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Antwort auf Carpenter et al. 2013: Bed sharing when parents do not smoke: is there a risk of SIDS?

Der Londoner Statistiker Robert Carpenter rechnet in einer viel beachteten Studie vor: Babys, die im Bett ihrer Eltern schlafen, hätten auch dann ein höheres Risiko für den Plötzlichen Kindstod, wenn die Mutter ihr Kind stille und nicht rauche (http://bmjopen.bmj.com/content/3/5/e002299.full.pdf+html).

Wir haben diese Studie kritisch gelesen und wollen darauf hinweisen, dass Carpenters Berechnungen teils auf unzulässigen Annahmen und auf veralteten Daten beruhen. Wir haben dies in einer Online-Reply im BMJ Open begründet:

http://bmjopen.bmj.com/content/3/5/e002299.abstract/reply - bmjopen_el_7055

Wir fassen hier die wichtigsten Gründe unserer Kritik kurz auf Deutsch zusammen und fügen eine Anmerkung zu der derzeitigen Diskussion in der Presse hinzu.

- Carpenter fasste für seine Analyse Daten aus verschiedenen Fall-Kontroll-Studien aus unterschiedlichen Ländern zusammen. Es handelt sich dabei nicht um eine systematische Zusammenfassung oder Meta-Analyse, sondern um eine statistische Auswertung von 5 Datensätzen, die für diese Arbeit nach unbekannten Kriterien ausgewählt wurden. Die Daten sind 15 - 26 Jahre alt.
- In dieser Zeit hat sich die Epidemiologie des Plötzlichen Kindstods deutlich verändert. So sind im Jahr 2011 in Deutschland insgesamt 147 Babys an Plötzlichem Kindstod (SIDS) verstorben. Das sind 89 % weniger als im Jahr 1991, als in Deutschland 1285 SIDS-Fälle auftraten.
- Bei seiner Hochrechnung der aktuellen Risiken geht Carpenter von hier und heute nicht zutreffenden Zahlen aus. So legt er beispielsweise 0,43 SIDS-Fälle pro 1000

Lebendgeborenen zugrunde, von denen 22% im Elternbett verstorben seien. In Wirklichkeit aber liegt die SIDS-Rate in Deutschland um etwa die Hälfte niedriger. Ausserdem liegt der Prozentsatz der im Elternbett auftretenden SIDS-Fälle in Deutschland nicht bei 22% sondern bei 14,4% [Vennemann 2009]. Damit liegt die Zahl der im Bett der Eltern an SIDS verstorbenen Babys in Deutschland um zwei Drittel niedriger als laut Carpenters Berechnungen anzunehmen - nämlich bei derzeit etwa 21 pro Jahr und nicht bei etwa 64.

