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**Major changes in the epidemiology of Sudden Infant Death
Syndrome: a 20-year population based study of all unexpected deaths
in infancy**

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Abstract 249 words (limit 250 words)

Background: Recent case-control studies suggest the epidemiology of Sudden Infant Death Syndrome (SIDS) may have changed since the 1991 'Back to Sleep' campaign and subsequent fall in rates. A unique collection of longitudinal data is used to measure these potential changes.

Methods: Population-based data from home visits have been collected for 369 consecutive unexpected infant deaths (300 SIDS and 69 explained deaths) in Avon over a 20-year period (1984-2003). Data collected between 1993-6 from 1300 control infants with a chosen sleep prior to interview has also been used for reference.

Findings: Social deprivation was increasingly more common amongst SIDS families; the proportion of social class IV,V & unemployed families rose from 47% to 74% ($p<0.003$), 86% of the mothers smoke, 40% are now single, and 16% are aged less than 20. Although many SIDS infants come from large families, first-born infants are now the most common group. The proportion of co-sleeping SIDS deaths increased from 12% to 50% ($p<0.0001$), but the actual number of SIDS deaths in the parental bed fell significantly ($p=0.01$). This rise in proportion is due partly to the limited effect of the "Back to Sleep" campaign on factors in this sleeping environment and partly to a rise in the number of bedsharing deaths on sofas. Infants who die as SIDS whilst bedsharing are now 4-5 weeks younger at death than in the 1980's.

Interpretation: Changes in the epidemiology of SIDS have implications both in the interpretation of causal mechanisms and how we should conduct future studies.

Introduction

The characteristics and risk factors associated with Sudden Infant Death Syndrome (SIDS) are numerous and consistent such that it has been described as an “epidemiological entity”[1]. In the last 40 years many studies have investigated these deaths and there is broad agreement on some of the epidemiological findings [2]. The majority of deaths occur within the first 8 months of life, few deaths in the first month with a peak around the third and fourth month. The risk is higher for infants placed to sleep in non-supine positions, males, infants of short gestation and low birthweight. SIDS occurs in all social groups but is more prevalent in the socio-economically deprived; maternal smoking, younger mothers and larger families are all associated with an increased risk. Since the ‘Back to Sleep’ campaign in 1991, encouraging parents to place their infant supine to sleep, the number of SIDS deaths has fallen by 75% in England & Wales [3].

Recent cross-sectional studies [4-7] show changes in the epidemiological picture, although interpretation of these changes is complicated by variations in infant care practices, differences in study design and differences in the actual questions and elicited responses from the parents. Longitudinal data is collected nationally in several countries but this is limited to basic demographics and in the UK at least, is complicated by inconsistent diagnosis of SIDS [8,9,10].

In the county of Avon it has been the practice since 1984 for a paediatrician to interview the family at home as soon as possible after all Sudden Unexpected Deaths in Infancy (SUDI). SUDI deaths include some explained infant deaths but the

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majority are unexplained, and thus meet the definition of SIDS. The parental interview and observations made at the time of death were systematically recorded providing detailed data on a population basis. Investigation of the death includes a postmortem examination by a paediatric pathologist, and a multi-professional case discussion meeting, at which the classification of the cause of death is agreed (2,10,11).

This approach ensured that no deaths were missed and the diagnosis of SIDS was consistent. The Avon study is thus unique in permitting the assessment of changes in the epidemiology of SIDS in a defined population over a 20-year period (1984-2003).

Methodology

The study area, Avon, includes the former Health Districts of Bristol & Weston, Frenchay & Southmead, and equates to the former Avon Health Authority area. The population over the study period from 1984 to 2003 was between 800,000 and 900,000 with around 10,000 live births a year. Avon includes both rural and urban areas, including the City of Bristol, ranked 13th of 354 in the UK index of local deprivation, and North Somerset ranked 111th of 354 [12]. The population is predominantly white with only 3-4% ethnic minorities.

