

The Lullaby Trust: Evidence Base

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Summary

Around 220 babies and toddlers still die every year as a result of sudden infant death syndrome (SIDS), in the UK.

Research has shown that there are several maternal and infant factors which are associated with babies who die of SIDS. While it is clear that not all the factors are modifiable, there are some that are amenable to change in order to reduce the risk of SIDS. As such, The Lullaby Trust, along with many other organisations, provides advice for parents to reduce the risk of SIDS.

The evidence supporting our advice on potential SIDS risk factors for babies under the age of 12 months is outlined in this document. Based on the evidence, a number of factors have been identified as the key, established, modifiable factors associated with either a high *increased* risk of SIDS or *decreased* risk of SIDS, as outlined below. There are also some factors that have been associated with sudden infant death but not necessarily SIDS, which parents should be aware of but need further research to conclusively define their relationship to SIDS risk.

1. Factors associated with an *increased* risk of SIDS:

- 1.1 Unsafe sleeping positions
- 1.2 Smoking
- 1.3 Unsafe sleeping environments, with particular high-risk circumstances highlighted:
 - 1.3.1 Co-sleeping
 - 1.3.2 Temperature and overwrapping
 - 1.3.3 Bedding and mattresses
- 1.4 Alcohol and drug use in pregnancy
- 1.5 Poor antenatal care

2. Factors associated with a *decreased* risk of SIDS:

- 2.1 Room sharing
- 2.2 Breastfeeding
- 2.3 Dummy (pacifier) use
- 2.4 Immunisations

3. Factors in need of further research to determine their relationship to SIDS:

- 3.1 Swaddling
- 3.2 Car seats and other sitting devices
- 3.3 Slings
- 3.4 Signs of ill health
- 3.5 Infant sleep products

Introduction

The Lullaby Trust provides the following definition of sudden infant death syndrome (SIDS), which used to be known as 'cot death':

'Sudden infant death' is the term used to describe the sudden and unexpected death of a baby that is initially unexplained. The usual medical term for this is 'sudden unexpected death in infancy' (SUDI). Some sudden and unexpected deaths can be explained by post-mortem examination, for example infections. Deaths that remain unexplained after post-mortem examination are usually registered as 'sudden infant death syndrome' (SIDS), or sometimes 'unascertained' or 'unknown'. Babies that die suddenly over the age of 12 months may also be registered as 'sudden unexpected death in childhood' (SUDC).

While SIDS is rare, around 240 infants still die every year as SIDS deaths in the UK (see Table 1). The number and rate of SIDS have been decreasing since 1989 but the fall was most marked after the Foundation for the Study of Infant Death (FSID, now The Lullaby Trust) launched the 'Reduce the Risk of Cot Death' campaign in 1991, which encouraged caregivers to change infant sleeping position from prone to supine.¹ In 1989 there were 1,545 SIDS cases in the UK ('sudden infant death', any mention, birth to two years) which fell dramatically to 647 in 1992.²⁻⁵ Similar campaigns to 'Reduce the Risk' were implemented in other countries with subsequent rapid falls in SIDS cases, indicating that these campaigns are effective.⁶⁻¹⁰ There has been a slower decline in the rate of SIDS cases since 1992 and numbers now appear to have stabilised when all sudden, unexpected and unexplained deaths are taken into account, including those classified as 'unascertained'.

Table 1 provides data from UK registries on SIDS cases up to the age of 12 months between 2006 and 2016; the latest available data. The data between nations are not strictly comparable as numbers are recorded in different ways, e.g. whether data includes cases identified as SIDS alone, or also those classified as unascertained or unknown.

SIDS is much rarer in babies over the age of 12 months. In 2016 there were 15 cases in babies aged between 12 and 24 months in the UK (15 in England and Wales, 0 in Scotland and 0 in Northern Ireland).¹¹⁻¹³ This number has remained relatively stable since the early 2000s and has not seen the same decline as SIDS in babies under 12 months.

Year	England & Wales	Scotland	Northern Ireland	UK Total	UK rate per/1,000 live births
2016	219	18	3	240	0.31

2015	191	21	4	216	0.28
2014	217	14	4	235	0.30
2013	252	17	9	278	0.36
2012	234	29	2	265	0.33
2011	247	29	5	281	0.34
2010	261	26	5	292	0.36
2009	283	24	3	310	0.39
2008	287	22	3	312	0.39
2007	273	31	4	308	0.40
2006	285	29	1	315	0.42

Table 1: UK SIDS cases between 2006 and 2016, birth to one year¹¹⁻¹³

What is meant by ‘risk factors’ and ‘reducing the risk’?

There is no advice that guarantees prevention of SIDS but it is possible to reduce the risk. This is based on evidence that looks at the impact of individual risk factors. This document focuses on the evidence underpinning the advice on modifiable risk factors. Odds ratios (OR) are used to illustrate the impact on the level of SIDS risk of different factors.

It should be noted that the statistical evidence within this document demonstrates association with SIDS risk, but does not prove a causal link or mechanistic explanation. In cases where the evidence for an association appears strong, The Lullaby Trust (and many other organisations) feel advice should be given to parents and any other caregiver responsible for an infant, although it is recognised that there is still a lot more to learn about why there may be such associations. In addition, advice may be provided where it is felt that on balance following it may confer a benefit in reducing risk and that any harm from following the advice is minimal. For example, although advice on room temperature is not strongly evidence-based, there is a general consensus among organisations on the temperature to aim for and parents may find the information a useful guide.

This document also presents evidence for some risk factors that may be related to sleep-related accidents rather than SIDS, for example cot bumpers. These deaths are similarly sudden and unexpected, but unlike SIDS may have a cause assigned, such as suffocation (although they may be the ‘external stressor’ in a SIDS death, rather than a cause of suffocation outright – see Triple Risk Hypothesis below). There has been a

‘diagnostic shift’ in some countries, notably the US, where the coding of deaths that might previously be considered SIDS are more likely to be assigned as ‘accidental suffocation or strangulation in bed’ (ASSB), often in the context of bed-sharing or unsafe items in the sleep environment. The distinction between SIDS and a sleep-related accident can be unclear even after investigation, and as such The Lullaby Trust feel that parents should be informed of all risks relating to infant sleep in addition to risk factors specifically linked to SIDS.

The triple risk hypothesis

Data from population (epidemiological) studies indicate that there are numerous risk factors for SIDS that act together to increase or decrease the chance of death. SIDS is therefore thought to be due to multiple factors acting in a given situation. The ‘triple risk hypothesis’¹⁴ has been suggested as a model of how risk factors might act to cause SIDS. This model suggests that SIDS occurs due to a combination of factors including:

1. The infant is vulnerable (e.g. they may have a physiological abnormality of some kind);
2. The infant is at a critical period of development (e.g. the first six months of life, when SIDS is more common);
3. There is an external factor in action that serves as a physiological stressor to the infant is placed prone to sleep, their breathing is compromised by soft bedding, etc.).

Research has identified different risk factors for physiological or developmental vulnerability as well as external factors, and is ongoing into how these factors combine to cause SIDS. This document outlines the identifiable intrinsic factors (e.g. prematurity and low birthweight) that are associated with increased SIDS-risk, and the external, or modifiable, risk factors for SIDS. For more information on some of the physiological vulnerabilities underlying SIDS, see the [Overview of Potential Mechanisms](#) document.

1. Factors shown to increase the risk of SIDS

1.1 Sleeping position

In most countries the traditional sleeping position for babies is on the back (supine). Up until the late 1960s, few babies in the UK slept on the front (prone). However, in the 1970s, babies in special care baby units in the UK were placed prone as this was reported to improve respiratory function in pre-term babies with respiratory distress^{15,16} and reduce vomiting in babies with gastro-oesophageal reflux.^{17,18} In the years that followed this practice was extended to healthy full term babies.

The idea that sleeping position might be associated with SIDS in the UK was first examined in 1965 but the association was not thought to be statistically significant, however later analysis has found it to be so.¹⁹⁻²¹ In the mid-1980s comparisons of SIDS rates in different communities showed that rates were lower amongst those communities that commonly placed their infants to sleep on their backs. This led to the suggestion that avoidance of prone sleeping might reduce SIDS^{22,23} and renewed interest in the association between prone sleeping and SIDS.

Subsequent studies from the UK, the USA, Europe, Australia, New Zealand and Hong Kong have consistently reported that the proportion of infants sleeping prone is significantly higher among SIDS babies than among surviving controls.^{7,8,23-39} For example, a major study carried out in the UK²⁶ found that the odds ratio of a SIDS death was 6.68 (95% CI 2.10-21.92) for infants placed prone as compared with those placed supine, even when a wide range of other factors relating to the mother, the infant and socio-economic conditions was considered. Research from the Nordic countries⁴⁰ and the UK⁴¹ has shown clearly that prone sleeping is particularly dangerous for babies born with low birth weight, both those born preterm (before 37 weeks) and those with intrauterine growth restriction. The odds ratio for infants in the former category was 48.8 (95% CI 19-128) and for those in the latter it was 38.8 (95% CI 14-108), compared with normal birth weight babies slept on their backs.⁴⁰ These infants are also at highly increased risk if placed to sleep on their side.

Publicity in the Netherlands in 1987⁷ and in Australia in 1988²² reduced the proportion of infants placed prone to sleep and the SIDS rate subsequently fell. Since the advice to put babies on their backs has been widely promoted, there have been changes in child care practice in many countries, and most babies now sleep supine.^{8,26,28-30} This change in practice has been accompanied by a fall in the SIDS rate and in some countries appears to explain the fall entirely.²⁸⁻³⁰

Infants who usually sleep supine but who are placed prone are at very high risk of SIDS.^{39,42,43} One study reported an adjusted odds ratio of 8.2 (95% CI 2.6-26) when babies were routinely placed in a supine position for at least two weeks and then were placed prone. A similar increase in risk was found for babies who were accustomed to sleeping supine and then were placed on their side for their last sleep (adjusted odds ratio 6.9, 95% CI 2.3-20.6).³⁹ The first prone sleep appears to be a particularly high risk occasion.²⁶

It is important that care is taken regarding the positioning of the baby from birth as there have been case reports of presumably healthy babies who have been placed in direct skin-to-skin contact with their mothers in the prone position shortly after delivery and then have experienced apparent life-threatening events or suddenly died, termed sudden unexpected postnatal collapse (SUPC).^{44,46} Other risk factors for SUPC are first breastfeeding attempt and co-sleeping, which often takes place in maternity units.^{46,47} A recent analysis in the US found the rate of SUPC in the first week of life was stable between 1994 and 2015, whereas sudden deaths in the postneonatal period declined.⁴⁸ Although SUPC is rare and evidence is mostly limited to case

reports, care should be taken at all times to ensure that the infant's breathing is not obstructed and safe sleep practices are followed.