- Für die überwältigende Mehrzahl dieser 21 Fälle muss angenommen werden, dass eines der bekannten Risiken für SIDS vorgelegen hat. In Carpenters eigener Studie waren 78% der SIDS-Fälle mit elterlichem Rauchen verbunden, mindestens 20 % mit starkem Alkohol-Genuss, 27% der verstorbenen Babys wurden auf dem Bauch zum Schlafen gelegt, und 65% der SIDS-Babys wurden ausschließlich mit der Flasche ernährt (die weitaus überwiegende Zahl der SIDS-Fälle tritt in den ersten 6 Lebensmonaten auf, und Stillen hat sich als wichtiger Schutzfaktor gegen SIDS herausgestellt [Hauck 2011]). Tatsächlich geht die SIDS-Forschung heute davon aus, dass bei fast allen SIDS-Fällen ein vermeidbarer Risikofaktor vorliegt. [Blabey 2009]
- Obwohl Stillen, und dabei insbesondere das ausschließliche Stillen, als Schutzfaktor gegen SIDS bekannt ist, rechnet Carpenter in seiner Statistik auch die teilweise Fläschchen-gefütterten Babys zu den "gestillten" Kindern. Bei seinen Berechnungen werden also auch solche Babys als "gestillt" eingerechnet, die nachts mit der Flasche ernährt wurden.
- Auch die Definition des "bed sharing" bedarf eines Kommentars: Carpenter zählt auch solche Fälle zum "bed sharing", in denen das Baby normalerweise gar nicht bei den Eltern im Bett schläft, sondern lediglich seine letzte Nacht im Bett der Eltern verbracht hat. Aus der Literatur ist aber bekannt, dass im letzteren Fall oft besondere Risiken vorliegen [Vennemann 2012]: das Baby war möglicherweise von einer aufkommenden Erkältung geplagt (was ein erhöhtes SIDS-Risiko bedingt) oder die Mutter war durch besondere Umstände angeschlagen (z.B. Silvesterparty). Bei generellen Aussagen zum Risiko von "bed sharing" müsste deshalb eigentlich zwischen "usual bed sharing" und "bedsharing during last night only" unterschieden werden, so wie dies in neueren Studien praktiziert wird [z.B. Vennemann 2012].
- Aus der Literatur ist ausserdem bekannt, dass das Schlafen von Babys bei einer "Nicht-Pflegeperson" mit einem deutlich höheren SIDS-Risiko verbunden ist als das Schlafen bei den Eltern [Blabey 2009]. Auch aus diesem Grund müssen generelle Aussagen zum SIDS-Risiko bei geteiltem "Eltern"bett sehr vorsichtig interpretiert werden.

Insbesondere muss aber darauf hingewiesen werden, dass die Angabe relativer Risken (z.B. "5 fach erhöhtes Risiko") im Falle sehr kleiner Gesamtrisiken irreführend sein kann. Eine solche Angabe wird unwillkürlich als groß und bedrohlich wahrgenommen - auch in der Presse, wie die Einleitung zu einem Bericht über Carpenters Studie auf Spiegel online zeigt:

"Die meisten Mütter kennen die Situation: Das Baby wacht nachts auf und will trinken. Die Mutter nimmt es zu sich, stillt, beide schlafen ein. Das passiert, weil die Übermüdung groß ist, weil die körperliche Nähe das Kind beruhigt, weil es einfach schön ist. Und es passiert, obwohl mittlerweile viele Eltern wissen, dass ihr Kind ein größeres Risiko für den plötzlichen Kindstod hat, wenn es mit ihnen in einem Bett schläft." (Quelle: http://www.spiegel.de/gesundheit/schwangerschaft/ploetzlicher-kindstod-schlafen-im-bett-der-eltern-erhoeht-das-risiko-a-900984.html).

Eine solche Schilderung weist auf eine drohende Gefahr hin und weckt bei Eltern große Ängste. Wir wollen deshalb hier die auf Deutschland bezogenen absoluten Zahlen nennen, wie sie aus den Statistiken des Bundes und den letzten Erhebungen der SIDS-Forschung [GeSID-Studie, Vennemann 2005] abzuleiten sind. In Deutschland werden pro Jahr 675 000 Babys geboren. Etwa 21 von diesen werden tragischerweise im Bett ihrer Eltern an SIDS versterben. Von diesen 21 Babys wird nur eine deutliche Minderheit voll gestillt gewesen sein, und in den allermeisten Fällen werden (allein, zusätzlich oder in Kombination) Zigarettenrauchen, Drogen, Schlafmittel, Alkohol und andere riskante Einflüsse eine Rolle gespielt haben.

Das heisst: anders als die Angabe eines "mehrfach" erhöhten Risikos suggeriert, bei dem man sofort an sehr viele, vielleicht sogar an Hunderte von toten Babys denkt, handelt es sich beim Plötzlichen Kindstod im Elternbett um ein sehr seltenes Ereignis. Dessen Risiko wird noch einmal deutlich kleiner, wenn das Baby gestillt wird und die Eltern auf bekannte und vermeidbare ungünstige Einflüsse wie Rauchen, Alkohol oder Drogen verzichten. Es mag tatsächlich Fälle geben, in denen SIDS bei einem voll gestillten Kind auftritt, dessen Eltern alles richtig gemacht haben. Wie häufig diese Fälle genau sind, und ob sie ursächlich überhaupt etwas mit dem Schlafort zu tun haben, kann die Wissenschaft nicht sicher beantworten. Auf jeden Fall aber sind diese Fälle Raritäten.