The Avon Infant Mortality Study (AIMS) was established in January 1984 to investigate all unexpected deaths of infants (birth to one year). A standard protocol was established, with all unexpected deaths being reported to the AIMS team as soon as possible (usually within 4 hours). All families were then interviewed by a member of the AIMS team (Consultant Paediatrician, Health Visitor or Fellow in Paediatrics) in the emergency department and at home, within 24 hours of the death, and a detailed history obtained of the infant's medical and social history, family history, social circumstances, events leading up to and the circumstances of the death. Information collected at this interview was shared with the paediatric pathologist before the post mortem examination, which was conducted to an agreed protocol [2,10,11]. A multi-professional case review meeting was held 2 - 3 months after the death, in the primary care setting, to review the cause of death and identify any potentially significant contributory factors, as well as planning further support and care of the family [2,10,11,13]. The AIMS team worked closely with the primary care team in

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providing support, care and information to the family, and with the Coroner's Officers and members of the Avon and Somerset Police Child Protection team. [2,10,11].

Unexpected deaths were defined as those that were not anticipated 24 hours before the death or the catastrophic collapse that led to death. Infants who suffered a major collapse and were resuscitated, but subsequently died after a period in intensive care, were thus included in the study [2].

Throughout the study period, SIDS was defined as "the sudden unexpected death of an infant (aged less than one year), for which a postmortem examination to an agreed protocol, and a review of the clinical history and the circumstances of death failed to identify a sufficient explanation" [2,10,11]. Potentially contributory factors were classified according to the Avon Clinicopathological classification [2,10,11,13].

Bedsharing deaths were only attributed to overlying or accidental asphyxia (and thus excluded from the SIDS definition) when the histopathology, review of history or scene of death investigation provided evidence of such a cause.

Ethical Considerations.

During the study period four separate case-control studies of sudden unexpected deaths in infancy were conducted in Avon (1987-9, 1990-91, 1993-6, and 2003-6). All of these studies received approval from the Local Research Ethics Committees, and appropriate informed consent was obtained from the parents. Throughout the study period, information obtained as part of the routine clinical care of the families as outlined above, was transcribed by a member of the clinical staff (PJF) from

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individual case notes into anonymised data summary sheets. Potentially identifiable data were categorised and then removed before entry into the database, which was thus fully anonymised before analysis [14]. (e.g. dates were categorised by month and day of the week; postcodes by Townsend Score).

The age-matched control infants from the CESDI case-control study of SUDI (1993-1996), which included Avon [2], closely matched the socio-economic status of mothers in the South-West Region with one dependent child as recorded in the 1991 census data [15]. These 1300 CESDI control infants have been used to demonstrate approximate demographic characteristics and practices within the sleeping environment of the normal population during a period around the midpoint of the present study.

Variable definition

The social class coding was based on the Registrar General's occupational coding, choosing the classification closest to the professional end of the spectrum if more than one parent. The Townsend deprivation score for each postcode area is derived from the distribution of normalised socio-economic indicators within the UK population, and allowed us to identify from the anonymised database those infants who lived in the 10% most deprived areas in the South-West of England (equivalent to a score of +4.44 or above) [16]. "Single" mothers included only those who did not live with a partner. Factors in the infant sleeping environment relate to the final sleep of the infants who died or the "reference" sleep of the controls (in the 24-hour period preceding the interview) [2]. Solitary sleepers were defined as those infants who slept alone for the last or reference sleep, bed sharers as those who slept with an adult in a

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bed or on a sofa. When dichotomising factors the lowest quintile of a distribution was chosen if a universal cut-off was not available.

Statistical Methodology

Non-parametric distributions were described using medians and inter-quartile ranges [IQR]. The Mann Whitney U test was used to test whether two non-parametric independent samples were from the same population. Confidence intervals for death rates were calculated as incidence rates per 10,000 births. Intervals for proportional changes in factors were calculated using the Wilson Method [17]. The chi-square test using Yates's correction was used to test dichotomous differences. The linear chi-square test for trend (one degree of freedom) was used to test for any changes in factors over 5 yearly intervals.

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Results

Ascertainment

In the 20-year period of the study, 369 unexpected infant deaths were notified to the study team. A careful review of registered deaths from the study area over this period revealed no further deaths of infants normally resident in Avon that had not been included. The median delay from an infant being found dead to a member of the AIMS team contacting the family was less than 4 hours, and 319 of the 369 deaths (86%) were contacted within 24 hours of the death. Parental interviews were conducted for 348/369 deaths (94.3%), and home visits were carried out for 331/369 deaths (89.7%).

Classification.

Of the 369 deaths, 300 (81.3%) were classified as Sudden Infant Death Syndrome (SIDS). The remaining 69 were considered to have been fully explained, most commonly as a consequence of previously unrecognised infection, accidental or non-accidental injury, congenital malformations, or metabolic disorders. Investigation of the circumstances of death showed direct evidence of overlying or suffocation whilst bed-sharing in 3 unexpected deaths, which were therefore not categorised as SIDS.