Back versus side

Sleeping on the side increases the risk of SIDS, as compared with sleeping on the back.^{39,49,50} This may partially be because it is easier for a baby to turn from the side to the prone position, although this is unlikely to be the whole explanation since SIDS infants were more likely to be found in the side position, as well as having been put down on their side.⁴¹ A case-control study conducted in the USA found that infants who were placed on their side to sleep were at twice the risk of SIDS when compared to infants who were last put down on their backs (adjusted OR 2.0, 95% CI 1.2-3.4).³⁹ The same study found the risk of SIDS to be even higher when the infant was placed on their side but found in a prone position with an adjusted odds ratio of 8.7 (95% CI 3.3-22.7).

At least two studies have found that side sleeping is particularly risky if the baby was born prematurely (before 37 weeks gestation) or with low birth weight (<2.5 kg/5.5 lbs), and that the combined risk of low birth weight and side sleeping was more than multiplicative.^{40,41} In one of these reports,⁴⁰ the odds ratio for SIDS was 36.6 (95% CI 13.0-107.0) if the baby was premature and 9.6 (95% CI 4.3-22) if the baby was born light for gestational age, compared with normal birth weight babies slept on their backs.

Health considerations

It is often thought that sleeping healthy babies on the back puts an infant at greater risk of death through aspiration of vomit and choking but there is no evidence to substantiate this.⁵¹ The widespread adoption of the supine position in the UK has been accompanied by a fall in post perinatal mortality rates² and no increase in aspiration death rates.⁵² Similarly in a USA study there was a fall in SIDS incidence but no cases of aspiration.⁵³ With the exception of infants with rare abnormalities such as the Pierre-Robin syndrome, who have abnormally shaped airways, there is no documented evidence of adverse effects of supine sleeping.⁵⁴ Some newborn babies with respiratory distress and others with particular medical problems may benefit from being nursed prone,⁵⁵ and in these cases parents should follow medical advice about sleeping position.

Plagiocephaly

Deformational plagiocephaly (known as 'flat-head' syndrome) refers to the common asymmetric flattening of the infant skull, which may be present from birth or develop postnatally and is often accompanied by abnormal neck positioning (torticollis).⁵⁶ Plagiocephaly was thought to be linked primarily to the supine position for infant

sleep, however this has been challenged by research,⁵⁷ and craniofacial asymmetries and torticollis have been found to be very common among newborns.⁵⁸ Plagiocephaly is associated with developmental delays though is mainly considered an aesthetic issue.⁵⁹ Both positional head deformities and developmental delays are mostly back to within the normal range by the age of 3–5;⁶⁰ however many parents report anxiety about head deformities, and may resort to non-supine sleep positions or use pillows marketed as preventative aids,⁶¹ despite both being risk factors for SIDS. Orthotic helmets can be prescribed for cases of moderate to severe plagiocephaly, but one randomised controlled trial has shown they are not effective, and side effects are common.⁶²

Another randomised controlled trial from 2016⁵⁹ identified some safer measures to prevent or reduce plagiocephaly, including alternating the side of the head held when handling the infant; prone positioning (or ‘tummy time’) when awake; and stretching exercises for the neck should an early imbalance be detected. These recommendations significantly reduced the prevalence of plagiocephaly at three months. An earlier prospective, controlled trial found similar results at four months, when parents were encouraged to allow spontaneous and unhindered movement from birth⁵⁷. Prone positioning when awake can also aid gross motor development, reducing the time taken to reach developmental milestones compared to infants who spent less than 15 minutes a day in the prone position,⁶³ but should only be allowed under adult supervision.

Older infants

As babies get older the sleeping position cannot be controlled, as they will move to find the sleeping position they find most comfortable. It is important to remember that the risk of SIDS decreases after a peak at the age of 1–3 months and that the vast majority of babies sleeping on their front do not die. Furthermore, sleeping position is not the only risk factor that can be changed. Advice is therefore to put a baby on the back to sleep at the start of every sleep period. It is as important to do this for daytime naps as it is for night sleep.⁶⁴ This recommendation should be followed unless there is medical advice to the contrary. If a parent finds that their baby has rolled onto their stomach, the baby should be turned onto their back again, but parents should not feel that they have to get up all night to check. Babies will learn at some point to roll onto their front. When the baby can roll from back to front and back again, on their own, then they can be left to find their own position.

Recommendation:

Parents should be advised that placing an infant to sleep on their stomach or side is significantly associated with an increased risk of SIDS. Infants should always be placed on their backs to sleep at the start of every sleep period. Infants who usually sleep on their back but are unusually placed on the front or side are at a high risk; therefore it is important that babies are put on their backs consistently as part of their regular sleep routine. The risk is further increased in babies who are either pre-term or low

birth weight. Babies should be allowed supervised time in the prone position when awake to avoid development of plagiocephaly and aid motor development.

1.2 Smoking

Evidence from a very large number of studies worldwide consistently demonstrates that maternal smoking both during pregnancy and after the baby is born increases the risk of SIDS.⁶⁵ The risk appears to be dose related. For example, the following odds ratios were found in two separate studies (Table 2):

Study 1 ⁶⁶		Study 2 ²⁶	
Cigarettes per day	Odds ratio	Cigarettes per day	Odds ratio
1-10	2.6	1-9	4.25
11-20	2.8	10-19	6.49
>20	6.9	>20	8.56

Table 2. Smoking during pregnancy and risk of SIDS, by number of cigarettes smoked.

A 2013 meta-analysis of 23 case control studies gave an OR of 2.25 (95% CI 2.03-2.50) for SIDS risk among women who smoked in pregnancy. Heavy cigarette consumption (more than 10 a day) further increased the risk of SIDS (OR 2.30, 95% CI = 1.27–4.18).⁶⁷ It has been suggested that if maternal smoking during pregnancy were eliminated, the SIDS rate would be reduced considerably; for example by up to 30%⁶⁵⁻⁶⁸ or by up to 40–50%.^{69,70}

Smoking during pregnancy is associated with low birth weight, a factor linked to SIDS, but data from research studies shows that this does not explain its importance.^{69,71-73} Prenatal smoking has been associated with SIDS with an OR of 2.7 (95% CI 2.4-3.0).⁷⁴ Smoking still contributes to SIDS when allowance is made for a range of confounding factors such as maternal age,^{27,66,69,71,72,73,75,76} parity,^{66,70,75,76} marital status,^{27,69,70,75} education,^{27,68,70,77} breastfeeding,^{27,69} sleeping position,^{27,69} family situation^{66,70,71} and sex of infant.^{66,69}

Environmental tobacco smoke exposure

Some of the studies of SIDS and smoking during pregnancy make reference to the effects of smoking after birth on the risk of SIDS.^{27,69,75,78,79} However, it can be difficult to distinguish between the effects of smoking during pregnancy and exposure to second-hand smoke after birth. There are studies that do link SIDS to exposure to second-hand smoke after birth.^{65,69,75,80,81} A meta-analysis of 18 case control studies found the risk of SIDS almost doubled for maternal postnatal smoking (OR 1.97 95% CI 1.77–2.19). Smoking more than 10 cigarettes per day increased the OR to 2.65 (95% CI 1.33–2.04).⁶⁷ Environmental tobacco smoking in a European population has been estimated to be responsible approximately for 24-32% of SIDS incidents.⁸² Studies also demonstrate an increased risk if the father also smokes.^{69,78,80,81,83,84} There is also an

increased risk when mothers smoke only after their baby is born⁷² above but the small number of such mothers makes these studies difficult. A study published in 2011 highlighted postnatal smoking as an important risk factor, after adjustment for supine sleeping position.⁸⁵ The odds ratios found were as follows: one parent OR 2.5 (CI 1.2-5), both parents OR 5.77 (CI 2.2-15.5), maternal OR 2.7 (CI 1.0-6.4) and paternal OR 2.4 (CI 1.3-4.5). A study in the USA showed that when the prevalence of smoke-free households with infants increased by 1%, the rate of SIDS declined by 0.47%.⁸⁶ A meta-analysis conducted by the Royal College of Physicians found an increased risk of SIDS for paternal or other member of the household smoking where the mother is a non-smoker (OR 1.45, CI 1.1-2.0).⁸⁷ The US Surgeon General concluded in 2006 that there is sufficient evidence infer a causal link between exposure to environmental tobacco smoke and SIDS.⁸⁸

Smoking cessation

Pregnant women who smoke and would like to quit may be offered nicotine replacement therapy (NRT) if non-pharmacological interventions fail.⁸⁹ There does not appear to be any research conducted specifically on the risk of SIDS and NRT; however a large, randomised, placebo-controlled trial found no increase in infant mortality up to the age of 2 years in women who used NRT patches in pregnancy compared to placebo.⁹⁰ A systematic review found no evidence for NRT increasing the risk of premature birth or low birthweight (risk factors for SIDS) or neonatal death.⁹¹ There is limited evidence on the use of other pharmacological treatments in pregnancy such as varenicline and bupropion, which should not be taken by pregnant or breastfeeding women.⁸⁹

There is no evidence yet relating to electronic ('e') cigarettes and the risk of SIDS although it is hoped that these may be safer than standard tobacco cigarettes.⁹² E-cigarette use is common among women of reproductive age including pregnant smokers⁹³; however research on e-cigarette use among pregnant women has been limited.⁹⁴ The Lullaby Trust is an active member of the Smoking in Pregnancy Challenge Group. This group recommends that pregnant women who find using an e-cigarette helps them to remain smoke-free should not be discouraged from doing so.⁹² There is currently no evidence to show that second-hand exposure to e-cigarette vapour is harmful to others.^{74, 95}, however there are currently no published data on the effect of the chemicals in e-cigarette vapour on the developing embryo/foetus and caution is therefore advised.⁹⁴

Bed sharing and smoking

The risk of SIDS is greatly increased in association with a combination of bed-sharing and smoking by either parent, even if they do not smoke in the bed.^{26,96-100} Parents who smoke should avoid sharing a bed with their infant (see section 1.3.1 below).

Recommendation:

Parents should not smoke during pregnancy or after birth; this applies to both parents. Postnatal exposure to secondhand smoke also puts a baby at risk, therefore it is important to keep a baby out of smoky atmospheres. Bed sharing is unsafe if either parent smokes or the mother has smoked in pregnancy.

1.3 Sleep environment

1.3.1 Co-sleeping

In this document co-sleeping refers to the practice of sharing a bed, sofa, armchair or other surface with an infant for sleep, which can take place either intentionally or unintentionally. A majority of research studies conducted over the past 20 years have found that co-sleeping increases the risk of SIDS, with the level of risk varying according to the sleep environment and individual factors relating to the infant and caregiver. A NICE review of co-sleeping and SIDS¹⁰¹ determined that bias and other deficiencies exist in all of the SIDS case-control examining co-sleeping so far. Consequently NICE cautions us to remember that the cause of SIDS is multifactorial and none of the studies conducted to date provide evidence that co-sleeping causes SIDS, but that the two are linked in some way (i.e. there is an association)¹⁰¹.

NICE reported on co-sleeping rather than bed-sharing because sofa-sharing was combined with bed-sharing for analysis in some of the studies reviewed, however. Those studies that have examined bed and sofa-sharing separately have found a dramatic difference in the strength of any association with SIDS (see below).

