The Lullaby Trust: Evidence Base

Last updated: June 2016

Summary

Around 300 babies and toddlers still die every year of Sudden Infant Death Syndrome (SIDS), in the UK.

Research has shown associations between a number of infant care practices and 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 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 (p4)
   1.2 Smoking (p6)
   1.3 Unsafe sleeping environments, with particular high risk circumstances highlighted:
       1.3.1 Bed sharing and sofa sharing (p7)
       1.3.2 Temperature and overwrapping (p12)
       1.3.3 Bedding and mattresses (p14)

2. Factors associated with a decreased risk of SIDS:
   2.1 Room sharing (p15)
   2.2 Breastfeeding (p15)
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3. Factors in need for further research to determine their relationship to SIDS:
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   3.4 Signs of ill health (p21)
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 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 the post mortem 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 300 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 2014; 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.

SIDS is much rarer in babies over the age of 12 months. In 2014 there were 17 cases in babies aged between 12 and 24 months in the UK (15 in England and Wales, 2 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.
<table>
<thead>
<tr>
<th>Year</th>
<th>England &amp; Wales</th>
<th>Scotland</th>
<th>Northern Ireland</th>
<th>UK Total</th>
<th>UK Rate per 1000 live births</th>
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<td>27</td>
<td>1 (R95) 26 (R96-R99)</td>
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<td>4 (R95) 26 (R96-R99)</td>
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<tr>
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<td>3 (R95) 20 (R96-R99)</td>
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<tr>
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<td>23</td>
<td>3 (R95) 34 (R96-R99)</td>
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<td>26</td>
<td>5 (R95) 25 (R96-R99)</td>
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<tr>
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<td>29</td>
<td>5 (R95)</td>
<td>281</td>
<td>0.34</td>
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<tr>
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<td>221</td>
<td>29</td>
<td>2 (R95)</td>
<td>252</td>
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<tr>
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<td>2014</td>
<td>212</td>
<td>14</td>
<td>4</td>
<td>230</td>
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</table>

**Table 1:** UK SIDS cases between 2006 and 2014, birth to one year

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) feels advice should be given to parents, 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.

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1. ONS data includes sudden infant deaths, unascertained deaths and all unexplained infant deaths; classified as ICD 10 codes R95-R99 (data grouped together).  
2. GROS data includes sudden infant deaths only; classified as ICD 10 code R95. Other cases (classified as R96-R99) are unable to teased out from broader data therefore the statistics listed here in Table 1 is likely to be an underestimate of the true number of cases.  
3. NIRSA data includes sudden infant deaths, classified as ICD 10 code R95, and other ill-defined and unknown causes of mortality, classified as ICD 10 codes R96-R99.
Modifiable risk factors

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\(^\text{14,15}\) and reduce vomiting in babies with gastro-oesophageal reflux.\(^\text{16,17}\) 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.\(^\text{18–20}\) 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\(^\text{21,22}\) 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.\(^\text{7,8,22–38}\) For example, a major study carried out in the UK\(^\text{25}\) 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 countries\(^\text{39}\) and the UK\(^\text{40}\) 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 retardation. 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.\(^\text{39}\) These infants are also at highly increased risk if placed to sleep on the side.

Publicity in the Netherlands in 1987\(^\text{7}\) and in Australia in 1988\(^\text{21}\) 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.\(^\text{8,25,27–29}\) This change in practice has been accompanied by a fall in the SIDS rate and in some countries appears to explain the fall entirely.\(^\text{27–29}\)

Infants who usually sleep supine but who are placed prone are at very high risk of SIDS.\(^\text{38,41,42}\) 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
acclimated 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). The first prone sleep appears to be a particularly high risk occasion.

It is important that care is taken regarding the positioning of the baby even in the first 24 hours of life 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. Although these events are rare and there are limited case studies to provide evidence, care should be taken at all times to ensure that the infant’s breathing is not obstructed.

**Back versus side**

Sleeping on the side increases the risk of SIDS, as compared with sleeping on the back. 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. 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 odds ratio 2.0, 95% CI 1.2-3.4). 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 kilograms), and that the combined risk of low birth weight and side sleeping was more than multiplicative. In one of these reports, the odds ratio for SIDS was 36.6 (95% CI 13-107) 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.