SIDS deaths

Changes in Incidence

In the 1980's in Avon 25-40 SIDS deaths occurred each year, falling by more than 75% after 1991. Figure 1 compares the SIDS rate in Avon over the last 20 years with the SIDS rate in England & Wales. In Avon, a campaign led by local health care professionals in 1989-90 was followed by a marked fall in SIDS rates approximately

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one year ahead of the national fall that followed the “Back to Sleep” campaign in 1991 [18].

The national SIDS rate peaked in 1988 with nearly 1600 deaths in that year. These deaths halved by the early 1990’s and have now fallen to less than 300 a year in England & Wales [3], though it is not possible to say how much the recent fall has been an effect of changes in certification practice [9]. In Avon, where there has been no change in diagnostic criteria, recent SIDS rates are slightly higher than the national rate.

Changes in socio-economic classification

Figure 2 compares the social class distribution amongst the SIDS families before (1984-1991 inclusive) and after (1992-2003 inclusive) the national “Back to Sleep” campaign. Amongst the CESDI controls in the mid 1990’s the proportion of families receiving no waged income was 18%, and nationally unemployment has been falling since the mid 1980’s. Amongst the SIDS families however we see the opposite trend; before the intervention campaign 28% of SIDS families received no waged income, whilst subsequently this proportion has since grown to 48%. Table 1 shows the socio-economic status of SIDS families over the 4 consecutive 5-year intervals.

Most of these markers of socio-economic deprivation were more highly represented amongst SIDS families in Avon in the mid 1980’s compared to the CESDI controls and all have become increasingly more prevalent in recent years; three-quarters of SIDS families are now classified as being in Socio-economic class IV, V or

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unemployed, 86% of the mothers smoke, 40% are now single, 16% are aged less than 20 and 48% of SIDS infants live in the 10% most deprived postcode areas.

Changes in infant sleeping environment

Table 2 shows the change in infant care practices in the sleeping environment over the last 20 years. In the 1980's the majority of SIDS infants were put to sleep in the prone position, as were most infants in the normal population [13,19]. Over the last 20 years infant sleeping position has dramatically changed in Avon; the proportion of SIDS infants who had been placed prone to sleep has fallen from 89% to 24%. Notably, amongst the CESDI controls, a study conducted after the fall in SIDS rate, only 3% were placed prone. Clearly the 'Back to Sleep' campaign in 1991 has had a dramatic effect on parental choice of infant sleeping position. The most common sleeping position for both SIDS infants and controls since 1991 is supine. The side position has also become more common, in particular with pre-term SIDS infants, 31% (8/26) being put down in this position over the last 10 years compared to 6% (3/47) amongst SIDS term infants (Chi-sq: 5.99 1df, p=0.01)

The increase in the prevalence of bedsharing deaths appears to be dramatic, rising from 12% in the 1980's to almost 50% of SIDS deaths in 1999-2003. Yet the actual *number* of SIDS deaths in the parental *bed* has halved over the last 20 years (Figure 2) from a median of 4 [IQR: 3-5] deaths a year in 1984-91 inclusive, to 2 deaths a year [IQR1.25-2.75] in 1992-2003 inclusive (p = 0.01, Mann Whitney U test). This fall in bedsharing SIDS deaths, whilst significant, is smaller than the fall in deaths in the cot, which may partly be due to differences in sleeping position between cot-sleeping and bedsharing infants. Prior to the 1991 campaign 91% of SIDS infants who died in a cot

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were placed prone, but only 55% of the bedsharing SIDS infants were placed prone, and over a third (37%) were placed on their side. Thus avoiding the prone sleeping position would be expected to have a smaller effect on deaths when bedsharing than on deaths in cots.

Although the number of deaths in the parental *bed* has fallen, the number of bedsharing deaths on a *sofa* has worryingly risen in recent years.

Changes in SIDS infant and family characteristics

The age at death of solitary sleeping SIDS infants has remained stable over the last 20 years. The median age of death of these SIDS infants was similar before and after the 1991 campaign (85 days [IQR: 55-129 days] and 81 days [IQR: 53-136 days] respectively), averaging 12 weeks old with few deaths in the first month (7%) or after 8 months old (6%). However, the median age of infants dying as SIDS whilst bedsharing has changed from 88 days (IQR 44-127 days) before the end of 1991, to 54 days (IQR 33-84 days) after this time (Mann Whitney U test $p = 0.007$). The reason for this change is unclear.