Bed sharing

The prevalence of bed sharing in the UK has been estimated as being between 7%¹⁰² and 49%¹⁰³ with an overall prevalence estimate of 13.2% across 9 studies, although some of those with lower prevalence rates included duplicate samples¹⁰⁴. Prevalence studies of bed-sharing often produce inconsistent results within the same population because the survey questions posed about infant sleep location are not standardized and validated tools for assessing bed-sharing practices and prevalence have not been developed¹⁰⁵. This same issue affects case-control studies of SIDS and sleep location¹⁰⁶. A meta-analysis published in 2012¹⁰⁷ (and an earlier review in 1996⁸¹) reported there were no studies showing an association of reduced SIDS for infants who bed-share (that met the inclusion criteria for the analysis) (Figure 1). A previous review also demonstrated that no study had found bed sharing to be associated with a reduced risk of SIDS.¹⁰⁸

A recent study¹³⁶ found no association between SIDS and bed-sharing in the UK in the absence of key hazardous circumstances for infants under 3 months of age, and found an association that was in the direction of protection for infants of 3 months and older. These UK data emphasise there is a greatly increased association between bed-

sharing/co-sleeping and SIDS in the presence of alcohol, drugs, and sleeping on sofas. These are the key circumstances that should be avoided.

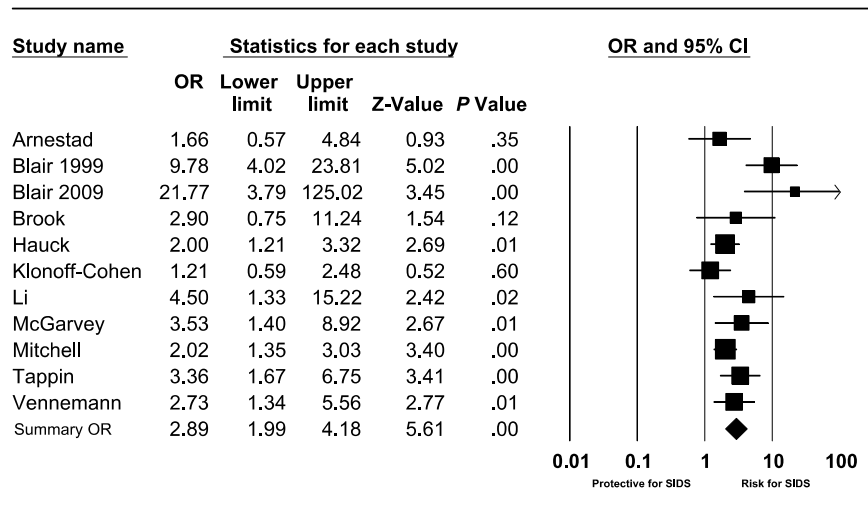


Figure 1. The association of bed sharing and risk of SIDS across 11 studies published before 2012¹⁰⁷.

Sharing a sofa or chair

Studies have found that sharing a sofa or chair with an infant is associated with an extremely high risk of SIDS.^{99, Error! Bookmark not defined., 109} One UK case-control study found an OR of 48.99 (CI 5.04 to 475.60) for sofa-sharing infants.¹¹⁰ In England and Wales approximately one-sixth of infants who died of SIDS were found sleeping with an adult on a sofa¹¹⁰ and similar proportions have been reported in Scotland¹⁰⁰ and Northern Ireland.¹¹¹ Infants who sofa share are at risk of entrapment or overlaying, but are also more likely to be placed in a non-supine position, to have been exposed to tobacco smoke prenatally, and for the sofa to be an unusual sleep location (e.g. parents falling asleep on the sofa accidentally),¹¹² although the sofa is still an extremely risky environment even if it is the customary place for the infant to sleep.

Smoking and bed sharing

It is widely accepted that bed sharing with a baby if either parent is a smoker significantly increases the risk of SIDS, whether or not they smoke in the bedroom, and that smoking during pregnancy is a significant background predictor of SIDS among bed sharing infants.^{26, 96- Error! Bookmark not defined., 110, 113} In a study from 2004,⁹⁶ the risk of bed sharing was 10-fold greater amongst mothers who smoked and, in another paper published in 2012, ^{Error! Bookmark not defined.} the subgroup analysis of four studies for maternal smoking and bed sharing found an OR of 6.27 (95% CI 3.94-9.99).

Some studies have found a small, but statistically significant, increase in risk even if the parents are non-smokers, although the magnitude of the estimated risk is much smaller than for smokers.^{96,99,100,114-116} Figure 2 illustrates the forest plot and odds ratios of the association between bed sharing and risk of SIDS by smoking status found in studies conducted prior to 2012, and analysed in a meta-analysis.^{Error! Bookmark not defined.}

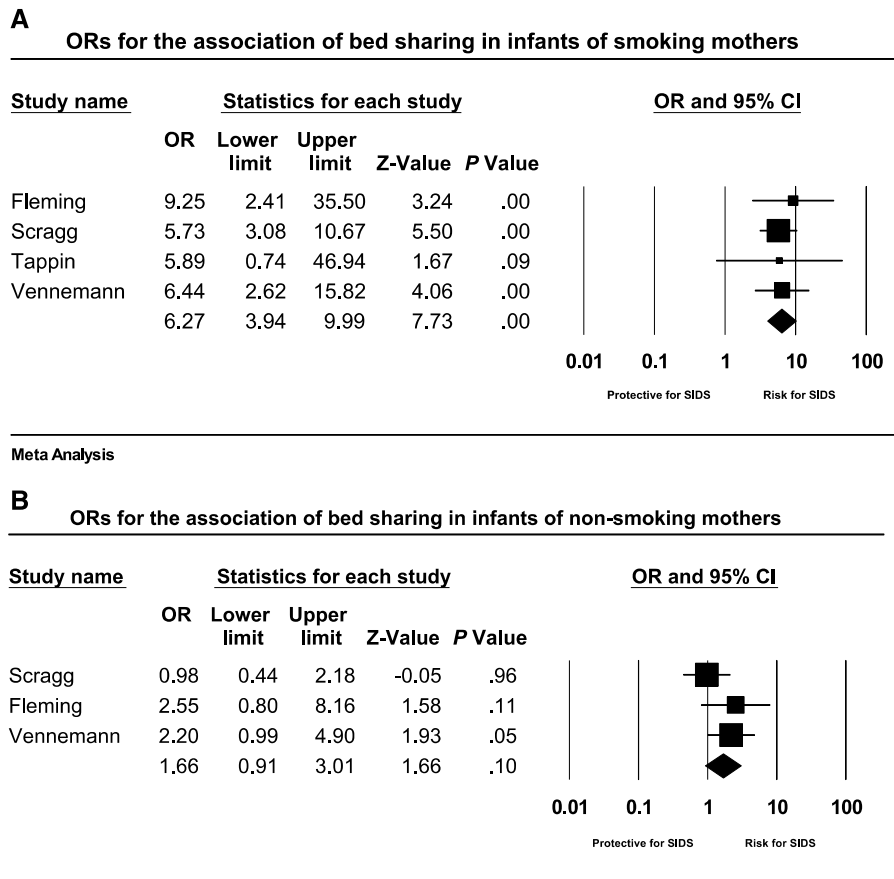


Figure 2. Association of bed sharing and risk of SIDS: A. In infants of smoking parents; B. In infants of non-smoking parents¹⁰⁷.

The risk of bed sharing among non-smoking mothers was an OR of 1.66 (95% CI, 0.91-3.01) in a study from 2012,^{Error! Bookmark not defined.} and 2.09 (95% CI 0.98-4.39) in a study from 2006.⁹⁹ A systematic review of bed sharing from Canada concluded that ‘there may be an association between bed sharing and SIDS among smokers, but the evidence is not as consistent among non-smokers’.¹¹⁷ A more recent study in New Zealand¹¹⁸ found an adjusted OR of 4.96 (95% CI 2.6-9.6) for co-sleeping. However, an accompanying editorial in the same issue pointed out that the Canadian researchers took as their control group infants who were sleeping in a separate cot, without distinguishing between those who slept in the parents’ room and those who slept in their own room.¹⁰⁸ The appropriate control group (i.e. those at lowest risk) are those sleeping in their own cot in the parents’ room, since sleeping in a separate room is known to double the risk.^{96,100,114,119} Lumping these two groups together inevitably reduces the observed risk from bed sharing.

A subsequent study, from 2013, has identified an increased SIDS risk from bed sharing in infants of both smoking and non-smoking parents.¹²⁰ The study revealed that infants who bed share at two weeks of age with parents who both smoke are at a 65-fold increased risk of SIDS compared with infants room sharing with parents who do not smoke. However, the results also showed that even where neither parent smokes, there was an adjusted OR of 8.3 (95% CI 3.7-18.6) in bed sharing infants at two weeks old, and an adjusted OR of 3.6 (95% CI 1.8-7.2) at 10 weeks old. A more recent study in New Zealand¹²¹ found an adjusted OR of 4.96 (95% CI 2.6-9.6) for bed sharing (defined as sharing any sleep surface with an infant), which increased to 32.8 (95% CI 11.2-95.8) when mothers smoked in pregnancy. The report from this study does not differentiate between more or less hazardous sleep locations.

Very young infants, low birth weight infants and premature infants

The risk of bed sharing for non-smoking parents mainly affects infants with low birth weight (<2,500 grams)^{41,100,122} or infants born pre-term (<37 weeks of gestation).¹¹⁰ Younger infant age has often been found to be associated with an increased risk of SIDS.^{96,99} For example, one study¹¹³ found that bed sharing with a young infant (aged less than one month) increased the risk of SIDS sevenfold where either the mother had smoked during pregnancy or was currently a smoker. One study¹²³ found that bed sharing with younger infants (<2 months) is a prominent independent risk factor for SIDS (no correlation was found with other risk factors, including smoking). A study from the Netherlands found that, after adjustment for maternal smoking, the OR for bed sharing compared with non-bed sharing was 9.1 (95% CI 4.2-19.4) below 2 months, falling to 1.3 (95% CI 1.0-1.6) at 4–5 months,¹²⁴ and was not significantly altered by the presence or absence of breastfeeding. Additionally, another study found that, after adjustment for maternal smoking, the OR for bed sharing was 8.02 (95% CI 1.97-32.54) for infants 0-10 weeks old and 6.63 (95% CI 0.95-45.81) for infants 10-20 weeks old.⁹⁹ A very large study from the US suggests that younger infants (<3 months) were particularly at risk from bed-sharing, while rolling into objects in the sleep area is a greater risk factor for infants of four or more months.¹²⁵

Co-sleeping and alcohol and drugs

The risk of SIDS is increased where a parent has used alcohol or drugs, or is excessively tired.^{96,98,Error! Bookmark not defined.,110} One analysis of case-control studies found that where the mother had consumed two or more units of alcohol in the last 24 hours, there was a very substantial increase in SIDS risk when bed sharing (adjusted OR at 2 weeks of age = 89.7, 95% CI 25.3-317.7; at 10 weeks = 38.6, 95% CI 12.6-117.8; at 20 weeks = 13.5, 95% CI 4.6-39.5).¹²⁰ The study also showed that the use of any illegal drugs by the mother, including cannabis, increased the risk 11-fold even when the baby was room sharing and that the risks associated with a drug-using mother who is bed sharing are 'inestimably large'. One case control study¹¹⁰ found the interaction between drug and alcohol use and co-sleeping increased the risk of SIDS by over 50

times (OR 53.26, 95% CI 4.07-696.96). It should be noted that many studies do not have data available on whether the bed sharer had taken drugs or consumed alcohol, or whether they were excessively tired; such missing data may explain some of the inconsistencies in data produced by the studies discussed above.

