Infant death

New knowledge, new insights, and new recommendations

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Scientific controversy and media hype in unexpected infant deaths

The fall in numbers of unexpected infant deaths that followed ''Back to Sleep'' intervention campaigns in many countries in the early 1990s has been one of the striking achievements of applied epidemiology in the field of child health in modern western society.[1 2] The possibility that other modifiable risk factors might be amenable to similar interventions in this mysterious group of conditions has led to multiple studies of the epidemiology of the residual unexpected infant deaths. Having been central participants in the implementation of the ''Back to Sleep'' campaigns in many countries, the media remain acutely alert to the possibility of any new or significant developments in this field. Thus any public pronouncements by professional organisations must be made in the knowledge that they will attract intense media attention.

The recent Policy Statement by the American Academy of Pediatrics (AAP) on the changing concept of sudden infant death syndrome (SIDS) and approaches to its prevention[3] aroused an unusual level of criticism and hostility both within and beyond that organisation.[4–8] Despite the careful presentation of the evidence on which their recommendations were based, and the largely uncontroversial nature of most of the recommendations, the responses—by media and professionals alike—to the report of the AAP Task Force on SIDS have concentrated on the two issues of bedsharing and pacifier (dummy) use, and largely ignored the other nine recommendations (box 1)—most of which are based on stronger and less controversial data.

The scientific rigour with which data is gathered is not easily applied to the dissemination of the results and formulating advice can be a subjective exercise of weighing up the available evidence and constrained by attempts to simplify the message. The AAP's recommendations to advise against bedsharing and promote dummy use needs to be questioned, not for the carefully weighed evidence presented but rather the gaps in our knowledge of infant care practices and their consequences that still remain.

An infant sharing a bed with an adult (usually the mother) who smokes or has taken alcohol or other consciousness affecting medications has been clearly shown in multiple studies to be at substantially increased risk of unexpected death, over and above the risk associated with maternal smoking.[9–11] Most studies have shown no increased risk from infants bedsharing with non-smoking mothers,[9–11] though the large multicentre European study[12] showed a small risk, and a Scottish study[13] showed a larger risk, particularly for younger infants, though no account was taken of parental alcohol intake. Sleeping with an infant on a sofa is also associated with a particularly high risk, compounded by the circumstances in which sofa sharing occurs—e.g. changes to normal sleep routines, or social deprivation. Clearly there are inappropriate circumstances or environments in which co-sleeping occurs,[9–11] with increased vulnerability of some infants,[14] and these deserve further investigation.

Over the last three years we have been investigating all unexpected infant deaths in the southwest of England (population 5 million), approximately half of whom were co-sleeping with a parent. The vast majority (>90%) of these co-sleeping deaths occurred in an unsafe co-sleeping environment as defined by current UK guidelines (parents smoke, have recently consumed alcohol or taken drugs, slept on a sofa, or a combination of these factors). After thorough death scene and postmortem investigations we have no evidence that the few SIDS deaths that occurred in a relatively safe co-sleeping environment are more than would have happened if the infants had slept alone in cots. Nationally up to 100 000 non-smoking mothers bring their infant into the parental bed to sleep each night.[9 15] Changing current guidelines to advise against co-sleeping for this particular group of mothers would seemingly have little if any effect on the SIDS rates but could deny these mothers and infants any potential advantages in co-sleeping, including accessibility to the breast.

The relative *proportion* of unexpected infant deaths in which the infant was sharing a sleep surface with an adult has undoubtedly increased in several countries over the past few years, and been widely reported among recent case-control studies of SIDS infants.[11–13] However, there is no evidence that the *number* of bedsharing deaths has risen—and some evidence that the absolute number of such deaths has fallen in the UK,[16] at a time when the practice of bedsharing has increased.[3 4 16] The

Box 1: Summary of recommendations by the American Academy of Pediatrics to reduce the risk of SIDS[3]

(1) Put infants on their backs to sleep
(2) Use a firm sleep surface
(3) Keep soft objects and loose bedding out of the crib
(4) Do not smoke during pregnancy and avoid exposure of infants to second hand tobacco smoke
(5) A ''separate but proximate'' sleep environment is recommended. Use a crib, in the parents' bedroom, but avoid bedsharing during sleep, and avoid sleeping on a couch or armchair with an infant
(6) Consider offering a pacifier at nap time and bedtime
(7) Avoid overheating
(8) Avoid commercial devices marketed to reduce the risk of SIDS
(9) Do not use home monitors as a strategy to reduce the risk of SIDS
(10) Avoid the development of positional plagiocephaly (''tummy time'' when awake; vary position of infant's head)
(11) Continue the ''Back to Sleep'' campaign. Intensify public education for secondary caregivers (e.g. child minders, baby sitters, grandparents, foster parents)

consistently low rates of unexpected infant deaths in some societies in which bedsharing is a routine cultural practice raises further doubts about the validity of generalised recommendations against bedsharing.[17]