Table 3 shows the change in other background factors that characterise SIDS infants and families over the last 20 years. SIDS has remained more common amongst males throughout the 20 years. Prematurity, low birthweight, multiple births and larger families have always been features of SIDS infants but these features are now much more marked. First-born infants have previously been seen to be at lower risk of SIDS, but now, surprisingly, form the largest single group.

Discussion

The 'Back to Sleep' campaign in the UK was successful in getting its primary message over; parents avoided using the prone position and the number of SIDS deaths, especially those put down in a cot, have fallen dramatically. Initially the side sleeping position was recommended as a safe alternative to prone but this advice changed in the mid-nineties when further research [20] revealed the side position was unstable because of small infants rolling prone. This is reflected in the higher prevalence of Avon SIDS parents placing their infants on their side shortly after the campaign, whilst the continued use of this practice more recently is predominantly amongst pre-term infants. Many midwives and neonatal nurses still use the side sleeping position in preference to the supine position at the time of discharge from hospital because of a perceived risk of aspiration [21], despite a lack of forensic, pathological or epidemiological evidence to substantiate these fears [22].

The change in sleeping position has not just led to a dramatically reduced number of SIDS deaths; the epidemiology of SIDS has changed significantly.

The Avon longitudinal data clearly show that SIDS is now largely confined to deprived families and almost half occur whilst bedsharing. The rather alarming rise in prevalence of bedsharing in recent SIDS case-control studies [4-7] has led some to recommend against bed-sharing [7,23], indeed some countries have already adopted this stance. However the Avon data shows that this apparent rise in prevalence is more due to the effectiveness of risk reduction campaigns in reducing SIDS deaths in the solitary sleeping environment (where deaths have fallen to one sixth of their previous levels) than an increase in deaths when bedsharing. Indeed, the *number* of SIDS

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deaths in the parental bed in Avon has halved since the 'Back to Sleep' campaign. More worrying is the rise in both prevalence and number of SIDS infants with a parent on a *sofa*. Whatever the contribution of unrecognised overlying amongst such deaths, we should continue to strongly recommend against parents co-sleeping in such an inappropriate environment [24].

The change in socio-economic status has led to some expected changes in the characteristics of SIDS families; an increase in single mothers, younger mothers, mothers who smoke and lower birthweight infants. However the prevalence of maternal smoking during pregnancy amongst SIDS mothers (80-90%) is twice the level expected amongst control mothers with similarly deprived socio-economic backgrounds, lending support to the hypothesis that infant exposure to tobacco smoke is some part of a causal mechanism. The prevalence of pre-term infants amongst those dying as SIDS has now tripled; over a third of SIDS infants are now pre-term compared to a population prevalence of 5%. This may partly be explained by the continued practice of using the side position for pre-term infants in maternity units [22].

Some changes however have occurred with no obvious explanation. The age of bedsharing SIDS infants has significantly decreased and in terms of birth order, first-born SIDS infants are now the most common. The decreased age of bedsharing SIDS may suggest that these vulnerable infants are infants being inadvertently overlain, but this does not hold up to closer scrutiny. The prevalence of bed-sharing in England is at its highest in the first month of life when the infant is most vulnerable [25] yet the peak age of death whilst bedsharing is a month later than this.

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The pathology of SIDS needs to be re-evaluated, not just for consistent diagnosis but also to again explore potential causal mechanisms. In recent years, pathologists in the UK have been reluctant to diagnose SIDS when the death occurred whilst bedsharing in an adult bed or when parents had been known to use illegal drugs [9]. This may explain the discrepancy between the national SIDS rate and that in Avon since 1997.

There are clues in pathology as to why SIDS occurs but these have previously been thought to be too general for diagnostic purposes [26]. Careful collection of clinical and pathological data may allow the construction of detailed clinicopathological correlations between important findings. The recognition of the changes in the epidemiology of SIDS since the “Back to Sleep” campaign should be a trigger for careful re-analysis of the relationship between clinical and pathological findings.

Most SIDS infants are now found supine, most come from poorer families and many are bedsharing. To understand why SIDS infant die we need to compare families that live in similar deprived circumstances and infants that sleep in particular sleeping environments. The recognition of changing epidemiology may allow appropriate comparisons to be made in future studies.