Neue Fragen in der Debatte

SIDS-Forscher weisen deshalb darauf hin, dass bei der Debatte um die Risiken des geteilten Elternbetts inzwischen ein weiterer Faktor berücksichtigt werden muss: dass nämlich manche Mütter aus Angst, ihr Kind zu sich ins Bett zu nehmen, nachts dann an solchen Orten stillen (und dort möglicherweise einschlafen), wo mit Sicherheit ein erhöhtes Risiko besteht: auf der Couch oder im Sessel [Blair 2009]. Auch wird darauf hingewiesen, dass das Stillen (das selbst einen Schutzfaktor gegen SIDS darstellt, aber auch sonst einen Bonus für die Gesundheit des Kindes darstellt) möglicherweise früher aufgegeben wird, weil das

nächtliche Aufstehen als stressig empfunden wird. Und nicht zuletzt wird immer häufiger angeführt, dass es sich beim gemeinsamen Elternbett für Eltern auch um eine Lebensstilfrage handelt, die für manche Eltern das Leben mit einem Säugling erleichtert und die Beziehung zum Baby unterstützt. Die Schlaf-Forscherin Helen Ball fordert daher eine angemessene und evidenzbasierte Aufklärung über die mit dem Elternbett verbundenen Risiken auch aus ethischen Gründen [Ball 2013].

Zu den auf einem sicheren Datengrund stehenden Aussagen gehört, dass das geteilte Elternbett für ein Baby dann ein erhöhtes Risiko bedeuten kann, wenn die Eltern rauchen, Alkohol trinken, Drogen oder Schlafmittel nehmen, wenn das Baby bei Nicht-Pflegepersonen schläft, wenn das Bett nicht babygerecht ist (Sofa, Wasserbett, zu weiche Matratzen, Federbetten etc), wenn das Baby in Bauchlage schlafen gelegt wird, wenn es sich um ein frühgeborenes Baby handelt oder wenn das Baby nicht gestillt wird (letzteres gilt womöglich nur im ersten Lebenshalbjahr). Bekannt ist auch, dass diese Risiken deutlich und oft exponentiell größer werden, wenn sie in Kombination vorliegen. Bekannt ist auch, dass heute durch Balkonbetten viele dieser Risiken minimiert werden können.

Eine solche Aufklärung - über deren Inhalt sich die SIDS-Forschung einig ist - ist für die Eltern hilfreicher und entlastender als der pauschale Rat gegen das Schlafen mit einem Baby (eine solche pauschale Aussage ist auch unter den SIDS-Forschern umstritten).

Weitere Details und Literatur: siehe Online-Letter to the BMJ Open: Renz-Polster, H und De Bock, F: More questions than answers, online unter: http://bmjopen.bmj.com/content/3/5/e002299.abstract/reply - bmjopen_el_7055 sowie hier im Folgenden angehängt (Seite 4 ff).

In response to: Carpenter et al. 2013: Bed sharing when parents do not smoke: is there a risk of SIDS [1]

(published as e-Letter "More questions than answers" to BMJ Open June 11, 2013: http://bmjopen.bmj.com/content/3/5/e002299.abstract/reply - bmjopen_el_7055)

Dear Editor,

This publication[1] is confusing to parents and physicians because it draws far reaching conclusions from unconvincing data.

METHODOLOGICAL PROBLEMS

In our opinion, the validity of this analysis is threatened by selection bias, imputation bias and presentation bias. We think that the conclusions drawn from this study are not generalizable and that many current issues pertaining to SIDS epidemiology have not been adequately addressed.

