Factfile 2. Research background to the Reduce the Risk of Cot Death advice by the Foundation for the Study of Infant Deaths

Introduction
Sudden infant death syndrome (SIDS) is defined as the sudden unexpected death of an infant less than one year of age, with onset of the fatal episode apparently occurring during sleep, that remains unexplained after a thorough investigation, including performance of a complete autopsy and review of the circumstances of death and the clinical history. In this factfile the term SIDS is used but in the UK such deaths may also be called *cot death or unascertained*. See FSID Factfile 1 for more detail on definitions. Research has shown that several maternal and infant care factors are more commonly associated with babies who die as SIDS than those who survive. Some of these factors are amenable to change. Most importantly, an active programme to change infant sleeping position has resulted in a change in child care practice which is accompanied by a reduction in SIDS rates. These findings formed the basis for FSID’s Reduce the Risk of Cot Death campaign launched in October 1991, and, together with subsequent findings, now inform the advice that parents are given to reduce the risk of cot death. This advice is:

- Place your baby on the back to sleep (and not on the front or side)
- Cut smoking in pregnancy — dads too! And don’t let anyone smoke in the same room as your baby
- The safest place for your baby to sleep is in a crib or cot in a room with you for the first six months
- Do not let your baby get too hot, and keep your baby’s head uncovered
- Never sleep with your baby on a sofa or armchair

It’s dangerous for your baby to sleep in your bed if you (or your partner):
- are a smoker (even if you never smoke in bed or at home)
- have been drinking alcohol
- take medication or drugs that make you drowsy
- feel very tired
- if your baby was premature (born before 37 weeks)
- if your baby was low birth weight (less than 2.5kg or 51/2lb)
- if your baby is less than 4 months old.
- Settling your baby to sleep (day and night) with a dummy can reduce the risk of cot death, even if the dummy falls out while your baby is asleep.
- Breastfeed your baby. Establish breastfeeding before starting to use a dummy.

What is the incidence of SIDS?
The number and rate of SIDS have been decreasing since 1989, but the fall was most marked between 1991 and 1992, when the “Reduce the Risk” campaign was launched. There has been a slower decline since then 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: Sudden Infant Death (any mention) - Birth to 2 years, in the UK, 1989-2004 (note - FSID figures include deaths classified as “cause unascertained” from 1996)

<table>
<thead>
<tr>
<th>Year</th>
<th>England &amp; Wales</th>
<th>Scotland</th>
<th>N. Ireland</th>
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<td>24</td>
<td>13</td>
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<td>0.43</td>
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Sources for table 1: figures provided by the Office for National Statistics, the General Register Office for Scotland, and the Northern Ireland Statistics and Research Agency.

The rapid drop following the campaign in the UK and similar campaigns in other countries indicate that they are effective. The campaign messages must continue to be emphasised to parents and carers, for the benefits to be sustained.

What is meant by reducing the risk?
There is no advice which guarantees prevention of SIDS, but there are ways in which the risk can be reduced. Following the advice in the “Reduce the Risk” leaflet produced by FSID and the Department of Health, will lessen the chance of such a tragedy occurring.

What evidence is this advice based on?
FSID has spent more than £10 million on research into the causes and prevention of sudden infant death. The findings of research in the UK and other countries provide the scientific basis for this advice.

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 preterm babies with respiratory distress17, 20 and reduce vomiting in babies with gastro oesophageal reflux18, 30. 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 although later analysis has found it to be so2, 31, 32. 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 SIDS11, 33 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 controls5, 6, 9, 13, 15-18, 33-41. For example, a major study carried out in the UK6 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 countries42 and the UK43 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 backs42. These infants are also at highly increased risk if placed to sleep on the side (see below).

Publicity in the Netherlands in 198733 and in Australia in 198834 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 supine6. 15-18. This change in practice has been accompanied by a fall in the SIDS rate and in some countries appears to explain the fall entirely6, 16-18.