Since 1996 the ‘Reduce the Risk’ campaign has recommended that infants should always be placed to sleep supine.

**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. The widespread adoption of the supine position in the UK has been accompanied by a fall in post perinatal mortality rates and no increase in aspiration death rates. Similarly in a USA study there was a fall in SIDS incidence but no cases of aspiration. 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.\textsuperscript{50} Some newborn babies with respiratory distress and others with particular medical problems may benefit from being nursed prone,\textsuperscript{51} and in these cases parents should follow medical advice about sleeping position.

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 2–3 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.

The ‘Reduce the Risk’ 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.\textsuperscript{52} 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.

\begin{center}
\textbf{Recommendation:}
Parents should be advised that placing an infant to sleep on their stomach or side significantly increases the 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 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.
\end{center}

\begin{center}
\textbf{1.2 Smoking}
\end{center}

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.\textsuperscript{53} The risk appears to be dose related. For example, the following odds ratios were found in two separate studies (Table 3):

\begin{center}
\begin{tabular}{|c|c|}
\hline
\textbf{Cigarettes per day} & \textbf{Odds ratio} \\
\hline
1-10 & 2.6 \\
11-20 & 2.8 \\
>20 & 6.9 \\
\hline
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\end{center}

\begin{center}
\begin{tabular}{|c|c|}
\hline
\textbf{Cigarettes per day} & \textbf{Odds ratio} \\
\hline
1-9 & 4.25 \\
10-19 & 6.49 \\
>20 & 8.56 \\
\hline
\end{tabular}
\end{center}

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

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\%\textsuperscript{54,55} or by up to 40–50\%.\textsuperscript{56,57}
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.\textsuperscript{56,58-60} Prenatal smoking has been associated with SIDS with an OR of 2.7 (CI 2.4-3.0).\textsuperscript{61} Smoking still contributes to SIDS when allowance is made for a range of confounding factors such as maternal age, parity, marital status, education, breast feeding, sleeping position, family situation and sex of infant.\textsuperscript{54,56}

Some of the studies of SIDS and smoking during pregnancy make reference to the effects of smoking after birth on the risk of SIDS but it is difficult to distinguish between the effects of smoking during pregnancy and exposure to passive smoking after birth. There are studies that do link SIDS to exposure to passive smoking after birth.\textsuperscript{26,56,62,65,66} Environmental tobacco smoking in a European population has been estimated to be responsible approximately for 24-32\% of SIDS incidents.\textsuperscript{69} Studies also demonstrate an increased risk if the father also smokes.\textsuperscript{56,65,67,68} There is also an increased risk when mothers smoke only after their baby is born 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.\textsuperscript{72} 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\%.\textsuperscript{73} However, more research is needed to address the possible causal link between risk of SIDS and postnatal exposure to tobacco smoke. There is no evidence yet relating to electric (‘e’) cigarettes and the risk of SIDS although it is hoped that these may be safer than standard cigarettes.\textsuperscript{74}

The risk of SIDS is greatly increased by bed sharing when either parent smokes, even if they do not smoke in the bed.\textsuperscript{25,75-79} Parents who smoke should avoid sharing a bed with their infant.

| Recommendation: |
| Parents should not smoke during pregnancy or after birth; this applies to both parents. Postnatal passive smoking also puts a baby at risk, therefore it is important to keep a baby out of smoky atmospheres. Bedsharing is unsafe if either parent smokes. |

1.3 Unsafe sleep environments

1.3.1 Bed sharing

A meta-analysis published in 2012 found that not a single study (that met the inclusion criteria for the analysis) published since January 1970 showed a reduced risk of SIDS in bed sharing infants; all studies found an increased risk (Figure 1).\textsuperscript{80} This same analysis found that the combined odds ratio for all bed sharing versus non-bed sharing infants was 2.89 (95\% CI 1.99-4.18). Other studies have found the OR for bed sharing to be 2.9 (CI 1.8-4.7).\textsuperscript{81} Bed sharing is unsafe when either parent smokes.
sharing versus non-bed sharing to be 3.53 (95% CI 1.40-8.93)\textsuperscript{77} and 2.89 (95% CI 1.40, 5.97).\textsuperscript{78} A study of all infants under one year who died in Sweden found the OR of bed-sharing to be 7.77 (95% CI 2.36, 25.57) for SIDS versus explained unexpected deaths.\textsuperscript{81} A previous review also demonstrated that no study had found bed sharing to be associated with a reduced risk of SIDS.\textsuperscript{82}