Old data sets

The authors perform a secondary analysis of 5 previously published datasets from 1987 through 2003 from different parts of the world. It remains unclear by which criteria these studies have been selected and why the authors have chosen to include exactly these 5 studies and leave out other datasets from the same time period (a priori inclusion criteria are neither described in the paper nor in the supplementary data).

Sleep environments and habits have considerably changed since the time when most cases re-analyzed in this study have been recorded.[2] Public campaigns have resulted in a safer sleeping environment and the use of babybays (sidecar cribs) has changed the practice of bed-sharing profoundly. It is therefore questionable if the results of this study can be generalized to today's situation and questions of young families.

Problematic selection of control groups and adjustment

The weaknesses of some of the older studies now re-analyzed by Carpenter et al have not been done away with by lumping the datasets together. In 3 of the 5 studies now combined the controls born at the same maternity ward have not been selected randomly or by a predefined protocol, which may explain the wide discrepancies between cases and controls for important characteristics like marital status or maternal age in Carpenter's current publication (table 1). These discrepancies indicate that the control sample has not been drawn from the same source population as the cases - which in a case-control design of a condition like SIDS with its much higher prevalence in lower socioeconomic strata may introduce substantial bias.[3] Unfortunately, direct measures of socioeconomic status like household income or educational background do not seem to have been part of the original data sources of Carpenter's study. So, as a matter of fact, this study of a condition that is clearly more prevalent in disadvantaged social settings remains unadjusted for any direct measures of socioeconomic status. This may explain some of the surprising findings in table 1, according to which for instance - after multivariate adjustment - a mother in her late twenties is at nearly double the risk of losing her baby to SIDS than a mother aged over 30 years.

Problematic imputation

Alcohol and drug consumption are among the most important risk factors associated with SIDS in bed-sharing infants and are also more prevalent in the social settings in which SIDS most frequently occurs. In an analysis of all SIDS cases in Alaska between 1992 and 2004 for example, 32% of the bed-sharing victims had slept with an adult person impaired by alcohol or drugs during the night of their death [4] - a percentage that underscores that accurate information on this exposure has to be considered crucial for any valid statement on risk attribution to bed-sharing versus room-sharing.

In the source datasets of the study by Carpenter et al data on alcohol and drug consumption are missing for over 60% of the cases (table 1). To fill the gaps the authors resort to imputing the missing data. However, given the large amount of missing data, this strategy may introduce substantial bias.[5] [6] The imputation model as described by the authors in the supplementary online material is based on the assumption that values are missing at random between their datasets. This is almost certainly not the case for alcohol or drug consumption, the patterns of which differ along secular trends and between cultures and socioeconomic strata.[7] [8] In a study that draws cases from countries with widely disparant cultural backgrounds and drinking habits like Ireland and New Zealand it is, in our opinion, not valid to assume equal distribution and determinants for alcohol and drug consumption.

Important exposures missing

In spite of its claim to analyze risk factors "in depth as never before" (p 8) this study does not include some important risk factors for SIDS like paternal aclohol and drug use. This is not a trivial shortcoming as alcohol and drug use are one of the few plausible explanations why SIDS cases occur significantly more often on weekends than on week days[9], with an exceptional peak on New Year.[10] The authors do not see this as a threat to the validity of their result and claim in the discussion that paternal alcohol and drug use "does not add further to the risk of SIDS" (above and beyond maternal alcohol and drug use). They base this statement on an analysis from their ECAS study. [11] We remain unconvinced. For one, maternal alcohol and drug use is far from reliably ascertained in this study (see above). Also, it is plainly not conceivable to us why a drugged or drunken father sleeping next to his infant should not pose an additional and independent risk to baby's welfare.

Data on other important risk factors for SIDS, like the quality of the sleep environment or sleeping with a non-caregiver (see below), are also absent.