Co-sleeping and breastfeeding

Bed-sharing is related to prenatal intention to breastfeed⁴ and there is evidence that bed-sharing is associated with prolonged and easier breast feeding¹²⁶⁻¹²⁹ but a causal link has not been demonstrated.^{130, Error! Bookmark not defined.} It is at least as likely that when mothers stop breastfeeding they are less likely to bed share. A large US survey¹³¹, where parents are strongly advised against bed-sharing,^{132,133} found that room sharing without bed-sharing was the norm for the majority of both breastfeeding and non-breastfeeding mothers, although mothers who chose to bed-share were more likely to be exclusively or partially breastfeeding.

A 2013 study found that there was an association between bed-sharing and SIDS (adjusted OR 5.1, 95% CI 2.3-11.4) for breastfed babies less than 3 months old who bed shared with non-smoking parents.¹²⁰ It should be noted that the study defined breastfeeding as where the 'infant was being partially or completely breastfed at the time of death or interview', so it is not known whether there was a difference in the risk of bed sharing between those babies who were partially breastfed or those who were exclusively breastfed.

Hazardous vs non-hazardous co-sleeping

Many parents chose to bed share for a variety of reasons, and in some cultures it is a common practice, and the associations with bed sharing are complex. One cohort study in a bi-ethnic population in the UK found that 15.5% of families had ever bed shared, 7.2% of families regularly bed shared, and 9.4% of families had ever sofa shared with their infants; 1.4% reported both¹⁰⁰. The data showed that bed sharing and sofa sharing are distinct practices, where regular bed sharers were more commonly Pakistani and sofa sharers were less likely to be Pakistani. The association between breastfeeding and bed sharing was greater among white British than Pakistani families, and sofa sharing occurred in association with smoking and breastfeeding for more than eight weeks. The determinants of co-sleeping were found to differ between the UK Pakistani and UK majority communities, and from those of US minority communities. Data from the US showed different patterns of bed sharing across population groups. As such, the study authors suggest we should be cautious about generalising SIDS risk factors across populations.

Some researchers argue that in the absence of key risk factors for SIDS, bed sharing is not inherently dangerous¹³⁴ and blanket advice not to bed share may do more harm by increasing the possibility of more risky accidental co-sleeping, for example on a sofa^{110,135}. A study in 2013 aimed to resolve uncertainty as to the risk of SIDS associated with bed sharing where neither parent smokes and the baby is

breastfed.¹²⁰ This individual patient analysis of pooled data from five case-control studies found that while the association between SIDS and bed sharing decreased with age, there was still a five-fold increase versus room sharing, (adjusted OR 5.1, 95% CI 2.3-11.4) for bed sharing babies less than three months old who were breastfed, where neither parent smoked, and had no other risk factors for SIDS. Smoking and alcohol consumption of parents also greatly increased the bed sharing risk, although a large proportion of this data was imputed as the original data was missing.

A more recent study of 400 SIDS infants in England found that bed sharing was associated with an increased risk of SIDS when parents smoked or had consumed alcohol (OR 18.3 95% CI 7.7–43.5), but notably this risk did not reach significance in the absence of these factors for infants less than three months old (OR 1.6, 95% CI 0.96-2.7) and was in the direction of protection for infants older than three months, a finding that has not yet been replicated elsewhere (OR 0.1, 95% CI 0.01-0.5).¹³⁶ The control group for this study included some infants who slept alone, which as a known risk factor for SIDS might have led to smaller differences in the odds ratios between cases and controls.

Recommendations

In England, the National Institute for Health and Care Excellence (NICE) reviewed the two analyses above and other available evidence on co-sleeping in 2014, and recommended that parents should be informed of its association with SIDS, particularly when parents are smokers, have consumed alcohol or drugs, or the baby was low birthweight or premature.¹³⁷ It should be noted that the guidance grouped bed sharing with sharing sofa or chair, yet the sofa has been shown to be a much more risky environment than an adult bed. The Lullaby Trust strongly advises parents to avoid sleeping with their baby on a sofa, and to avoid bedsharing in association with alcohol or drug use, or with a smoker. We encourage parents to always ensure their baby sleeps in a clear safe space, whether sleeping on their own in a cot or Moses Basket. Some parents will create an alternative space in their beds for their baby. If adults choose to share a bed with their baby in this way, they should be aware of the baby's presence and be familiar with the safer sleep guidance.

However, as also recommended by NICE, it is important to recognise that co-sleeping can happen both intentionally or unintentionally^{138, 137}. As co-sleeping is common,¹³⁹ parents who make an intentional choice to bed share for cultural or personal reasons, or feel it may happen accidentally, should be aware of steps they can take to make it more safe, such as keeping their baby away from pillows or planning what to do if they will be drinking alcohol¹⁴⁰. This risk-reduction approach is echoed in AAP guidelines, updated in 2016, which states it is less hazardous for parents to accidentally fall asleep with their baby on an adult bed rather than on a sofa or armchair. The AAP therefore recommends it may be safer to feed an infant in bed, placing the infant back on a separate sleep surface when the parent awakens.¹⁴¹

Recommendation:

Babies should be placed on their backs for sleep, in a clear safe space, in the presence of a caregiver day and night.

Parents should be made aware that bed-sharing is associated with an increased risk of SIDS where:

- Either parent smokes
- Either parent has consumed alcohol or taken drugs (including medications that may make them drowsy)
- The baby was premature
- The baby was low birth-weight

Co-sleeping on a sofa or armchair is significantly more unsafe than bed-sharing. Parents who choose to bed-share should be made aware of the above risks and of resources that can help them to make the co-sleeping environment less hazardous.

1.3.2 Temperature and overwrapping

Initial reports that overheating arising from high room temperature, excessive insulation (overwrapping) or both, may contribute to sudden infant death were largely circumstantial.¹⁴²⁻¹⁴⁴ Subsequently, case control studies have demonstrated that the level of bedding and clothing (insulation) was significantly higher among babies who died from SIDS than controls,¹⁴⁴⁻¹⁴⁶ and that cases were more likely to have had the heating on all night.¹⁴⁶ There is also evidence to show that overheating interacts adversely with other important factors such as prone sleeping and infection.^{145,147-149} In one case-control study, SIDS was significantly associated with sleeping in the prone position (unadjusted OR 4.5, 95% CI 2.1-9.6) and this association was further strengthened among infants who slept in heated rooms ($p=0.006$).¹⁴⁷ However, when the infants were not placed in the prone position to sleep, this did not have a significant effect. Another study reported that infants sleeping in a prone position and with >2 tog extra thermal insulation above what was needed to maintain the lower critical temperature (temperature below which the metabolic rate is likely to increase) were at a significantly increased risk (OR 6.07, 95% CI 3.83-9.60).¹⁴⁸ Babies should not wear hats for sleep during the day or night as they can increase the risk of SIDS by more than three times (OR 3.12, 95% CI 1.39-7.01).²⁵

Studies that took place before the fall in incidence began in 1989, when SIDS was much more prevalent in the winter months, have shown that the amount of bedding put on babies during winter is often greater than the amount used during the summer, even when the room temperature is the same.^{150,151}

Fever

Some studies have shown that SIDS may occur against a background of minor illness.^{152,153} A number of factors such as fever following an infection, prone sleeping

position, overwrapping or bedclothes covering the head, can affect the thermal balance in a baby by either making the baby too hot or reducing their ability to lose heat. There is a substantial and growing body of evidence that raising the temperature in the upper airway (nasopharynx) of babies may favour the production of potentially dangerous toxins by colonising bacteria (such as *Staphylococcus aureus*), and that these may contribute to the deaths of at least some infants.^{154–156} There is also evidence that some infants may be predisposed to an exaggerated and potentially catastrophic inflammatory response to these toxins, due to minor genetic variations (polymorphisms) in the structure of certain chemicals (cytokines) that are involved in the biological response to infection^{157–159} and that these small variations may partly explain the differing incidence of SIDS in different ethnic groups.¹⁶⁰

Too little insulation

There have been many studies examining the effect of excessive heating and SIDS; however one study found that SIDS can also be associated with too little thermal insulation. A case-control study that took place over three years in New Zealand showed an OR of 2.63 (95% CI 1.61-4.30) when too little thermal insulation was used, after adjusting for a number of variables including demographic, pregnancy, infant and postnatal factors.¹⁴⁸ In addition, an interaction effect was seen when the infants had too little thermal insulation and were not tightly wrapped leading to an increased risk of SIDS (OR 3.81, 95% CI 2.04-7.09).¹⁴⁸ However, examining the effect of too little thermal insulation does not appear to be commonly researched and therefore similar evidence to support these findings was not found in other studies.

There is a consensus view in the UK, not strongly evidence based, that an ambient room temperature of 16-20°C, combined with light bedding or a lightweight well-fitting sleeping bag, offers a comfortable and safe environment for sleeping babies but further research is necessary to establish this with confidence.

Recommendation:

While it is important to ensure that a baby does not get too cold, it is also important to avoid care practices that may result in the baby getting too hot. As such, babies should be checked to ensure that they are a suitable temperature and clothes and bedding are appropriate for the room temperature. Babies should not wear hats indoors or when asleep.

1.3.3 Bedding and mattresses

Soft/loose bedding

The head is an important source of heat loss for a normal baby.¹⁶¹ A high proportion of infants who die as a result of SIDS are found with their head covered with bedding.^{26,51,77,162,163} The use of bedding, which covers the head is an independent risk

factor.⁷⁷ One study reported that the risk was 2.5 times when the infant's head or face was covered with bedding (OR 2.5, 95% CI 1.3-4.6).¹⁶⁴ Bedding, such as quilts, pillows and duvets, is associated with an increased risk of SIDS in the UK.^{26,164,165,166} Pillow use alone has been shown to increase the risk of SIDS by 2.5 times (OR 2.5, 95% CI 1.5-4.2).¹⁶⁴

Infant sleeping bags have risen in popularity in recent years and may have contributed to the reduction to SIDS rates in England by reducing the possibility of head-covering¹¹⁰ and rolling into the prone position.¹⁶⁷ There have been very few studies that have investigated the use of sleeping bags and existing evidence is mixed: one case-control study in the Netherlands¹⁶⁷⁶ found a protective effect (OR 0.30, 95% CI 0.13-0.67), although only for cotton rather than quilted sleeping bags, whereas a larger case-control study in England¹¹⁰ did not find a significant effect. A review of incidents relating to sleeping bags and swaddling reported to the US Consumer Product Safety Commission between 2004 and 2012 found that five of the 36 incidents involved sleeping bags, including one death (in which the infant was placed prone on thick blankets and pillows) and two injuries and two potential injuries (all involving the zipper of the sleeping bag among older infants).¹⁶⁸ This review is not likely to have captured all incidents relating to sleeping bags, however they appear to be at least as safe as sheets and blankets when no other risk factors are present, and when well-fitted around the neck and chest can prevent head-covering and rolling into the prone position.