<table>
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<tr>
<th>Study name</th>
<th>Statistics for each study</th>
<th>OR and 95% CI</th>
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<tr>
<td>Blair 1989</td>
<td>9.78 4.02 23.61 5.02 .00</td>
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<tr>
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Figure 1. The association of bed sharing and risk of SIDS.\textsuperscript{80}

Studies have found that sharing a sofa with an infant is also associated with an extremely high risk of SIDS.\textsuperscript{78,80,83} In England and Wales approximately one-sixth of infants who died of SIDS were found sleeping with an adult on a sofa\textsuperscript{84} and similar proportions have been reported in Scotland\textsuperscript{86} and Northern Ireland.\textsuperscript{86}

**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.\textsuperscript{25,75–80,84,87} In one study from 2004,\textsuperscript{79} the risk of bed sharing was 10-fold greater amongst mothers who smoked and, in another paper published in 2012,\textsuperscript{80} the subgroup analysis of four studies for maternal smoking and bed sharing found an OR of 6.27 (95% CI 3.94-9.99).

However, studies have also 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.\textsuperscript{77–79,88–90} 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 analysed in a 2012 meta-analysis.\textsuperscript{80}
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,\textsuperscript{80} and 2.09 (95% CI 0.98-4.39) in a study from 2006.\textsuperscript{77} 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.’\textsuperscript{91} 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.\textsuperscript{82} 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.\textsuperscript{78,79,88,92} Lumping these two groups together inevitably reduces the observed risk from bed sharing.

A subsequent study, from 2013, has identified a greater increased SIDS risk from bed sharing in infants of both smoking and non-smoking parents.\textsuperscript{93} The study revealed that infants who bed share at 2 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 2 weeks old, and an adjusted OR of 3.6 (95% CI 1.8-7.2) at 10 weeks old.
Very young infants, low birth weight infants and premature infants and bed sharing

The risk for non-smoking parents mainly affects younger infants (less than 3–4 months postnatal age) and those with low birth weight (<2,500 grams)\textsuperscript{40,78,94} such as pre-term infants.\textsuperscript{84} Younger infant age has often been found to be associated with an increased risk of SIDS.\textsuperscript{77,79} For example, one study\textsuperscript{87} found that bed sharing with a young infant (aged less than 1 month) increased the risk of SIDS sevenfold, although this was where either the mother had smoked during pregnancy or was currently a smoker. One study\textsuperscript{95} 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) and another\textsuperscript{96} observed in their study that the majority (72\%) of SIDS cases in infants <3 months were bed sharing. A 2012 meta-analysis\textsuperscript{80} found that in three studies reporting on infant’s age, the risk of SIDS in bed sharing infants was 10 times higher than non-bed sharers in infants <12 weeks old (OR 10.37, 95\% CI 4.44-24.21), and the risk for infants ≥12 weeks old was not elevated (OR 1.02, 95\% CI, 0.49-2.12). The authors of this analysis highlight that other studies have demonstrated that this risk persists even when the parents do not smoke. 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,\textsuperscript{97} 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.\textsuperscript{77} A very large study from the US suggests that younger infants (<3 months) are particularly at risk from bed-sharing, while rolling into objects in the sleep area is a greater risk factor for infants of 4 or more months.\textsuperscript{98}

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.\textsuperscript{93} This study found that while the SIDS risk of bed sharing decreased with age, there was still a five-fold increase in risk, versus room sharing, (adjusted OR 5.1, 95\% CI 2.3-11.4) for bed sharing babies less than 3 months old who were breast-fed, 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. Another study of 400 SIDS infants in England found that bed-sharing was not associated with increased risk in the absence of other risk factors (smoking, alcohol use or being on a sofa).\textsuperscript{99}

A useful figure, from a study in 2004,\textsuperscript{79} highlights that the risk of bed sharing is much greater for infants of smoking mothers than for those of non-smoking ones. However, there is also a small but significant increased risk for infants of non-smoking mothers in the first 6-7 weeks of life (Figure 3).
Alcohol and drugs and bed sharing

The risk of SIDS has also been found to be increased where the bed sharer has used alcohol or drugs, or is overtired.\textsuperscript{76,79,80,84} 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).\textsuperscript{93} 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’. 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 overtired, so data is currently relatively limited on these factors.