Infants who usually sleep supine but who are placed prone are at very high risk of SIDS44, 45. The first prone sleep appears to be a particularly high risk occasion6.

**Back versus side**

Sleeping on the side increases the risk of SIDS, as compared with sleeping on the back46, 47. This may 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 side42. 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 multiplicative42, 43. In one of these reports42, 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.

In the light of these findings, it is particularly regrettable that a recent survey of practice in UK neonatal units found that, although 83% of responding units instituted supine sleeping 1-2 weeks before discharge from the unit, only 38% actively discouraged prone sleeping after discharge and 17% recommended side sleeping as an acceptable option48.

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

**Other 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 this4. The widespread adoption of the supine position in the UK has been accompanied by a fall in post perinatal mortality rates49 and no increase in aspiration death rates49. Similarly in a USA study there was a fall in SIDS incidence but no cases of aspiration50. 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 sleeping51. Some newborn babies with respiratory distress and others with particular medical problems may benefit from being nursed prone49, 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 day-time naps as it is for night sleeps53. 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.

**Smoking**

Evidence from a very large number of studies worldwide consistently demonstrates that maternal smoking during pregnancy increases the risk of SIDS. The risk appears to be dose related. For example:
Risk of smoking

Cigarettes per day Odds ratio
1-10 2.6
11-20 2.8
>20 6.9
Source: 54

Cigarettes per day Odds ratio
1-9 4.25
10-19 6.49
>20 8.56
Source: 6

It has been suggested that if maternal smoking during pregnancy were eliminated, the SIDS rate would be reduced considerably - by 27%\(^\text{64}\), 30%\(^\text{55, 56}\), 50%\(^\text{66}\) and by 30-40%\(^\text{67}\) in a population where 30% of mothers smoke. If these estimates are applicable to the current position in the UK, then over 100 babies a year could be saved, if no pregnant woman smoked.

Smoking during pregnancy is also associated with low birth weight, a factor linked to SIDS, but data from research studies shows that this does not explain its importance\(^\text{56, 58-60}\). Smoking still contributes to SIDS when allowance is made for a range of confounding factors such as maternal age\(^\text{6, 9, 54, 56, 58-62}\), parity\(^\text{7}\), marital status\(^\text{9, 56, 57, 61}\), education\(^\text{9, 55, 57, 63}\), breast feeding\(^\text{9, 54}\), sleeping position\(^\text{9, 56}\), family situation\(^\text{54, 57, 58}\) and sex of infant\(^\text{54, 56}\).

Some of the studies of SIDS and smoking during pregnancy make reference to the effects of smoking after birth on the risk of SIDS\(^\text{7, 56, 61, 64}\) but it is difficult to distinguish between the effects of smoking during pregnancy and exposure to passive smoking after birth. There are studies which do link SIDS to exposure to passive smoking after birth\(^\text{54, 56, 61, 65-66}\). Studies also demonstrate an increased risk if the father also smokes\(^\text{5, 56, 65-68}\). Considering mothers who smoke only after their baby is born shows that postnatal smoking is an independent risk factor\(^\text{69}\) but the small number of such mothers makes these studies difficult. The risk of SIDS is greatly increased by bed sharing when either parent smokes, even if they do not smoke in the bed\(^\text{10, 70-73}\). Parents who smoke should avoid sharing a bed with their infant.

FSID’s advice to parents is not to smoke during pregnancy or after birth; this also applies to fathers. Keep the baby out of smoky atmospheres. More detailed advice can be found in the FSID/Department of Health leaflet ‘Reduce the risk of cot death: an easy guide’.

Temperature/overwrapping

Initially reports that overheating arising from high room temperature, excessive insulation (overwrapping) or both, may contribute to sudden infant death were largely circumstantial\(^\text{74-75}\). 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\(^\text{6, 76-78}\) and that cases were more likely to have had the heating on all night\(^\text{69, 70}\). The risk for overheating alone is less than that for sleeping position and smoking. However, there is evidence to show that overheating interacts adversely with other important factors such as prone sleeping and infection.