Although bedsharing is perceived to be and is treated as a risk factor in the field of SIDS epidemiology, it is accepted as normal human practice by anthropologists and infant physiologists. Indeed, much research has been conducted into mother–infant interactions, skin-to-skin care (Kangaroo care), arousal patterns, and the architecture of infant sleep. These studies are often conducted on small selected populations and because of the complex issues involved are more qualitative than quantitative, but are necessary to derive a balanced argument on the potential benefits of bedsharing.[17] While many studies have shown a positive correlation between bedsharing and breast feeding, the lack of conclusive evidence that bedsharing has a causal role in the establishment and continuation of breast feeding may be a reflection of the lack of appropriate studies rather than the lack of such an effect.[18]

Similar arguments can be applied to dummy (pacifier) use. While some studies have shown a relation between dummy use and a reduction in duration of breast feeding, other studies have not confirmed this,[19 20] and the significance of the reported association between dummy use and otitis media is not clear.[21] The physiological effects of dummy sucking and of finger/thumb sucking (which is inhibited by dummy use) are virtually identical,[22] and both are similar to the effects of non-nutritive suckling on the breast, though few studies have addressed the occurrence of these patterns of sucking behaviour in infants in various sleep environments. While the evidence that the use of dummies is associated with a decreased risk of SIDS is convincing, the potential adverse effect of a reduction in breast feeding duration that may result must be taken into account in any assessment of population risks/benefits for dummy use.

The AAP's recommendation on widespread dummy use inherently implies a causative protective effect. Postulated arguments of the protective mechanism include the avoidance of the prone sleeping position, protection of the airways, reduction of gastro-oesophageal reflux through sucking, or a lowering of the arousal threshold. However, observational studies of infant dummy use[22–24] suggest the dummy falls out within 30 minutes of the onset of sleep while many SIDS victims are discovered several hours after this onset. Studies of SIDS generally only record whether the cases and controls were given a dummy for the final sleep along with routine use which appears to have a much reduced protective effect. Using Bradford Hill's criteria of causation, the temporal sequence, biological plausibility, and indeed gradient of dummy use affording some protection is as yet speculative. The physiology of non-nutritive sucking, its frequency, duration, and relationship with infant sleep deserves further investigation.

The AAP recommendations[3] should be considered in the light of the principles of evidence based medicine (EBM) on which it relies. Sackett and colleagues[25] argue that EBM procedures and conditions require: (1) reaching consensus before recommendations are put forth; (2) not relying exclusively on case control studies as the basis of the recommendation; (3) respecting patient values; (4) leaving room for clinical judgements that respect exceptions to population based recommendations; and (5) recognising the relationship between clinical judgements and the experiences and emotions of those for whom the recommendations are intended as a critical factor in assessing whether a public health message can or will be successful.

The demonstration by Chen and Rogan[26] in a multivariate analysis that the postneonatal infant mortality rate in the USA was 26% higher for bottle fed than breast fed infants raises the possibility that any action leading to reduced rates or duration of breast feeding may increase infant mortality. While many factors potentially contributed to this difference, it is likely that breast feeding itself has an important contributory effect, and thus any fall in breast feeding rates may lead to a significant increase in postneonatal infant mortality, even in Western societies.[27] There is thus a need for a careful assessment of potential adverse consequences before any public pronouncement on the desirability or otherwise of practices such as bedsharing or pacifier use that may affect breast feeding rates.

While the importance and the potential value of updated recommendations to reduce the risk of unexpected infant deaths must be recognised, potential unintended adverse consequences must also be fully taken into account. Many mothers—particularly those who breast feed—will fall asleep while feeding their infant during the night regardless of their initial intentions about bedsharing. If bedsharing is proscribed, the risk may be increased of mothers unintentionally falling asleep on armchairs or sofas on which they are feeding, with a resultant much higher risk to the infant.[9 16]

If we are going to accurately assess the potential harm or benefits of co-sleeping and dummy use we need to specifically explore the environments in which they occur and the variation in practice. The findings by SIDS case-control studies that one may be a potential risk and the other afford protection should be seen as a starting point rather than an end-point on which recommendations are based. In future studies of unexpected death we should investigate potential mechanisms of causality and to whom in the population this may apply, while outside this field we need to look at the potential adverse effects on breast feeding initiation or duration which have not so far been adequately addressed.