It could be argued that the less-than-perfect ascertainment or imputation of environmental influences is negligible as "it all dials out somehow between groups". This, however is not true and a serious misconception. Many of the exposures relevant in SIDS "act" primarily through the proximity to the baby and therefore affect bed-sharing infants and room-sharing infants *differentially*. In SIDS research, an equal influence of missing or unreliable data on subgroups therefore *can not* be assumed. Any mind altering influence for example (like alcohol or drug use) will have a much greater impact on the risk associated with bed-sharing than on the risk associated with room-sharing. Therefore, the less a study is able to capture exposures which act more effectively on bed-sharing infants than on room-sharing infants, the more risk will be falsely attributed to the bed-sharing cases. We wish the authors had commented on this very relevant issue in their discussion.

<u>No information on intended versus non-intended bed-sharing</u>

One of the co-authors, Mechthild Vennemann, has, in her recent meta-analysis of SIDS-cases[12] as well as in the report of her German study (which is also part of the dataset of the current study) [13] brought up an important issue. It is well known that bed-sharing occurs under two fundamentally different circumstances: in some families sharing the bed with the baby is part of the normal, everyday sleep routine (these cases have been called primary, routine or "usual" bed-sharers). Other mothers or families use bed-sharing only on special, exceptional occasions. It has to be assumed that some of the latter cases are associated with a higher a priori or subsequent risk. The baby may have been taken into the family bed because it has been unusually fussy during daytime (which may indicate the onset of an infection), or the mother may not have felt up to getting up at night, therefore taking her baby to bed with her. Some of these maternal choices may represent the influence of mind altering influences like alcohol, drug or medication use.

The differentiation of routine versus non-routine bed-sharing has proven important. In Vennemann's meta-analysis SIDS was twice as likely for non-routine bed-sharers than for primary bedsharers. As a matter of fact, in her dataset primary bed-sharing was not associated with a higher risk of SIDS at all ("Routine bed sharing did not increase the risk of SIDS. However, bed sharing during the last night when bed sharing was not routine increased the risk two-fold."). Given the importance of this ongoing discussion, brought up by one of the study authors herself, it certainly comes as a surprise that this issue is not even mentioned as a limitation of this study.

POTENTIAL MISCLASSIFICATION BIAS

Problematic definition of breastfed cases

The authors report breastfed versus bottle-fed cases. However, in their definition of "breastfeeding" they also include cases that are being partially bottle-fed. This is problematic as some of the cases labeled as "breastfed" may indeed not have been breastfed during sleep time but instead may have been in the process of being weaned during the period of their death.

Weaning is not a trivial issue in SIDS research as the peak-incidence of SIDS (with most cases occurring between 2 and 4 months of life) parallels the incidence of weaning especially in the social groups where SIDS is most common. [14] [15] This association asks for explanation and may indeed be causally related if one considers findings from sleep research: sleep regulation is entirely different in bed-sharing babies being breastfed during the night than in babies being bottle-fed at nighttime, with the former babies spending less time in deep sleep and showing higher arousability than the latter. [16] [17] A baby that is being actively weaned and for example not nursing at nighttime may therefore indeed be ridded of the protective dyadic sleep regulation typical for the fully breastfed infant.

The issue of a protective effect of a lighter, more active sleep is being widely discussed in the context of pacifier use, which has been shown to be one of the few protective influences against SIDS [18] [19] and which presumably also acts through its influence on sleep regulation - frequent suckling providing for an overall lighter, more active sleep with more arousals. This explanation is also in keeping with the epidemiological evidence that clearly shows a link between the intensity of breastfeeding and SIDS. [20]

Grouping fully breastfed and partially weaned babies together in a study of SIDS therefore is problematic to say the least. Indeed this lumping may be equivalent to lumping together protective factors and risk factors in one exposure - with all the confusing implications when

it comes to interpreting the results. And again, as in the case of missing data, this putative misclassification may lead to an exaggerated risk attribution to the bed-sharing cases.

Possible lack of identification of non-caregivers

We are also concerned about another potential misclassification. Studies suggest that sleeping with a "non-caregiver" may pose a higher risk of SIDS to the infant than sleeping with a "usual caregiver" (who is usually a parent). In the study by Margaret Blabey of SIDS and bed-sharing, 29% of cases had slept with a non-caregiver (like an aunt, sibling or friend) during the night of their death. [21] It is not clear to us if the cases in the Carpenter study have really been classified along the line of parents versus non-parents, at least there is no mention about any exclusion of cases based on their status as non-parents or non-caregivers.