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\(^\text{75, 80}\). Some studies have shown that SIDS may occur against a background of minor illness\(^\text{81, 82}\). There is a tendency to increase the amount of clothing and bedding when a baby is unwell. The combination of overwrapping and signs of infection confers a greatly increased risk of SIDS\(^\text{84}\). Similarly, the combination of overwrapping and prone sleeping carries a higher risk than either alone\(^\text{77}\).

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\(^\text{84-86}\). 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\(^\text{87-89}\) and that these small variations may partly explain the differing incidence of SIDS in different ethnic groups\(^\text{90}\).

FSID’s advice to parents in the FSID leaflet (“Reduce the Risk of Cot Death”, FSID/Department of Health, 2009) is that while it is important to ensure that a baby does not get too cold, it is also important to avoid care practices that result in the baby getting too hot. Babies should be checked to ensure that they are not too hot. Further advice may be found in the leaflet. There is a consensus view in the UK, not strongly evidence based, that an ambient room temperature of 16-20ºC, 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.

Unsafe sleep environments

The head is an important source of heat loss for a normal baby\(^\text{78}\). A high proportion of infants who die as SIDS are found with their head covered with bedding\(^\text{6, 8, 63, 91}\). The use of bed linen, which covers the head is an independent risk factor\(^\text{64}\). In addition, bed linen such as quilts, pillows and duvets is associated with an increased risk of SIDS in the UK\(^\text{6}\).

FSID’s advice is to use the “Feet to foot” position, which has been devised to ensure that the bedding does not cover the infant’s head during sleep. Pillows, bean bags and waterbeds should also be avoided. For further advice, see the information leaflet Reduce the Risk of Cot Death.
Contact your doctor if your baby is unwell or shows signs of illness

Most SIDS babies are apparently healthy prior to death. Several studies have reported signs of illness among SIDS babies and a higher incidence of minor illness and/or infection amongst cases than controls. 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. However, these investigations were undertaken before the widespread implementation of back sleeping, and a recent report from Germany suggests 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. Another 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. These occurred throughout the life of the baby rather than in a close temporal relation to the time of death. 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 found that the severity of the illness in SIDS babies was underestimated by parents in 39%, and by doctors in 28%, of the cases studied. A similar failure to recognise the symptoms of serious illness was reported by Stanton et al., and they 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, 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 but this has yet to be demonstrated.

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 protects against the risk of SIDS. One meta-analysis of 23 reports concluded that formula fed infants were more than twice as likely to die from SIDS than breastfed infants with an adjusted odds ratio of 2.11 (95% CI 1.66-2.68). Recently the USA Agency for Healthcare Research and Quality (AHRQ) performed a more stringent meta-analysis incorporating 6 studies in which SIDS was rigorously defined and the duration of breastfeeding specified. They found that ever breastfeeding reduced the risk of SIDS compared with never breastfeeding, with an adjusted odds ratio of 0.64 (95% CI 0.51-0.81). It is clear that breastfeeding should be recommended as a protective measure against SIDS, in addition to the other well known reasons for promoting the practice. The meta-analysis on which this advice is based is shown in Figure 1.

A more recent study from Germany found that both partial and exclusive breastfeeding offered substantial protection from the risk of SIDS, after adjustment for the effects of maternal smoking, bed sharing and the use of a pacifier (dummy) during the last sleep.

Bed sharing

As stated above, it is widely accepted that taking a baby into the parental bed to sleep is dangerous if either parent is a smoker, whether or not they smoke in the bedroom. In addition, at least 5 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. This risk mainly affects younger infants (less than 3 months postnatal age) and those with low birth weight (<2,500 grams). A recent study from the Netherlands found that, after adjustment for maternal smoking, the odds ratio 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 4-6 months, and was not significantly altered by the presence or absence of breastfeeding.
A recent 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". However, in an accompanying editorial in the same issue, Mitchell 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. 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. Lumping these two groups together inevitably reduces the observed risk from bed sharing.