Death certification data for whole populations are vulnerable to variation in ascertainment, standards of investigation, and the definition of terms used, though they do allow accurate identification of changes in overall mortality. The present study, with virtually complete ascertainment, standardised protocols, and uniform definitions in a population of close to 1 million people over a twenty-year period

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avoids each of these potential errors, and allows the identification of potentially highly significant changes over this time period.

The Kennedy Report [10] has emphasised the importance of a thorough investigation, including a multiprofessional review process in the identification of the causes of unexpected deaths in infancy, and the CESDI study showed that such a process was achievable in a well-funded large-scale three-year research study. Recent publications [27,28] have suggested that for many centres, such thorough investigations are unlikely to be maintained. The present study shows that, with close collaboration of all relevant agencies, such standards can be reached and maintained in a large population over a prolonged period of time.

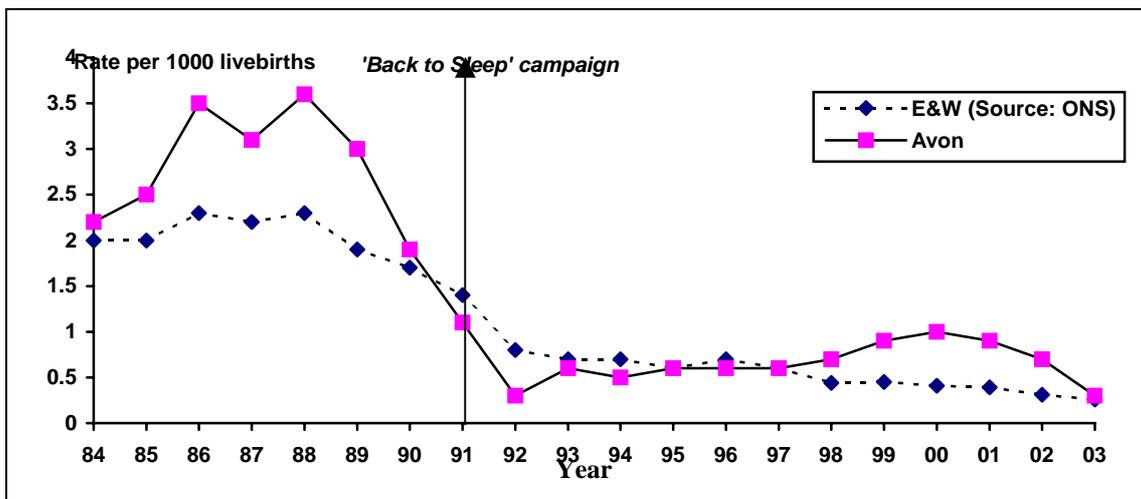
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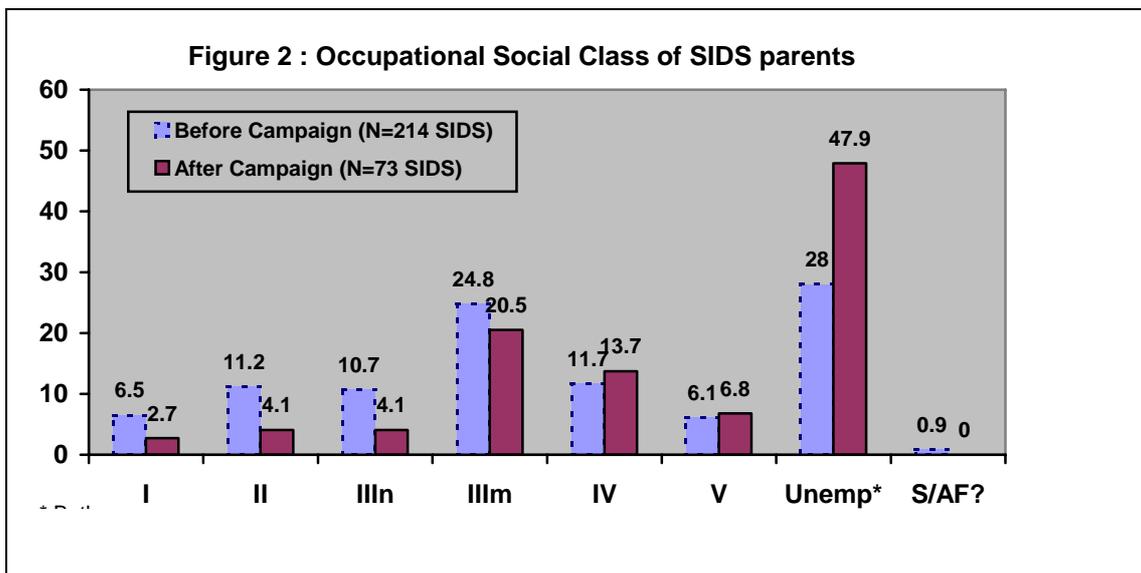
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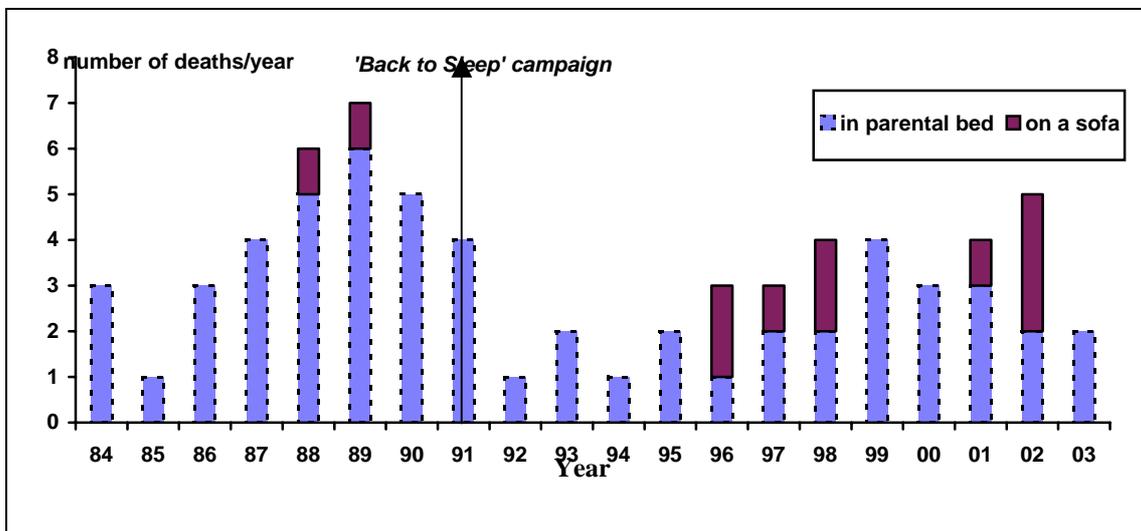