How easily misclassification or missing data can lead to false risk attribution to bed sharing may be illustrated by the following example: A mother may breastfeed her baby at daytime but bottle-feed at nighttime. As bottle feeding can be delegated, she may, to catch a good night's sleep, ask her partner to feed the baby at night while she sleeps in a seperate bed. Had the baby died during that night while sleeping at the side of the mom's partner, the case would have been classified and analyzed in this study as a breastfed baby dying of SIDS while bed-sharing. Had the partner chosen to drink alcohol in the evening, it would not have been identified as an additional risk.

INADEQUATE DISCUSSION OF ISSUES RELATED TO RISK INTERPRETATION OF BED SHARING

Breastfeeding has a protective effect on SIDS, cutting its risk by about 50%.[22] It also has a protective effect on maternal and child health, including risk reduction for infections, autoimmune disorders, and metabolic disorders. [23] It is well known that bed-sharing facilitates breastfeeding [24] [25] and is associated with higher rates of breastfeeding (as well as a longer duration). [26] [27] Therefore the question if general advice against bed-sharing - as put forward by Carpenter et al - may inadvertently jeopardize the practice and promotion of breastfeeding, is an important one as it may introduce the risk of not being breastfed in the name of avoiding possible risks associated with bed-sharing. [28] [29] The authors deal with this complex issue by referring to secular data from the Netherlands, in which bed-sharing incidence, according to a personal communication to the author,

apparently dropped while breastfeeding rates went up. This resorting to ecological associations that have not been examined for causal relationship is unsatisfartory in this debate, and clearly other studies show opposite associations (i.e. decreasing incidence of SIDS in the face of increasing prevalence of bed-sharing) [30] [31], none of which are mentioned or discussed.

Bed-sharing as a lifestyle choice

The authors describe bed sharing as easily avoidable. This misses two important points. First, babies do sleep better in proximity with their attachment person, they fuss less, cry less and need less soothing. [32] For many families life with a small baby is a stressful period, as evidenced by the high prevalence of maternal fatigue, depression (peaking at 4 - 12 weeks post partum) and emotional dysregulation on the baby's part (e.g. excessive crying resp. "colics", peaking at 4 - 8 weeks post partum). [33] [34] So, for many parents, it is *not* easy to relinquish soothing care practices like bed-sharing. [35] [36] Second, it has been suggested that parents anxious about possible hazards of bed-sharing may choose alternative settings for breastfeeding instead, like sofas or armchairs, with the obvious risk of falling asleep in a clearly hazardous sleep environment. [37]

SUMMARY: A MISSED OPPORTUNITY

SIDS and bed sharing have been an interesting topic for scientists from many fields and specialties. Anthropologists point out that human infants have evolved as co-sleepers, i.e. they have, for reasons of thermoregulation and protection from predators, among others, slept with their (nursing) mothers during most of human history. According to this line of scientific enquiry, a baby sleeping solitarily would have been a dead baby until very recently. In fact, the overwhelming majority of human infants who have ever slept on earth have done so in close proximity to a nurturing, protecting and warming mother. [38] [39]

Modern sleep research supports this assumption of an evolved dyadic sleep arrangement by pointing out that the sleep physiology of an infant is clearly geared toward reciprocal regulation: sleep states are co-regulated in a sense that brain activity and sleep stages are synchronized. [40] [41] As part of intuitive interactions during light sleep the co-sleeping baby is frequently being repositioned by the mother and placed face to face in a position facilitating subsequent nursing, i.e. on its side or on its back. [42] [43] [44] Indeed, the observations of widespread supine sleeping in cultures where co-sleeping is part of the traditional cultural practice has been the starting point for questioning the prone position as the safest option for baby sleep in the 1980ies and has given decisive support to the back-

to-sleep campaign so successful in preventing SIDS in industrial nations worldwide since the early 1990ies. [45] [46]

So from an ethological perspective it is ever more important to approach the core question in SIDS research with appropriate scientific tools - namely, if the well described risks associated with bed-sharing are a feature of bed-sharing in and of itself or if they stem from potentially avoidable environmental exposures that in some cases go along with bed-sharing.