Soft surfaces

There is evidence to show that soft sleep surfaces are associated with a significant increase in the risk of SIDS.^{164,165} A case-control study conducted over 2.5 years in the USA reported that a soft sleep surface (defined as the infant's head sinking one inch or more into the surface) led to a five-fold increase in the risk of SIDS (OR 5.1, 95% CI 3.1-8.3).¹⁶⁴ Furthermore, this same study showed that placing infants to sleep in the prone position may be especially dangerous when combined with unsafe sleep environments. A significant interaction was found between the prone position for sleeping and the presence of a soft bedding surface with an adjusted OR of 21.0 (95% CI 7.8-56.2). An interaction effect was also seen for sleeping in the prone position and pillow use (OR 11.8, 95% CI 4.0-34.4).¹⁶⁴ Sheepskins have been found to increase the risk of SIDS for infants sleeping in the prone position but not for supine sleepers (adjusted OR 27.92, 95% CI 6.45-120.91).¹⁶⁹ However, when quilts are used, the greater risk of SIDS has been shown to be in infants sleeping in a supine position and particularly in older infants as it may be possible for the bedding to be pulled up over their face.¹⁶⁶

The available evidence indicates that there is an association between sleeping on a soft mattress and increased risk of SIDS. A study in New Zealand, which surveyed SIDS case families and control families, found that soft cot mattresses were associated with a significantly increased risk of SIDS (adjusted OR 2.36, 95% CI 1.06 to 5.25) compared with average and firm mattresses.¹⁷⁰ It was noted, however, that the firmness of the

cot mattress was subjective as no guidelines were provided on this. The American Academy of Pediatrics (AAP) recommend that a surface should be firm enough so that it will not indent or conform to the shape of an infant's head.¹⁷¹

A four-year population based case-control study conducted in England suggested that some risk factors for SIDS have changed over the years and may be helping to cause an overall decline in SIDS rates.¹¹⁰ These factors include a reduction in the thermal insulation of bedding and the widespread uptake of the 'feet to foot' message (i.e. placing the baby's feet to the foot of the cot to avoid them wriggling down under the covers). These factors are intended to keep the head from being covered, a risk which has previously been seen in a high proportion of SIDS victims but was significantly less common amongst the SIDS infants in this study.¹¹⁰ In contrast, this study found that the placing an infant's head or body on a pillow was more widespread in the sleeping environments of the SIDS infants who were included in the study.¹¹⁰

Second-hand mattresses

One case-control study in Scotland assessed the use of a secondhand mattress and the association with SIDS.¹⁷² The study found that routine use of an infant mattress previously used by another child was significantly associated with an increased risk of SIDS (OR 3.07, 95% CI 1.51 to 6.22). Use of a used infant mattress for last sleep was also associated with increased risk (OR 6.10, 95% CI 2.31 to 16.12). The association was significantly stronger if the mattress was from another home (OR 4.78, 95% CI 2.08 to 11.0) but was not significant if it was from the same home (OR 1.64, 95% CI 0.64 to 4.2). However, the study authors conclude that there is insufficient evidence available to judge whether this relation is cause and effect. Several studies¹⁷³⁻¹⁷⁶ have attempted to investigate why this risk may be increased, including increased risk of bacterial carriage and allergens, but the mechanism of any increased risk is not clear. Another earlier case-control study in Scotland from 1997 also found an increased risk of SIDS associated with infants sleeping on a mattress used previously by at least one other infant or adult (OR 2.51, 95% CI 1.39 to 4.52).¹⁷⁷ However, there was no detectable increase in risk with old mattresses completely covered in polyvinyl chloride (PVC), which the authors suggested that this may be because these mattresses can be kept clean whereas others cannot.

Should parents choose to buy a new mattress for a second-hand cot, to avoid the risk of accidents it should be well-fitted to the cot with no gaps around the sides. Using a mattress specifically designed for the cot will ensure the best fit.

Mattress covers

Using a mattress with either integral waterproof PVC coating or a separate waterproof layer has been found to be protective against SIDS in univariate analysis in several case-control studies^{26,178,169} but failed to reach significance when adjusted for other risk factors. Therefore, using a plastic-coated mattress or a separate waterproof cover

is advisable more as a practical measure to help keep an infant's sleep environment clean rather than to reduce the risk of SIDS. Parents may wish to consider using a waterproof mattress particularly if the mattress came from another home. Theories that PVC-coated mattresses or covers (as well as foam mattresses) emitted toxic gases that increased the risk of SIDS have proved to be unfounded.^{179,180,181}

Alternative sleep spaces

Some products marketed for infant sleep, such as hammocks and nests or pods, are not firm and flat and so are not recommended for use by The Lullaby Trust, although their relationship to SIDS has not yet been established. See section 3.5 ('Infant sleep products') for more information. Similarly, accidental deaths have occurred in babies sleeping in sitting devices not designed for this purpose, such as car seats and baby bouncers. See section 3.4 ('Car seats and other sitting devices')

Recommendation:

It is important to keep a baby's head uncovered while they are sleeping; therefore parents should be advised to place their baby on their back in the 'feet to foot' position and the use of pillows, quilts and duvets should be avoided. In addition, babies should sleep on a firm, flat mattress that is clean and in a good condition, ideally new. A mattress with a waterproof cover will help parents to keep it clean and dry.

1.4 Alcohol and drug use

A number of studies have suggested that drinking alcohol or using illicit drugs is associated with an increased risk of SIDS. However, findings are mixed and are complicated by the confounding effects of smoking, which is correlated with both drug and alcohol use, and drug and alcohol use are often related to one another. Substance misuse is also related to other SIDS risk factors such as low socioeconomic status, poor antenatal care and low birthweight,¹⁸² and drug- or alcohol-addicted parents are more likely to have chaotic lifestyles, which can impact infant care and decision-making. Underreporting is likely to be common due to social stigma or illegality of drug-taking,¹⁸³ limiting the power of statistical analyses. Studies are presented here separated into the antenatal and postnatal period, but in reality it is difficult to differentiate the effects of drugs and alcohol use before and after birth. Both alcohol and drug use impair parental decision-making around their infant's safety.^{184,185}

1.4.1 Alcohol

Drinking in pregnancy

In studies that control for smoking and other confounding variables, moderate to heavy alcohol use in pregnancy appears to be related to SIDS as opposed to lighter

drinking. Women with an alcohol-related disorder diagnosed in pregnancy, indicating heavy drinking, have a significantly increased risk of SIDS (adjusted hazard ratio (HR) 3.85, 95% CI 1.53–9.69).¹⁸⁶ Binge drinking (defined as five or more drinks on one occasion) also increases the risk of SIDS (adjusted OR 8.2, 95% CI 1.9-35.3), although only in the three months prior to conception and/or the first trimester, in a study amongst American Indian mothers. Any drinking in the other trimesters was not associated with an increased risk.¹⁸⁷ Binge drinking appears to increase the risk for postneonatal mortality (including SIDS) more generally, as one prospective Danish study¹⁸⁸ found for women who had three or more binge-drinking episodes during pregnancy (adjusted HR 2.2, 95% CI 1.0–4.7). Drinking four or more drinks per week was also found to increase the risk of postneonatal mortality (adjusted HR 2.9, 95% CI 1.2-7.0).

Results from other studies have been less consistent: a retrospective case-control study found no increased risk of SIDS for drinking alcohol during pregnancy,¹⁸⁹ and another Danish prospective study,¹⁸³ found no relationship between any alcohol consumption and a significantly increased risk of death at any point in the first year of life, although women who consumed higher levels of alcohol were underrepresented in the sample. Although there does not appear to be a relationship between SIDS and lighter drinking, guidance from the Royal College of Obstetricians and Gynaecologists in the UK states that as no 'safe' level of alcohol has been established, it is advisable for pregnant women to abstain from alcohol completely.¹⁹⁰

Drinking postnatally

Usual maternal and paternal alcohol consumption after birth is not significantly related to SIDS, although SIDS parents tend to drink more than control parents on average.^{26,167,189,191} Several case control studies^{26,83,167,189} have found that mothers' consumption of at least two units of alcohol in the 24 hours before the final sleep increases the risk of SIDS (for example, adjusted OR 7.83, 95% CI 2.13-28.73).²⁶ Paternal alcohol consumption in the last 24 hours was not significant. Other studies have found either no effect for postnatal drinking at any level of consumption,¹⁹¹ or consumption in the last 24 hours to increase the risk of SIDS only in the context of co-sleeping.⁹⁶ A number of studies have demonstrated the dramatically increased risk of co-sleeping under the influence of alcohol – see section 1.3.1 'Co-sleeping'.

1.4.2 Drugs

Drug use in pregnancy

Many studies have identified an increased risk of SIDS from prenatal exposure to illegal drugs, most commonly heroin and methadone,¹⁹²⁻¹⁹⁴ cocaine^{195,196} and

multidrug use.^{182,195} However these early studies did not control sufficiently for confounders such as quality of antenatal care and low birthweight.¹⁹⁷

A prospective cohort study¹⁹⁸ that controlled for many variables found an increased risk of SIDS with prenatal use of methadone (OR 3.6, 95% CI 2.5-5.1), heroin (OR 2.3, 95% CI 1.3-4.0), methadone and heroin (OR 3.2, 95% CI 1.2-8.6) and cocaine (OR 1.6, 95% CI 1.2-2.2). Maternal cannabis use in pregnancy is less studied but most of the evidence shows no significant association with SIDS¹⁹⁷⁻²⁰⁰ and one study found it increased the risk of SIDS but only at night. (OR 2.35, 95% CI 1.36-4.05).²⁰¹ The risk of postneonatal mortality in general is increased with the use of drugs in pregnancy, as one study of birth records in California found for amphetamine (OR 1.77, 95% CI 2.63-4.64), cocaine, (OR 1.43, 95% CI 4.15-5.59) and multidrug use (OR 2.01, 95% CI 4.21-6.10). However, several other controlled studies have found no effect of drug use in pregnancy on SIDS risk after adjusting for other factors as socioeconomic status, maternal alcohol use and smoking, although SIDS parents were more likely to use drugs than controls.^{26,197}

Postnatal drug use

Like alcohol consumption, evidence for drug use after birth is mixed. Studies have shown that SIDS parents were more likely to use drugs than control parents, but this was not significant in multivariate analysis.^{26,197} However, one case-control study from 20 regions across Europe found an OR of 1.92 (95% CI 1.0-3.7) for maternal drug use after birth.⁹⁶ For drug use in the last 24 hours before the infant's death, one case control study found more parents of SIDS infants (14%) had taken drugs than controls (6%), but the difference was not significant after adjustment for other factors, apart from when parents co-slept with their baby.¹¹⁰ Other studies that have demonstrated the risk of SIDS when co-sleeping under the influence of drugs can be found in section 1.3.1 'Co-sleeping'

Recommendation:

Some evidence shows that heavier alcohol consumption and drug-taking, either in pregnancy or after birth, appears to be related to an increased risk of SIDS, although other factors may impact this. Women have been advised to abstain from drinking alcohol and taking drugs in pregnancy, and parents should carefully consider infant care arrangements for the whole night if they plan to drink or use drugs recreationally, including avoiding co-sleeping.