The media attention to the AAP statement appears to ignore and thus undermine the wide professional and public acceptance and support for the majority of the recommendations while widening an unresolved and seemingly polarised debate.

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REFERENCES

1 **Wigfield R**, Gilbert R, Fleming PJ. SIDS: risk reduction measures. *Early Hum Dev* 1994;**38**:161–4.
2 **Fleming PJ**. The implementation of risk reduction for SIDS in the UK. *Proc R Coll Physicians Edinb* 1995;**25**:213–20.
3 **American Academy of Pediatrics**. Policy Statement. The changing concept of sudden infant death syndrome: diagnostic coding shifts, controversies regarding the sleeping environment, and new variables to consider in reducing risk, *Pediatrics* 2005;**116**:1245–55.
4 **Gessner BD**, Porter TJ. Bed sharing with unimpaired parents is not an important risk factor for sudden infant death syndrome. *Pediatrics* 2006;**117**:990–1.
5 **Eidelman AI**, Gartner LM. Bed sharing with unimpaired parents is not an important risk factor for sudden infant death syndrome. *Pediatrics* 2006;**117**:991–2.
6 **Bartick M**. Bed sharing with unimpaired parents is not an important risk factor for sudden infant death syndrome. *Pediatrics* 2006;**117**:992–3.
7 **Pelayo R**, Owens J, Mindell J, *et al*. Bed sharing with unimpaired parents is not an important risk factor for sudden infant death syndrome. *Pediatrics* 2006;**117**:993.
8 **Kattwinkel J**, Hauck F, Moon RY, *et al*. In reply. *Pediatrics* 2006;**117**:994–6.
9 **Blair PS**, Fleming PJ, Smith IJ, *et al*. Babies sleeping with parents: case-control study of factors influencing the risk of the sudden infant death syndrome. *BMJ* 1999;**319**:1457–62.

10 **Scragg R**, Mitchell EA, Taylor BJ, *et al*. bed Sharing smoking and alcohol in the sudden infant death syndrome. *BMJ* 1993;**307**:1312–18.
11 **McGarvey C**, McDonnell M, O'Regan M, *et al*. An eight year study of risk factors for SIDS: bedsharing vs non bedsharing. *Arch Dis Child* 2006;**91**:318–23.
12 **Carpenter R**, Irgens LM, Blair PS, *et al*. Sudden unexplained infant death in 20 regions in Europe: case control study. *Lancet* 2004;**363**:185–91.
13 **Tappin D**, Ecob R, Brooke H. Bedsharing, roomsharing and sudden infant death syndrome in Scotland. *J Pediatr* 2005;**147**:32–7.
14 **Blair PS**, Ward-Platt M, Smith IJ, *et al*. Sudden infant death syndrome and sleeping position in preterm and low birthweight infants: an opportunity for targeted intervention. *Arch Dis Child* 2006;**91**:101–6.
15 **Blair PS**, Ball HL. The prevalence and characteristics associated with parent infant bedsharing in England. *Arch Dis Child* 2004;**89**:1106–10.
16 **Blair PS**, Sidebotham P, Berry PJ, *et al*. Major changes in the epidemiology of sudden infant death syndrome: a 20-year population based study of all unexpected deaths in infancy. *Lancet* 2006;**367**:314–19.
17 **McKenna JJ**, McDade T. Why babies should never sleep alone: a review of the co-sleeping controversy in relation to SIDS, bedsharing and breastfeeding. *Paediatr Respir Rev* 2005;**6**:134–52.
18 **Ball HL**. Breastfeeding, bedsharing and infant sleep. *Birth* 2003;**30**:181–8.
19 **Howard CR**, Howard FM, Lanphear B, *et al*. Randomised clinical trial of pacifier use and bottle feeding or cupfeeding and their effect on breastfeeding. *Pediatrics* 2003;**111**:511–18.
20 **Kramer MS**, Barr RG, Dagenais S, *et al*. Pacifier use, early weaning and cry/fuss behaviour. *JAMA* 2001;**286**:322–26.
21 **North K**, Golding J, Fleming PJ. Pacifier use and morbidity in the first six months of life. *Pediatrics* 1999;**103**:e34.
22 **Pollard K**, Fleming PJ, Young J, *et al*. Night time non-nutritive sucking in infants aged 1 to 5 months: relationship with infant state, breast feeding, and bed- versus room-sharing. *Early Hum Dev* 1999;**56**:185–204.
23 **Franco P**, Scaillet S, Wermenbol V, *et al*. The influence of a pacifier on infants' arousals from sleep. *J Pediatr* 2000;**136**:775–9.
24 **Weiss P**, Kerbl R. The relative short duration that a child retains a pacifier in the mouth during sleep: implications for sudden infant death syndrome. *Eur J Pediatr* 2001;**160**:60–70.
25 **Sackett DL**, Strauss SE, Richardson WS, *et al*. *Evidence based medicine: how to practice and teach EBM,* 2nd edn. Edinburgh: Churchill Livingstone, 2000.
26 **Chen A**, Rogan WJ. Breastfeeding and the risk of postneonatal death in the United States. *Pediatrics* 2004;**113**:435–9.
27 **Bjerrre LM**, LeLorier J. Expressing the magnitude of adverse effects in case-control studies: ''the number of patients needed to be treated for one patient to be harmed''. *BMJ* 2000;**320**:503–6.

