 3 months and 3 month or more. Logistic models were used because of convergence problems with multilevel models.

Goodness of fit of the models to the data

Goodness of fit tests are not available for multilevel logit models nor are they available after using Rubin's combination rules for the analysis of multiple imputed data sets. Therefore single level (i.e., standard) logistic models, using the same parameters as the overall model plus fixed effect parameters for study, were fitted to each of the 10 data sets completed with imputed data; both the log link and goodness of fit tests were applied to each. The link tests confirmed that all the models were correctly specified: p(for regression on hat^2) averaged 0.44 and all were> 0.15, and p(for the constant) averaged 0.75 and all were >0.56. The average Hosmer-Lemeshow goodness of fit $\chi^2(48) = 40.3$ was less than expectation. and none had a p value < 0.13. It was, therefore, concluded that the model fit was excellent. Checks on the model, without the age trend, fitted to infants aged <3 months showed equally good fit.

To check the fit of the overall model to the data relating to the breast fed cases, age <3 months, whose parents did not smoke and whose mothers did not consume alcohol or use drugs but who were bed sharing, their deviance residuals were computed. The AOR for this groups is represented by the lower line in Fig 2. As above, the deviance residuals could only be computed after fitting a logistic model to each of the 10 completed data sets. Again, the The results were pooled using Rubin's rules[A4]. It was found that the mean deviance for this group = - 0.098, s.e. 0.1004. Also there was not evidence of any systematic deviation from the fitted line in that there was no evidence of a trend in the residual deviances with age; b = -0.0015, s.e. 0.005.

Similarly residual deviances were computed for this group after fitting model 3. The pooled average residual deviance was -0.147 with s.e. 0.096; p = 0.122. The trend in the residuals was 0.00012 with s.e. 0.005. Thus, there is no suggestion that the model parameters do not represent these crucial data.

The Attributable Fraction

The attributable fraction (of deaths, computed as described by Brussi et al.[29]), was similarly computed for each of the 10 logistic models fitted to the imputed data sets. The results were combined using Rubin's combination rules.[A4]

Mortality rates

Rates were derived from the parameters of Model 2. Rates are given for all infants, computed by a weighted combination of the rates for boys and girls. The base rate for girls was the SIDS rate when none of the model risk factors were present. Then, logit(base rate) = model constant scaled by the addition of the logit of the population SIDS rate and the subtraction of the log(ratio of the number of cases to controls in the model). Combinations of AORs gave other rates from the base rate.

Estimating AORs and Rates for other groups

The AORs computed for other groups, as described on page 7 are approximate because the AORs for the factors which do not interact with age or bed sharing vary, but not significantly, across the 4 models used for the analyses. The AORs shown in the penultimate column of Table 1 are those given by model 2. These differ a little from the comparable AORs given by the Model 1, which includes the age×bed sharing interaction. Thus for the example on page 7, the AOR predicted by model 1 is 4,402 (1,758–11,022) compared with 4514 shown.

When computing SIDS rates for other groups from those give in Table 4, the procedure is similar. However, the observed rate must first be divided by 7.43 to reduce the rate baseline – the rates reported in Table 4 relate the second infant with birth weight 2500 – 3499g of a cohabiting white women age 26 to 30. The appropriate baseline rate, i.e., for various smoking groups may then be scaled up according to the other risk factors present. However, if the computed rate is r > 0.003 per 1000, it should be reduced by $-r^2$, because the scaling is based on AORs and rates are probabilities. Conversely if the starting rate is >0.003 it has first to be scaled to an AOR by adding its square.

For example the estimated SIDS rate for a bed sharing 18 year old cohabiting white mother, with her 1st baby, birth weight 2240g. bottle fed when both parents smoke and mother often has 2+units of alcohol is estimated to be

$$r = \{(0.0275 + 0.0275^2)/7.43\}\times 4.2\times 9.1 = 145.4$$

where:

- 0.0275 = rate from Table 4 when both smoke, mother uses alcohol and baby is bottle fed
- 0.0275^2 is added to obtain the corresponding AOR because the starting rate is >0.003
- /7.43 to obtain the corresponding baseline AOR
- ×4.2 from Table 1 for babies 2000-2499
- ×9.1 from Table 1 for mothers aged 18

Thus, r > 0.003. Hence

$$\text{Predicted rate per 1000} = 1000*(r-r^2) = 125 \text{ per } 1000,$$

which is exact because the AORs in Table 1 are derived from Model 2.

Supplementary tables show predicted SIDS rates for two groups of women other than those in Table 4.

Rates may also be scaled up or down in direct relation to the population SIDS rate. Thus if the population SIDS rate is 0.4 per 1000 instead of 0.5 the the estimated rates will be reduced by 4/5 =0.8.

Supplementary tables of predicted rates for two other groups of women.

a) Cohabiting white women age 30+ with 1st baby birth weight >3500g

Group No.	Risk factors present			Room sharing	Bed sharing	Ratio of rates	
	Feeding	smoking	Alcohol	Rate/1000	Rate/1000	Ratio	95% CI
Baseline	Br	no	no	**0.011**	**0.031**	**2.7**	1.4–5.3
1	**Bot**	no	no	**0.017**	**0.047**	**2.7**	1.4–5.3
2	Br	**P**	no	**0.013**	**0.070**	**5.6**	2.9–10.8
3	Br	**M**	no	**0.018**	**0.171**	**9.7**	4.4–21.7
4	Br	**B**	no	**0.033**	**0.254**	**7.7**	4.3–13.8
5	**Bot**	**B**	**Y**	**0.235**	**3.74**	**16.0**	5.8–44.2

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b) Cohabiting white women age 18 - 19 with 1st baby with birth weight 2000 - 2499g

Group No.	Risk factors present			Room sharing	Bed sharing	Ratio of rates	
	Feeding	smoking	Alcohol	Rate/1000	Rate/1000	Ratio	95% CI
Baseline	Br	no	no	**0.4**	**1.2**	**2.7**	1.4–5.3
1	**Bot**	no	no	**0.6**	**1.8**	**2.7**	1.4–5.3
2	Br	**P**	no	**0.5**	**2.7**	**5.6**	2.9–10.8
3	Br	**M**	no	**0.7**	**6.5**	**9.7**	4.4–21.7
4	Br	**B**	no	**1.2**	**9.5**	**7.6**	4.3–13.6
5	**Bot**	**B**	**Y**	**8.8**	**124.6**	**14.1**	5.7–39.0

References

A1 Carpenter JR, Goldstein H, Kenwood MG. (2012) Statistical modelling of partially observed data using multiple imputation: principles and practice. p20. In: Modern Methods for Epidemiology. Ed. Greenwood DC & Tu Y. Springer, London.2012.

A2 Carpenter JR, Goldstein H, Kenward MG. (2012). REALCOM-IMPUTE Software for Multilevel Multiple Imputation with Mixed Response Types. J Statistical Software. **45** :5: 1-14.

A3 StataCorp 2011. Stata Statistical Software: Release 12.1. College Station, TX: Stata Corporation.

A4 Rubin D. (1987) Multiple Imputation for Non-response in Surveys. Wiley. Chichester.

A5 Carpenter JR, and Kenward MG. Multiple Imputation and its Application. Chichester: Wiley, pp28 and 220.