Advocates of bed sharing suggest that the practice promotes breast feeding, but a causal link has never been demonstrated: it is at least as likely that when mothers stop breastfeeding they are less likely to bed share. It is noteworthy that no study has ever found bed sharing to be associated with a reduced risk of SIDS. Claims have also been made that the quality of sleep is somehow enhanced by bed sharing, but the one study to have examined this scientifically came to the opposite conclusion.

These considerations led FSID to the recommendation that the safest place for a baby to sleep for the first six months is in a separate cot in the parents' bedroom.

**Dummy use**

The use of dummies (pacifiers, 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 of 8 studies of the effect of dummy use on the risk of SIDS, 7 of which met the investigators' criteria for inclusion. Multivariate analysis showed that 'usual' dummy use was protective (odds ratio of 0.71, 95% CI 0.59-0.85) (Figure 2), and that use of a dummy during the last or reference sleep was even more so (odds ratio 0.39, 95% CI 0.31-0.50) (Figure 3). Another study from California, published too late to be included in the metaanalysis, showed an even greater degree of protection from dummy use (adjusted odds ratio 0.08, 95% CI 0.03-0.21). As a result of this the AAP now recommends that infants be offered a dummy once breast feeding has been established, typically at about 1 month of age. The dummy should be gently withdrawn between 6 and 12 months of age, since possible adverse effects of dummy use (ear infections, dental malocclusion) have not been described below one year.

As with bed sharing, it has been suggested that dummy use may be negatively associated with breast feeding. However, when this relationship is analysed statistically it appears that dummy use is more likely to be a consequence of breast feeding difficulties than a cause of them. A recent 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. In the light of all the evidence of a significant protective effect, FSID now recommends that a dummy be offered when settling the baby to sleep from one month to 6 months of age. If it falls out when the baby goes to sleep it should not

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**Multivariate Analyses**

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<td>0.24 (0.11-0.51)</td>
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<td>1.47 (0.62-3.50)</td>
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Summary Odds Ratio: 0.71 (0.59-0.85)

Test for homogeneity P = 0.016
Test for overall effect P < 0.001

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**Multivariate Analyses**

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<td>0.43 (0.24-0.78)</td>
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<td>0.59 (0.30-1.17)</td>
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Summary Odds Ratio: 0.39 (0.31-0.50)

Test for homogeneity P = 0.040
Test for overall effect P < 0.001

* "A little" pacifier use

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Figure 2. Multivariate analysis of 'usual' dummy use and risk of SIDS. Reproduced with permission from Pediatrics, vol. 116, pages e716-e723, copyright 2005 by the AAP.

Figure 3. Multivariate analysis of last/reference sleep dummy use and risk of SIDS. Reproduced with permission from Pediatrics, vol. 116, pages e716-e723, copyright 2005 by the AAP.
be replaced, and if the dummy is refused it should not be forced on the infant. The dummy should never be coated with something sweet. Two studies106,113 have suggested that if an infant is accustomed to dummy use it 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.

Concluding comment

The evidence is now very strong that by changing patterns of infant care we can reduce the risk of SIDS. More research is still needed if SIDS is to be entirely prevented. There are new factors still to be identified. We need to work out how the other factors such as smoking and temperature interact with one another, and with the growing and developing baby. We need to continue to monitor SIDS rates, in different areas and for different groups of people, to see how child care practices differ between groups, how they change with time and what effect this is having on the health of babies. Vigilance is needed to ensure that rates do not rise again. The Reduce the Risk campaign has been an exceptional success and there are many babies alive today who would otherwise have died; we need to continue to build on this success.

Reference List

24. HSG31UT1 OoNSD. Sudden infant deaths, unascertained deaths and all unexplained infant deaths by sex and age at death, 2001-2005. 2006.


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