Table 1: Socio-economic markers of SIDS families - trends in Avon over a 20 year period and comparison with CESDI controls

| Socio-economic marker | 1984-88 | | | 1989-93 | | | 1994-98 | | | 1999-2003 | | | Test for trend | | CESDI controls | | |
|--------------------------------------|---------|----|---------|---------|----|---------|---------|----|---------|-----------|----|---------|----------------|---------|----------------|----|---------|
| | n/N | % | 95% CI | n/N | % | 95% CI | n/N | % | 95% CI | n/N | % | 95% CI | Chi sq | p-value | n/N | % | 95% CI |
| Social class IV/V unemp.* | 72/153 | 47 | [39-55] | 33/73 | 45 | [34-57] | 18/27 | 67 | [48-81] | 25/34 | 74 | [57-85] | 8.8 | 0.003 | 223/1296 | 17 | [15-19] |
| 10% most deprived areas** | 34/146 | 23 | [17-31] | 23/69 | 33 | [23-45] | 9/30 | 30 | [17-48] | 16/33 | 48 | [33-65] | 7.6 | 0.006 | - | - | |
| Single mothers [§] | 24/152 | 15 | [11-22] | 12/74 | 16 | [10-26] | 15/30 | 50 | [33-67] | 14/35 | 40 | [26-56] | 17.2 | <0.0001 | 69/1300 | 5 | [4-7] |
| Maternal age < 20 years [¶] | 11/154 | 7 | [4-12] | 10/73 | 14 | [8-23] | 6/29 | 21 | [10-38] | 5/32 | 16 | [7-32] | 4.7 | 0.03 | 84/1300 | 6 | [5-8] |
| Maternal smoking during pregnancy | 85/148 | 57 | [49-65] | 43/72 | 60 | [48-70] | 23/29 | 79 | [62-90] | 31/36 | 86 | [71-94] | 12.4 | 0.0004 | 348/1299 | 27 | [24-29] |

* Based on the registrar General's occupational coding using the parental classification closest to social class I