1.5 Poor antenatal care

Several observational studies have shown that later initiation and fewer antenatal appointments is associated with an increased risk of SIDS.^{26,202-204} In one case control study,²⁰² initiation of prenatal care during the last trimester of pregnancy led

to an almost three-fold increase (OR 2.8, 95% CI 1.1-7.1) and attending fewer prenatal visits also was associated with a significant increase in risk (OR = 1.8, 95% CI 1.3-13.0). However, this study did not control for higher parity, which is likely to influence care-seeking behavior and is more common in SIDS mothers. When parity was controlled for in another study,²⁶ there was still a significantly increased risk for booking care in the second (OR 2.24, 95% CI 1.6-3.14) or third (OR 4.82, 95% CI 2.21-10.50) trimesters. In the UK it is currently recommended that women are booked for antenatal care by 10 weeks of pregnancy, and for uncomplicated pregnancies receive either 10 appointments for a first pregnancy or seven for subsequent pregnancies.²⁰⁵ Receiving adequate antenatal care is especially important for women who have previously lost a baby to SIDS, as they are more likely to experience pregnancy complications such as preterm birth and intrauterine growth restriction in subsequent pregnancies, increasing the risk for recurrent SIDS.²⁰⁶

Recommendation:

Receiving timely and regular antenatal care is associated with a lower risk of SIDS. All women should receive the recommended number and schedule of appointments during pregnancy.

2. Factors shown to be associated with lower risk of SIDS

2.1 Room sharing

There is evidence that when infants are placed in the same room as their parents, but they do not share the same sleep surface (i.e. room-sharing not bed-sharing), a significant decrease in the risk of SIDS is seen.^{96,114} A large study combining case-control studies from 20 regions across Europe showed the risks of SIDS in multivariate ORs of 0.48 (95% CI 0.34-0.69) and 0.32 (95% CI 0.19-0.55) when a room was usually shared and when a room was shared in the last sleep, respectively.⁹⁶

Babies should sleep in the same room as their parents during the day as well as night. One case control study found that the risk of unsupervised sleep during the day was almost double that of unsupervised sleep at night (adjusted OR for daytime sleep 10.57, 95% CI 1.47-75.96 vs nighttime sleep 5.38, 95% CI 2.67-10.85).⁶⁴ A travel cot, Moses basket, playpen, or carrycot is suitable for daytime sleep provided other safer sleep advice is followed.

Recommendation:

Parents should be advised that a baby should have a clear safe space to sleep in for the first six months and should sleep in the same room as the parents, day and night.

2.2 Breastfeeding

As long ago as 1965, Carpenter and Shaddick showed that babies who died of SIDS were significantly less likely to be exclusively breastfed than control infants who did not die at all ages between birth and three months.²⁰⁷ Several published studies, but not all, have found that breastfeeding is associated with lower risk of SIDS. One meta-analysis, in 2000, of 23 reports²⁰⁸ concluded that formula-fed infants had a death rate from SIDS that was twice that of breastfed infants. In 2007, the USA Agency for Healthcare Research and Quality (AHRQ) performed a more stringent meta-analysis²⁰⁹ incorporating 6 studies in which SIDS was rigorously defined and the duration of breastfeeding specified.^{109,210-212} They found that ever breastfeeding was associated with a lower rate of SIDS compared with never breastfeeding, with an adjusted odds ratio of 0.64 (95% CI 0.51-0.81). A study from Germany²¹³ found that both partial and exclusive breastfeeding was associated with lower SIDS rates, after adjustment for the effects of maternal smoking, bed sharing and the use of a pacifier (dummy) during the last sleep.²¹⁴

A meta-analysis published in 2011 supports the findings that breastfeeding is associated with lower rates of SIDS.²¹⁵ An adjusted analysis that compared any duration of breastfeeding against formula feeding reported an odds ratio of 0.55 for breastfeeding (95% CI 0.44-0.69) (Figure 4A). Exclusive breastfeeding (no intake of formula milk) was associated with the lowest risk, with an adjusted odds ratio of 0.27 (95% CI 0.24-0.31) (Figure 4B).

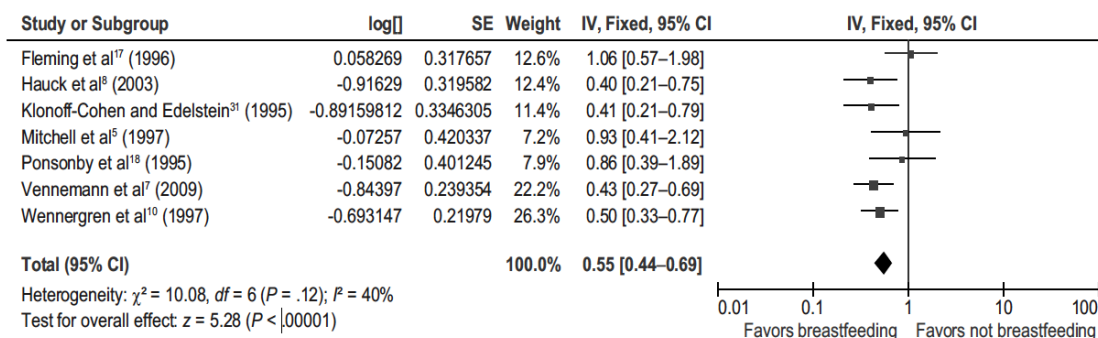


Figure 4A: Multivariable analysis comparing the effect of any duration of breastfeeding against no breastfeeding on the risk of SIDS.²¹⁵

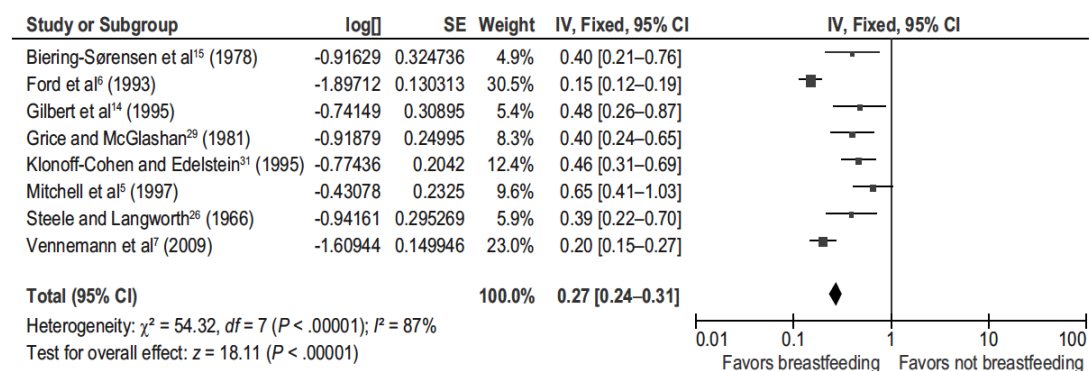


Figure 4B: Multivariable analysis comparing the effect of exclusive breastfeeding against no breastfeeding on the risk of SIDS.²¹⁵

The most recent meta-analysis,²¹⁶ published in 2017, examined the relationship between duration of breastfeeding and decreased SIDS risk. Eight international case-control studies were included, of which three controlled for all 19 identified potential confounders. Multivariate analysis showed that any breastfeeding (i.e. exclusive or mixed with formula feeding) for at least two months was protective, with greater protection seen with increased duration (2–4 months: adjusted OR: 0.60, 95% CI 0.44–0.82; 4–6 months: aOR: 0.40, 95% CI 0.26–0.63; and >6 months: aOR: 0.36, 95% CI 0.22–0.61). Exclusive breastfeeding was also found to confer protection after two months, (2–4 month: aOR: 0.61, 95% CI 0.42–0.87) and longer duration increased the protective effect; 4–6 months: aOR 0.46, 95% CI: 0.29–0.74). The analysis did not find evidence of a greater protective effect from exclusive breastfeeding compared to any breastfeeding.

For studies that examine the relationship between breastfeeding and bed-sharing, see section 1.3.1 ‘Co-sleeping’.

Recommendation:

Breastfeeding, either exclusively or in combination with formula milk, is associated with a reduced rate of SIDS in women where there are no contraindications that advise not to breastfeed. The minimum duration of breastfeeding needed to confer protection against SIDS is at least two months, with greater protection seen for longer durations of breastfeeding.

2.3 Dummy (pacifier) use

The use of dummies (also termed 'pacifiers' or 'soothers') excites strong feelings both for and against, largely determined by prevailing social custom and tradition rather than by scientific evidence of benefit or harm. A study group set up by the American Academy of Pediatrics (AAP) conducted a meta-analysis²¹⁷ of eight studies of the effect of dummy use on the risk of SIDS, seven of which met the investigators' criteria for inclusion.^{96,115,164,172,218-220} Multivariate analysis showed that 'usual' dummy use was associated with lower risk (odds ratio of 0.71, 95% CI 0.59-0.85), and that use of a dummy during the last or reference sleep even more so (odds ratio 0.39, 95% CI 0.31-0.50). A second meta-analysis²²¹ similarly showed a reduced risk of SIDS with usual dummy use (pooled OR 0.83, 95% CI 0.75–0.93) and for the last sleep (pooled OR 0.48, 95% CI 0.43–0.54). Another study from California,²²² published too late to be included in the meta-analyses, supported the association between dummy use and SIDS (adjusted odds ratio 0.08, 95% CI 0.03-0.21). A 2017 Cochrane systematic review found no studies on dummies and SIDS that met their eligibility criteria (i.e. randomised controlled trials (RCTs)) and therefore could not refute or support the use of dummies as a strategy to reduce the risk of SIDS, although the authors noted the practical and ethical issues inherent in conducting RCTs on SIDS risk factors.²²³

The evidence from observational studies for dummy use as a protective factor against SIDS is highly consistent, although the mechanism of action remains unclear.²²⁴ Based on the available evidence bodies such as the AAP recommend that parents consider offering infants a dummy once breastfeeding has been established, typically at about one month of age.²²⁵ The dummy should be gently withdrawn between six and 12 months of age, since possible adverse effects associated with dummy use (ear infections, dental malocclusion) have not been described below one year.

Two studies^{115,218} have suggested that if an infant who is accustomed to dummy use is not given one on a particular occasion, the degree of protection may be less than during sleep periods when a dummy is given, so if a baby uses a dummy as part of his or her general routine it should be given for every sleep period, day and night.