Bed sharing and breastfeeding

Some evidence has been put forward to show that bed sharing promotes prolonged and easier breast feeding\textsuperscript{100,101,102} but a causal link has not been demonstrated.\textsuperscript{103} it is at least as likely that when mothers stop breastfeeding they are less likely to bed share.

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 biethnic 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 both. 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 sleep-surface sharing 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 being cautious about generalising SIDS risk factors across populations.

A 2013 study found that there was still a significant increased risk of SIDS (adjusted OR 5.1, 95% CI 2.3–11.4) for breast-fed babies less than 3 months old who bed shared with non-smoking parents. It should be noted that the study defined breast-fed 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 breast-fed or those who were exclusively breast fed.

Recommendation:
Parents should be advised that bed sharing and sofa sharing significantly increase the risk of SIDS. The safest place for a baby to sleep for the first six months is in a separate cot or crib in the parents’ bedroom. Parents should be made aware that bed/sofa sharing particularly increases the risk of SIDS where:
- Either parent smokes
- The bed/sofa sharer has consumed alcohol or taken drugs (including medications that may make them drowsy)
- The baby was premature
- The baby was low birth-weight

The risk is also increased in babies less than 3-4 months old and is dramatically high where the parents also smoke.

3.1.3 Temperature and overwrapping

Initially reports that overheating arising from high room temperature, excessive insulation (overwrapping) or both, may contribute to sudden infant death were largely circumstantial. 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 and that cases were more likely to have had the heating on all night. There is also evidence to show that overheating interacts adversely with other important factors such as prone sleeping and infection. 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). 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).\textsuperscript{111}

Some studies have shown that SIDS may occur against a background of minor illness.\textsuperscript{113,114} There is a tendency to increase the amount of clothing and bedding when a baby is unwell. 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 \textit{Staphylococcus aureus}), and that these may contribute to the deaths of at least some infants.\textsuperscript{115–117} 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\textsuperscript{118–120} and that these small variations may partly explain the differing incidence of SIDS in different ethnic groups.\textsuperscript{121}

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.\textsuperscript{122,123}

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 3 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.\textsuperscript{111} 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).\textsuperscript{111} 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.

\textbf{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.
3.1.3 Bedding and mattresses

The head is an important source of heat loss for a normal baby. A high proportion of infants who die as a result of SIDS are found with their head covered with bedding. The use of bed linen, which covers the head is an independent risk factor. 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). Bed linen, such as quilts, pillows and duvets, is associated with an increased risk of SIDS in the UK. 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). In addition, there is evidence to show that soft sleep surfaces are associated with a significant increase in the risk of SIDS. 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 1 inch or more into the surface) led to a 5-fold increase in the risk of SIDS (OR 5.1, 95% CI 3.1-8.3). 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). However, when quilts were 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.

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. It was noted, however, that the firmness of the cot mattress was subjective as no guidelines were provided on this.

One case-control study in Scotland assessed the use of a secondhand mattress and the association with SIDS. 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) than 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 studies 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). 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.

A 4-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. These factors include a reduction in the thermal insulation of bedding, in combination with 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) and a rise in the use of infant sleeping bags. 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. 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.

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.

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. 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.

Recommendation:
Parents should be advised that the safest place for a baby to sleep for the first six months is in a separate cot or crib in the same room as the parents.

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 3 months. Several published studies, but not all, have found that breastfeeding is associated with lower risk of SIDS. One meta-analysis, in 2000, of 23 reports 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-analysis\textsuperscript{137} incorporating 6 studies in which SIDS was rigorously defined and the duration of breastfeeding specified.\textsuperscript{83,138–140} 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 Germany\textsuperscript{141} 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.\textsuperscript{142}

The most recent meta-analysis published in 2011 supports the findings that breastfeeding is associated with lower rates of SIDS.\textsuperscript{143} An adjusted analysis that compared any duration of breastfeeding against formula feeding reported an odds ratio of 0.55 for breastfeeding (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 (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.\textsuperscript{143}

Figure 4B: Multivariable analysis comparing the effect of exclusive breastfeeding against no breastfeeding on the risk of SIDS.\textsuperscript{143}
**Recommendation:**
Breastfeeding is associated with a reduced rate of SIDS in women where there are no contraindications that advise not to breastfeed. Exclusive breastfeeding (i.e. those who have never fed with formula milk) is associated with the lowest risk, but breastfeeding of any duration may be beneficial for SIDS risk compared to formula feeding alone.