** Based on the Townsend Deprivation Score linked to the postcode, the 10% most deprived areas scoring +4.44 or more, data not available for CESDI controls

§ Cohabiting mothers were not counted as single

¶ Lowest quintile was chosen as cut-off

Table 2: The final sleeping environment of SIDS infants - trends in Avon over a 20 year period and comparison with CESDI controls

| For the final sleep | 1984-88 | | | 1989-93 | | | 1994-98 | | | 1999-2003 | | | Test for trend | | CESDI controls | | |
|-----------------------------|---------|----|---------|---------|----|---------|---------|----|---------|-----------|----|---------|----------------|---------|----------------|-----|---------|
| | n/N | % | 95% CI | n/N | % | 95% CI | n/N | % | 95% CI | n/N | % | 95% CI | Chi sq | p-value | n/N | % | 95% CI |
| Put down on back | 2/121 | 2 | [0.5-6] | 8/71 | 11 | [6-21] | 17/26 | 65 | [46-81] | 20/33 | 61 | [44-75] | 86.7 | <0.0001 | 895/1295 | 69 | [67-72] |
| Put down on side | 11/121 | 9 | [5-16] | 14/71 | 20 | [12-30] | 3/26 | 12 | [4-29] | 5/33 | 15 | [7-31] | 1.1 | 0.3 | 361/1295 | 28 | [26-30] |
| Put down on front | 108/121 | 89 | [82-94] | 49/71 | 69 | [58-79] | 6/26 | 23 | [11-42] | 8/33 | 24 | [13-41] | 73.4 | <0.0001 | 39/1295 | 3 | [2-4] |
| Co-sleeping in parental bed | 16/147 | 11 | [7-17] | 18/74 | 24 | [16-35] | 8/28 | 29 | [15-47] | 14/36 | 39 | [25-55] | 17.3 | <0.0001 | 189/1299 | 15 | [13-17] |
| Co-sleeping on a sofa | 1/147 | 1 | [0-4] | 1/74 | 1 | [0-7] | 5/28 | 18 | [8-36] | 4/36 | 11 | [4-25] | 16.5 | <0.0001 | 6/1299 | 0.5 | [0.2-1] |

Table 3: Characteristics of SIDS infants and families - trends in Avon over a 20 year period and comparison with CESDI controls

| Characteristics | 1984-88 | | | 1989-93 | | | 1994-98 | | | 1999-2003 | | | Test for trend | | CESDI controls | | |
|------------------------------|---------|----|---------|---------|----|---------|---------|----|---------|-----------|----|---------|----------------|---------|----------------|-----|---------|
| | n/N | % | 95% CI | n/N | % | 95% CI | n/N | % | 95% CI | n/N | % | 95% CI | Chi sq | p-value | n/N | % | 95% CI |
| Proportion of males | 83/158 | 53 | [45-60] | 52/76 | 68 | [57-78] | 14/30 | 47 | [30-64] | 20/36 | 56 | [40-70] | 0.08 | 0.78 | 672/1300 | 52 | [49-54] |
| Pre-term (<37 weeks)* | 19/155 | 12 | [8-18] | 17/74 | 23 | [15-34] | 11/30 | 37 | [22-54] | 12/35 | 34 | [21-51] | 14.4 | 0.0001 | 70/1288 | 5 | [4-7] |
| Low birthweight (<2500g) | 21/155 | 14 | [9-20] | 13/73 | 18 | [11-28] | 10/29 | 35 | [20-53] | 6/32 | 19 | [9-35] | 3.2 | 0.07 | 66/1292 | 5 | [4-6] |
| Multiple births | 3/155 | 2 | [1-6] | 4/74 | 5 | [2-13] | 2/30 | 7 | [2-21] | 3/36 | 8 | [3-22] | 4.1 | 0.04 | 12/1300 | 0.9 | [0.5-2] |
| Larger families (4 or more)? | 22/154 | 14 | [10-21] | 9/74 | 12 | [7-22] | 6/30 | 20 | [10-37] | 13/36 | 36 | [22-52] | 7.9 | 0.005 | 100/1300 | 8 | [6-9] |
| First-time mother | 27/154 | 18 | [12-24] | 16/74 | 22 | [14-32] | 13/30 | 43 | [27-61] | 12/36 | 33 | [20-50] | 8.5 | 0.003 | 558/1300 | 43 | [40-46] |

* Defined as infants born below 37 completed weeks

? Cut-off chosen as approximate lowest quintile