It has been suggested that dummy use may be negatively associated with breastfeeding but more recent evidence suggests that that dummy use might not be

as harmful to breastfeeding as previously believed. When this relationship is analysed statistically it appears that dummy use is more likely to be a consequence of breastfeeding difficulties than a cause of them.²²⁶ A systematic review of four prospective, randomised controlled trials showed no evidence of an adverse effect of dummy use on breastfeeding rate or duration, when the dummy was introduced after the first week of life.²²⁷ A Cochrane systematic review and meta-analysis of two RCTs similarly concluded that dummy use had no effect on the number of infants exclusively (risk ratio (RR) 1.01; 95% CI 0.94-1.09) or partially (RR 0.99; 95% CI 0.97-1.02) breastfed at four months of age.²²⁸

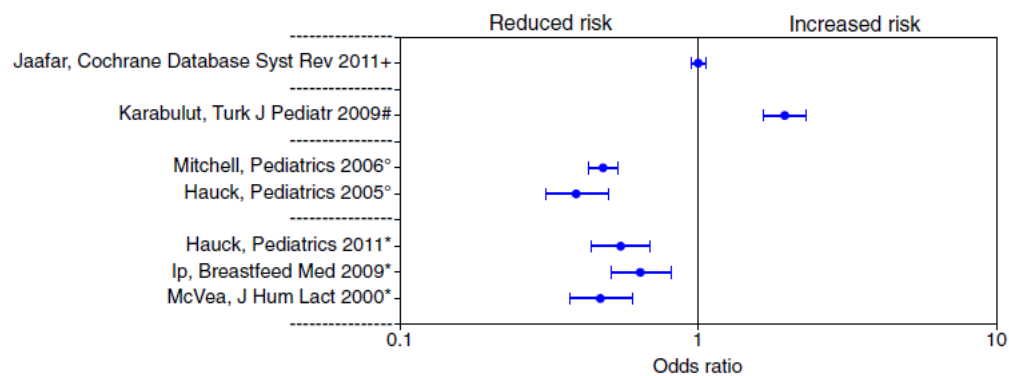


Figure 5: Pooled odds ratios from meta-analyses of: (+) two randomised controlled studies on the effect of a dummy on breastfeeding duration, (#) observational studies on the effect of a dummy on shortened breastfeeding, (°) observational studies on the effect of dummy use on sudden infant death syndrome (SIDS) and (*) observational studies on the effect of breastfeeding on SIDS.²²⁴

Recommendation:

The use of a dummy is associated with a reduced the risk of SIDS and parents should consider offering a dummy when settling the baby to sleep. The dummy should gently be withdrawn between the ages of six to 12 months to avoid any potential adverse effects. It is important to ensure that:

- The use of dummies is consistent within the baby’s sleeping routine
- A dummy is not forced on the infant or replaced if it falls out once the baby is asleep
- The dummy does not have any attachments on it
- The dummy is never coated with something sweet

If the mother chooses to breastfeed, breastfeeding should be established for at least a month before the dummy is introduced.

2.4 Immunisations

Most cases of SIDS occur between 2 and 4 months of age, the same time at which infants receive their first series of immunisations. This observed temporal association, and a 1974 report linking neurological reactions to the pertussis (whooping cough) vaccine, prompted fears that there was a causal link between SIDS and immunisation. The influence of anti-vaccine groups in the UK and other countries led to a fall in coverage of the diphtheria-tetanus-pertussis (DTP) vaccination and a concomitant rise in rates of pertussis.²²⁹ However, subsequent studies have shown that not only is there no increased risk of SIDS from vaccines such as DTP^{230,231} (now administered as part of a '6-in-1' injection at 8, 12 and 16 weeks in the UK²³²), immunised infants actually have a significantly lower risk of SIDS.

Several case-control studies such as from England, France, New Zealand and Germany have demonstrated the protective effect of immunisations against SIDS.^{26,233-235} Others also found a protective effect but did not control effectively for confounding variables such as maternal education and socioeconomic status, which are related to immunisation.²³⁶ A 2012 meta-analysis²³⁶ of controlled studies found an adjusted OR of 0.54 (95% CI 0.39–0.76), indicating that immunisation halved the risk of SIDS.²³⁶ An earlier meta-analysis²³⁷ found a similarly protective effect (OR 0.67, 95% CI 0.60–0.75). Furthermore, two analyses of incidents reported to the US Vaccine Adverse Event Reporting System (VAERS) between 1990–1997²³⁸ and 1997–2013²³⁹ found no evidence for a relationship between infant vaccines and SIDS, and that the fall in incidence of SIDS coincided with the start of the Back to Sleep campaign, a finding that has also been observed in the UK.²⁶ The earlier VAERS data, along with findings from epidemiological studies, was reviewed by the US Institute of Medicine in 2003 and it was concluded that a causal relationship between multiple vaccines and SIDS, and between the DTP vaccine and SIDS, could be rejected.²⁴⁰ A more recent ecological study has confirmed that there is an inverse relationship between DTP immunisation and SIDS in the US.²⁴¹

Parents should be aware that fever and other signs of illness are common side effects of the '6 in 1' vaccine.²³² Some parents may overwrap infants they perceive to be unwell but this could potentially increase the chance of SIDS – see section 1.3.2 '*Temperature and overwrapping*'.

Recommendation:

Immunisation is associated with a reduced risk of SIDS. Parents should be advised to ensure their infant receives all scheduled vaccinations.

3. Factors in need for further research to determine their relationship to SIDS

3.1 Swaddling

Swaddling is a common practice used to help settle babies and promote sleep. As an inability to arouse from sleep if there is a respiratory or cardiovascular challenge may be a contributor to SIDS,²⁴² studies have been conducted to examine more closely the effect of swaddling. The evidence to date for swaddling is not consistent. It has been shown that placing a swaddled infant in the prone position can increase the risk of SIDS;^{147,243} however the evidence is less clear for swaddled infants placed on their back. Some studies have suggested that swaddling is not a risk factor for infants who are placed in a supine position and may even reduce the risk of SIDS.^{147,244} If an infant is immobilised then they are unable to pull covers over their head or crawl into a potentially dangerous situation. However, out of 18 incidents relating to swaddling reported to the US Consumer Product Safety Commission between 2004 and 2012, 10 of the infants were placed supine and rolled prone (the others were either placed prone or there were other hazards in the sleep environment). No deaths were attributed to SIDS; the majority were positional asphyxia.²⁴⁵ One study found a significant risk from infants being swaddled for their last sleep (OR 31.06, 95% CI 4.21–228.94) but importantly the analysis was not stratified according to sleep position.¹¹⁰ In contrast, a case-control study conducted in the USA over 2.5 years reported that potential thermal factors including swaddling and sweating of the infant were not associated with an increased risk of SIDS; however again it is important to highlight that the sleep position of the swaddled infants was not specified.¹⁶⁴

A meta-analysis²⁴³ that combined data from four observational studies did not find a significantly increased risk for swaddling overall (although was borderline: OR 1.58, 95% CI 0.97–2.58, $p=0.06$). The degree of variability between studies was high; when one study was excluded to decrease variability the association became significant (OR 1.38, 95% CI 1.05–1.80 $p=0.02$). The risk of SIDS increased with age, with the highest risk for infants six months or older (OR 2.53, 95% CI, 1.21–5.23). Infants placed on their front (OR 12.99, 95% CI 4.14–40.77) or side (OR 3.16, 95% CI 2.08–4.81) to sleep had the highest risk, but there was also a small but significant risk for infants placed supine (OR 1.93, 95% CI 1.27–2.93). Data for position placed and found in were limited, but it was more common for SIDS infants to be found prone after being placed supine or on the side than controls, and the average age for these infants was 3.5 months.

Studies have examined the effects of swaddling on infant arousability as impaired arousal may contribute to SIDS.^{246,247} It was demonstrated that swaddling decreased infant arousability from sleep and was most apparent in babies who were more easily aroused from sleep when unswaddled.²⁴⁶ No effect on arousal was seen in infants who were routinely swaddled but full cortical arousal was reduced at three months of age in infants who were swaddled but were not used to this practice as part of their regular routine.^{246,247} This suggests there may be a potential risk of exposing infants to irregular sleeping practices, but further research is still needed to investigate the

mechanisms involved in reduced arousal when swaddled. It was also shown that while swaddling increased respiratory frequency, these rates remained within normal limits and the baseline heart rates, temperatures and oxygen saturation were not affected.²⁴⁶

Further evidence is needed to establish whether the risk of SIDS is increased in swaddled infants in the supine position. The number of studies conducted is small and definitions of swaddling varies between them.[Nelson 2017] Currently, the risks of swaddling in the supine position appear to be limited if it is done correctly and routinely from birth or early infancy.²⁴⁸ Swaddles should not be applied very tightly around the hips as this is strongly associated with developmental dysplasia of the hip.²⁴⁹ However, the swaddle should also be secure enough not to come apart, as loose soft bedding can increase the risk of SIDS.

Recommendation:

Further evidence is still required before a firm recommendation can be made on swaddling but parents who wish to practice this method should be informed how to do this correctly to reduce the risk. Swaddled infants should not be placed prone or on the side, and it is advisable to discontinue swaddling when the infant starts to learn how to roll. Infants should be swaddled securely to reduce the risk of overheating and face-covering, but more loosely around the hips to avoid hip dysplasia. Babies should never be swaddled when bed-sharing.

3.2 Car seats and other sitting devices

A 2014 study of sudden unexpected infant deaths over a 16-year period revealed 14 car seat-associated deaths from a total of 1,465 infant autopsies.²⁵⁰ Four involved infants who were being appropriately transported in the car seat, all of whom had a medical underlying cause of death (infection or congenital heart disease). The other 10 cases occurred while car seats were being inappropriately used (i.e. not for the purpose of transporting the child in a motor vehicle), outside of the car, including as an alternative to a cot or highchair. Five of these infants died of explained causes but four deaths remained unexplained after autopsy and in one no cause of death was available in the study database. There were no cases of previously healthy infants dying unexpectedly in a car seat when it was being used appropriately. The majority of the deaths occurred in infants below two months of age and only one infant was over the age of six months. The study authors conclude that infant deaths in car seats are rare but these data support the recommendation that car seats are only used for transport and not as alternatives for cots or highchairs.

A small number of sudden infant deaths or life-threatening events have occurred when the baby was in a car seat, according to several case report studies. A cohort study of all sudden and unexpected deaths of children younger than one year of age, between 1991 and 2000, was carried out in Quebec.²⁵¹ The study found that 10 deaths occurred while the infants were seated in a car seat; five of these were diagnosed as

SIDS. Infants less than one month of age accounted for an increased proportion of the deaths. The study authors concluded that although very few deaths occurred in car seats, their results suggest that caution should be used when placing younger infants in car seats and similar sitting devices, as time spent in the sitting position might be relevant, whether the infants have been born prematurely or not.

An Australian review of 30 cases of accidental asphyxia occurring in infants and young children who had been left to sleep unattended, between the years 1966 to 1993, identified two cases of infants who died while in a car seat.²⁵² Another study in New Zealand prospectively examined all infants referred to the Auckland Cot Monitoring Service after an apparently life threatening event in early infancy during 18 months between July 1999 and December 2000.²⁵³ Of the total of 43 infants referred to the service for evaluation after apparently life threatening event (all infants had been seen on one or more occasions to develop cyanosis or to turn pale, and the caregivers thought the infants were not breathing), nine infants had been restrained in a car seat appropriate for their age; all but one seat was rear facing and semi-reclining. The position of the infant appeared to be associated with the life-threatening events and all infants were very young (median age five weeks). Following these events parents were advised on positioning and told not to leave the infant for excessive periods in the car seat.