### 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-analysis\(^{144}\) of eight studies of the effect of dummy use on the risk of SIDS, seven of which met the investigators’ criteria for inclusion.\(^{79,85,89,127,145–147}\) 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). Another study from California,\(^{148}\) published too late to be included in the meta-analysis, showed a similar association between dummy use and SIDS (adjusted odds ratio 0.08, 95% CI 0.03-0.21). As a result of this the AAP recommends that parents consider offering infants a dummy once breastfeeding has been established, typically at about 1 month of age.\(^{149}\) The dummy should be gently withdrawn between 6 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\(^{89,145}\) 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.

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.\(^{150}\) However, 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.\(^{151}\) A systematic review of 4 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.\(^{152}\)
**Recommendation:**
Use of a dummy is associated with lower SIDS rates and parents may consider offering a dummy when settling the baby to sleep. The dummy should gently be withdrawn between the ages of 6 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 before the dummy is introduced.

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**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,\(^{153}\) 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;\(^ {110}\) 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.\(^ {110,154}\) If an infant is immobilised then they are unable to pull covers over their head or crawl into a potentially dangerous situation. 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.\(^ {84}\) 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.\(^ {127}\)

Studies have examined the effects of swaddling on infant arousability as impaired arousal may contribute to SIDS.\(^ {155,156}\) 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.\(^ {128}\) No effect on arousal was seen in infants who were routinely swaddled but full cortical arousal was reduced at 3 months of age in infants who were swaddled but were not used to this practice as part of their regular routine.\(^ {155,156}\) 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 where not affected. While further evidence is still needed, the risks of swaddling in the supine position appear to be limited if it is done correctly and routinely from birth or early infancy.

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.

3.2 Car Seats

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. 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. 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. 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. 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.

**Recommendation:**
There is currently a lack of extensive data on the use of car seats and SIDS. However, data available indicate that parents should be advised to follow the guidance on the correct positioning of infants in car seats and to only use them for the purpose of transportation. Car seats should not be used, outside the car, as an alternative to a cot or highchair, for example, and infants should not be left in car seats for very long periods or unsupervised.

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, caution on their use has been issued by Health Canada, U.S. Consumer Product Safety Commission and Australian Competition & Consumer Commission, as well as The Royal Society for the Prevention of Accidents in the UK. This is in response to a small number of infant deaths with the use of slings, particularly from suffocation and particularly in young infants (aged 3 months or under). Guidance on the safe use of slings is provided by various organisations in the UK, including The Royal Society for the Prevention of Accidents and consumer organisation Which?. The information from these two organisations points towards the guidance given by The Consortium of UK Sling Manufacturers and Retailers 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’s back should be supported. If a sling is too loose they can slump which can partially close their airway. 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 significant 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.

### 3.4 Signs of ill health

Most SIDS babies are apparently healthy prior to death.\(^{150,169}\) Several studies have reported signs of illness among SIDS babies\(^ {113,170}\) and a higher incidence of minor illness and/or infection amongst cases than controls.\(^ {23,25,114,171}\) 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.\(^ {25}\) 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.\(^ {172}\) 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.\(^ {95}\) This suggests that the pathogenesis of SIDS is complex and likely to involve the combination of multiple risk factors.\(^ {95,173}\) Single risk status for URTI was assessed in a 2010 study and was found to be evident in 10% of cases.\(^ {174}\) 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.\(^ {175}\)

A study based on infants recruited into the CONI (Care of the 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.\(^ {176}\) 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 1978\(^ {170}\) 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 study\textsuperscript{113} 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’\textsuperscript{177,178} 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.\textsuperscript{25,171}

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\textbf{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.

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References:

12 General Register Office for Scotland. Vital events reference tables 2010. Section 4: stillbirths and infant deaths. Table 4.5 includes data on infant deaths, by sex and cause, from 2000 to 2014.