We do not think that the study by Carpenter et al adds to answering this question. From a public health standpoint we are instead left with more confusion, as the answer given by Carpenter et al is based on an analysis with several shortcomings, including inadequate imputation, missing or unreliable ascertainment of confounders (like paternal and maternal drug use), missing data on routine versus non-routine bed-sharing as well as misclassification of some exposures (like partial bottle-feeding) - introducing a clear und possibly unidirectional bias in risk-attribution to the bed-sharing cases.

Given these constraints we would have hoped for a more cautionary interpretation. SIDS epidemiology has changed considerably since the times during which the data of this study have been collected, with the SIDS rate in countries like Germany now 89% lower than just 20 years back (down from a high of 1285 cases in 1991 to 147 cases in 2011). [47] In fact two recent analyses of SIDS cases in the post back-to-sleep era show that 99% of cases are now associated with at least 1 risk factor and that the vast majority of cases are now occurring in high risk environments. [48] So instead of making far reaching and statistically tenous claims about the dangers of bed-sharing even for those who do avoid the known risk factors, this study would have served parents and policymakers better by fitting their claims to their modest methodology.

The authors have shown that the vast majority of SIDS cases are related to avoidable environmental exposures: 78% of their SIDS cases were exposed to tobacco smoke, 65 % were not breastfed (and many more may have only partially been breastfed), 43 % were placed on their tummy for sleep and 43% died while sleeping in a separate room from their parents. These data are real and well ascertained. But the recommendations of the authors are directed against *any and all* bed-sharing in all kinds of circumstances during the first 3 months - which for us, given the source and limitations of their data, represents an overgeneralization. The authors, in our opinion, are advancing an issue to their core message, in which their data are the weakest.

No study so far has convincingly shown that there is a risk of dying for fully breastfed babies sleeping with their non-smoking or non-obtunded mother in a safe environment. We should therefore be more careful with the messages we bring out to the community, as many parents presume that whatever is being published by scientist represents rigorous research. Of course we should inform the public about the risks that can be associated with bed-

sharing and that bed sharing needs to be practiced in a safe way. We should warn about the dangers of using mind altering substances or tobacco while co-sleeping with a baby. We should warn about unsafe sleep environments like sofas, armchairs or waterbeds. We should inform families that co-sleeping with a baby may not be fully safe if practiced by a non-caregiver or even a non-breastfeeding mother or the father.

However, we should be careful not to overextend our warnings. We should bear in mind that the decision to share the bed with baby also represents a lifestyle and relational choice. [49] Burdening this choice with warnings derived from less than rigorous data does not serve families. It also does not serve the debate when Carpenter et al, in an attempt to infer a causal relationship between SIDS and bed-sharing per se, refer to the behaviour of piglets, implying that the dangers of bed-sharing may indeed be a mammalian heritage (see their application of Bradford Hill's criteria on page 9): "Sows are normally separated by a bar from piglets to prevent them from being crushed when she turns over, but allowing her piglets to feed." This, to us, is biologistic folklore.

What we find especially disconcerting is the mode and style in which the discussion and the key messages are being put forward to the reader. Most parts of the discussion of this paper read like a discussion of a seminal randomized controlled trial of immense power and homogeneity, while in fact this is a secondary analysis of a convenience sample of mostly old case-control studies from different sociocultural regions of the world with limited adjustment, missing and probably mislabeled data and daring imputation. This is not all the fault of the authors, some of these constraints are inherent to the methodology and data sets that SIDS research, by its very nature, is restricted to. But these restrictions should be ever more of a reason to stay away from inflated claims and generalizations.

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