There is little evidence on the use of other sitting devices (such as bouncers, pushchairs and swings) and sudden infant death. One 2015 study that reviewed incidents reported to the US CPSC between 2004-2008 in babies up to the age of two, identified 47 incidents in sitting devices that included 31 deaths in car seats, four in bouncers, three in pushchairs and four in swings.²⁵⁴ Positional asphyxia (generally caused by airway obstruction due to the extreme flexion of the infant head in an unsupported seated position) was the cause of death in around half of car seat cases and almost all pushchair, swing and bouncer deaths. The other half of car seat deaths were due to strangulation from straps. Out of the cases for which information about how straps were used was available, it was common for straps not to be used appropriately, for example being only partially or loosely buckled. Almost all (89%) of the car seat deaths occurred outside of a car, which the authors suggest infers that a properly-used car seat poses little risk to infants. The review also found that is not just younger babies who are at risk in sitting devices, as car seat deaths occurred up to the age of two and for other sitting devices up to the age of eight months.

Aside from the risk of positional asphyxia and strangulation, injuries have also been reported when sitting devices such as car seats and bouncers fall from high surfaces or overturn on soft surfaces such as beds.²⁵⁵[Parikh 2010] Parents should be cautioned against using these products on any unstable or elevated surface.

Recommendation:

Car seats are necessary for transporting infants in a moving vehicle. There is little evidence on car seats and other sitting devices and SIDS; however, the data available indicate that improperly-used devices can pose a risk of accidental asphyxia or

strangulation. Therefore parents should be advised to follow the guidance on the correct positioning of infants and to supervise them at all times. If an infant falls asleep in a car seat or sitting device they should be moved to a flat surface when it is safe to do so. Car seats should only be used for transportation, and no sitting device should be placed on a high or soft surface.

3.3 Slings

While large studies have not been undertaken to assess whether there is any association between the use of baby slings and SIDS, two smaller case series have reported sudden infant deaths in slings. A review of cases in France published in 2015²⁵⁶ included 19 deaths, 10 of which occurred in a soft material carrier and nine in a more structured strap-on carrier. All infants were under four months, and most under three. Post mortem data were only available for 11 cases, in which suffocation was the cause of death for the majority. Almost all deaths took place in winter, which the authors suggest points to the contribution of overwrapping and high room temperatures. Batra *et al.*²⁵⁷ report on five deaths in slings, all attributed to positional asphyxia and between the ages of 10 days and five months.

Caution on the use of slings has been issued by Health Canada,²⁵⁸ the US Consumer Product Safety Commission²⁵⁹ and Australian Competition & Consumer Commission,²⁶⁰ as well as The Royal Society for the Prevention of Accidents (RoSPA)²⁶¹ in the UK. Guidance on safe usage is provided by various organisations in the UK, including RoSPA and consumer organisation Which?.²⁶² The information from these two organisations points towards the guidance given by the UK Sling Consortium²⁶³ which provides the following advice to baby sling wearers:

When you're wearing a sling or carrier, don't forget the 'T.I.C.K.S':

- **Tight** - slings and carriers should be tight enough to hug your baby close to you as this will be most comfortable for you both. Any slack/loose fabric will allow your baby to slump down in the carrier which can hinder their breathing and pull on your back.
- **In view at all times** - you should always be able to see your baby's face by simply glancing down. The fabric of a sling or carrier should not close around them so you have to open it to check on them. In a cradle position your baby should face upwards not be turned in towards your body.
- **Close enough to kiss** - your baby's head should be as close to your chin as is comfortable. By tipping your head forward you should be able to kiss your baby on the head or forehead.
- **Keep chin off the chest** - a baby should never be curled so their chin is forced onto their chest as this can restrict their breathing. Ensure there is always a space of at least a finger width under your baby's chin.
- **Supported back** - in an upright carry a baby should be held comfortably close to the wearer so their back is supported in its natural position and their tummy and chest are against you. If a sling is too loose they can slump which can

partially close their airway. (This can be tested by placing a hand on your baby's back and pressing gently - they should not uncurl or move closer to you.) A baby in a cradle carry in a pouch or ring sling should be positioned carefully with their bottom in the deepest part so the sling does not fold them in half pressing their chin to their chest.

Photos of the correct positioning are also provided on the website.

Recommendation:

There is currently a lack of data on the use of baby slings and SIDS. However, parents who wish to use baby slings should be advised to follow the guidance on their safe use as a precaution. Younger infants may be particularly at risk.

3.4 Signs of ill health

Most SIDS babies are apparently healthy prior to death.²⁶⁴ Several studies have reported signs of illness among SIDS babies^{265,266} and a higher incidence of minor illness and/or infection amongst cases than controls.^{24,26,153,267} Signs of serious illness before death have been reported in 44% of babies who died suddenly where the cause was later found and in 11% of babies who died as SIDS.²⁶ However, these investigations were undertaken before the widespread implementation of supine sleeping, and a report from Germany suggested that SIDS infants put to sleep in the supine position are no more likely to have shown evidence of illness in the days preceding the death than surviving control infants.²⁶⁸ A more recent study, published in 2012, showed a decrease in the percentage of SIDS infants with upper respiratory tract infection (URTI) symptoms when comparing cohorts in 1991-1993 and 1996-2008 in San Diego. The decline was attributed to fewer infants prone sleeping, with a trend ($p=0.08$) identified between prone sleeping and URTI.¹²³ This suggests that the pathogenesis of SIDS is complex and likely to involve the combination of multiple risk factors.^{123,269} Single risk status for URTI was assessed in a 2010 study and was found to be evident in 10% of cases.²⁷⁰ URTI was identified in this study as the second highest non-modifiable risk factor. Another study that looked at the presence of bacteria *Staphylococcus aureus* found that 40% of unexplained SIDS cases presented as positive for the bacteria.²⁷¹

A study based on infants recruited into the CONI (Care of Next Infant) scheme in the UK, found that parents of infants who subsequently died were significantly more likely to record non-specific signs and symptoms than parents of infants who survived, although these occurred throughout the life of the baby rather than in a close temporal relation to the time of death.²⁷² While doubt remains, the recommendation that medical advice should be sought if a baby shows signs of illness that persist for more than 24 hours continues to seem prudent. Although most parents and doctors know when a baby is unwell, in a proportion of babies the severity of a baby's illness may not be fully recognised. Watson in 1978²⁷³ found that parents underestimated the severity of the illness in SIDS babies by 39%, and by doctors in 28%, of the cases

studied. A similar failure to recognise the symptoms of serious illness was reported in another study¹⁵² where the authors stressed the importance of non-specific signs, such as unusual drowsiness, altered character of cry or excessive sweating, as possible indications of serious illness.

A scoring system has been devised as the result of the FSID-funded Baby Illness Research Project, called 'Baby Check'^{274, 275} to help parents and health professionals assess the severity of acute systemic illness in babies less than six months of age, according to the combination of signs present. It has been suggested that using Baby Check could help reduce the rate of sudden death from all causes.

Recommendation:

Although the exact role of infant infection in SIDS is not well understood, it is recommended that medical advice should be sought if a baby shows signs of illness that persist for more than 24 hours.

3.5 Infant sleep products

Items such as cot bumpers, sleep positioners, pods, wedges, and specially-designed pillows are commonly advertised to parents with purported benefits including preventing accidents, treating gastroesophageal reflux, avoiding the development of plagiocephaly, and even preventing SIDS. It should be noted that no epidemiological research has been conducted to evaluate whether any such product increases or decreases the risk of SIDS; however, analysis of consumer safety reports in the US has implicated some products in infant deaths involving suffocation, strangulation and entrapment.²⁷⁶⁻²⁷⁸

Thirteen babies died in sleep positioners (devices designed to hold infants in one position, sometimes referred to as nests) in the US between 1997 and 2011, in cases reported to the CSPC. In most cases infants were placed on their sides to sleep and suffocated against the positioner.²⁷⁸ Deaths in positioners led to the US Food and Drug Administration (FDA) issuing warnings against their use in 2012 and again in 2017,²⁷⁹ prompting many UK retailers to withdraw them for sale.²⁸⁰ Some parents may be recommended to use a positioner or wedge due to their baby's medical condition, in which case its use should be discussed and reviewed by a healthcare professional.

'Pods' are soft sleep surfaces with raised or padded areas that are designed to enclose a sleeping baby. As they are relatively new to the market there is no research evidence on their relationship to SIDS or sleep-related accidents; however as sleeping on a soft surface can at least double the risk of SIDS,^{164,170,246} The Lullaby Trust recommends that infants should only be slept on firm and entirely flat surfaces.

Deaths have been reported in baby hammocks, although this is limited to case series data.²⁸¹ One small randomised controlled trial²⁸² investigated the effects of sleeping in a baby hammock on oxygenation, as the shape of the hammock could compromise

an infant's airway by bringing the chin closer to the chest, but found no significant difference to infants sleeping in a bassinet. Despite this the authors note the dangers of infants easily rolling into the prone position in a hammock and warn against their use.

Cot bumpers

Cot bumpers were implicated in 27 infant deaths and 25 non-fatal accidents reported to the US CSPC between 1985 and 2011.²⁷⁶ A follow-up study²⁷⁷ found the number of reports of deaths and accidents attributable to cot bumpers has significantly increased over time, though this may be in part due to changes in reporting. Cot bumpers pose risks for infants at any age and include becoming wedged between the bumper and cot mattress, getting into a position where their face is pressed up against the soft padding of the bumper, becoming entangled in the bumper or its ties, or falling from the cot after climbing on the bumper.²⁷⁷ Cot bumpers are primarily marketed to stop babies hurting themselves against cot bars or becoming trapped between them; however these injuries are generally not serious, and the risks posed by cot bumpers themselves are far greater.^{276,277} Modern cots conforming to British safety standards should have bars that are narrowly-spaced enough so that limb entrapment is not possible, negating the need for cot bumpers.

Baby boxes

Baby boxes, cardboard boxes given free to parents containing products for newborns, have been distributed in Scotland and parts of England and US and promoted as an alternative to a cot, following the example of long-standing baby box programme in Finland, where infant mortality rates are among the lowest in the world.²⁸³ There is no evidence to suggest that the introduction of baby boxes contributed to the fall in Finland's infant mortality over the 20th century, and no research has been published on their risks or benefits in the UK or US. Currently there is no safety standard for the use of cardboard box as a sleeping place for a baby, although one has been proposed for development by the British Standards Institute.²⁸⁴

Recommendation:

An infant's sleep environment should be kept as clear as possible to reduce the risk of accidental strangulation, suffocation or entrapment. More evidence is needed on the safety of products infants might sleep on. In the absence of this infants should only sleep on a firm, flat mattress to reduce the risk of SIDS and accidents.

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