Public health

Health and social care service changes: the potential to increase inequalities

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Perspective on the paper by Granerod *et al* (see page 805)

The paper by Granerod *et al*[1] shows how children seemed to have been ''lost'' when the Child Health Information Systems (CHISs) were interrogated to provide the routine immunisation statistics (COVER). This was at a time when the reports changed from being based on a resident population to being based on the primary care trust (PCT) responsible population, i.e. those children who were patients of the PCT's GPs, but not necessarily resident within the PCT's geographical boundaries.[2] The United Kingdom has probably the most accurate and timely system in the world for monitoring immunisation uptake.[3] Most other countries rely on either knowing the numbers of doses of vaccine administered or on representative surveys.[4 5] It is of concern that this system was compromised, but the trend of improvement in accuracy reported by the authors is encouraging. However, currently (April 2006), 10 of the 31 PCTs in London are unable to produce any COVER statistics because they are in the process of installing new ''interim'' CHISs.[6]

What the authors do not mention is that the CHISs are also frequently used to generate appointments for vaccination. This is particularly so in areas such as inner London. If the systems cannot produce statistics for immunisation, are they able to produce appointments for all their population? We know they cannot do this currently in London, and anecdotally, there are difficulties in other areas. At the time of writing, a new immunisation schedule is about to be introduced.[7] Whereas previously, the programme was fairly simple to remember and the vaccines given at 8, 12, and 16 weeks were the same on each occasion, in future, they will differ. In addition, there will be new boosters in the second year of life and a pneumococcal catch-up campaign. Without an efficient information system, it will be very difficult to ensure that appointments for this new programme can be generated and the new programme which includes the introduction of a new vaccine will not be effectively monitored.

But this has wider ramifications than ''just'' the immunisation programme. CHISs are used to monitor routine screening throughout childhood, e.g. newborn blood spot screening. Results are recorded on the systems and those children for whom there is no result available should be followed up, either to obtain a lost result or to take a repeat sample.[8] Since the introduction of PCTs in 2002, there has been a discordance between the population for whom they commission services and those for whom they directly provide services. Health visitors traditionally provide services to the resident population, whereas the PCT is responsible for providing services to the patients of ''their'' GPs and anyone resident in their area if not registered. It is primarily health visitors who are involved in ensuring that all children have had their newborn blood spot screening performed and often also that they have been immunised. The discordance in roles outlined above means there is potential for children to slip through the net.

Just as the team evaluating the Sure Start programmes commented that ''the people who have missing data are not randomly distributed in the population studied and may include some of the most disadvantaged'',[9] the same is likely to apply here. Those who are most disadvantaged are those we may have most difficulty in tracking and facilitating their access to health and social services. This may result in an increase in health inequalities. Reporting on the early outcomes, the Sure Start Evaluation Team noted that, among disadvantaged families, greater benefits were achieved in the moderately disadvantaged families than those with severe disadvantage, thus increasing inequalities. They also noted that some of the most disadvantaged families fared *worse* in areas where a Sure Start programme had been introduced, than where one was yet to be applied.

In 2005, the Health Inequalities Unit reported on progress in reducing inequalities.[10] Although infant mortality in all socioeconomic groups decreased in the period 1994–2003, the ratio of routine and manual socioeconomic groups to all socioeconomic groups increased from 1.15 to 1.19, indicating an increase in inequality. Similarly, between 1998 and 2003, despite an overall reduction in childhood injuries, the absolute difference between areas of different socioeconomic status remained unchanged and the relative difference increased. Over the same period, teenage