Report prepared for the Ministry of Health

Literature review of Sudden Unexpected Death in Infants

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30 November 2016

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Glossary

95% Confidence Interval	A confidence interval measures the probability that a population parameter will fall between two set values. A 95% CI means that 95% of the time, a population parameter will fall between the two values.
Odds Ratios and Adjusted Odds Ratios (AOR)	An OR is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure. An AOR is adjusted for the influence of confounders.
Pepi-pods	A plastic container for baby, that comes with a mattress and a sheet/merino blanket set, along with comprehensive safe sleep education resources and instruction.
p value	A measure of statistical significance, which tells us the probability of an event occurring due to chance alone. The higher the p-value, the higher the probability that the event you are observing can be explained by chance. A p-value of 0.05 is often used as a cut-off value for significance.
Sudden Infant Death Syndrome	Refers to a sub-set of these cases, in which the death remains unexplained after a full investigation. SIDS cases are included in SUDI case numbers.
Sudden Unexpected Death in Infants	Refers to deaths of infants aged under one year, which are initially unexplained. It is a broader term that includes deaths that can be explained after investigation, such as accidental asphyxiation.
Wahakura	A bassinet-like object woven from harakeke (New Zealand flax) that comes with a foam mattress and a set of rules to promote safe sleep practices. The term comes from 'waha' to carry, 'kura' precious little object.

1. Introduction

1.1 Purpose of document

This rapid literature scan presents a high-level overview of the available recent evidence in relation to interventions for sudden unexplained death of an infant (SUDI). This includes a focus on reaching vulnerable, or harder to reach people and families, in the New Zealand context.

1.2 Methods

As per our project scope, we performed a non-systematic, rapid, literature scan of key documents and the most recent publications (with a focus on those published after 2010). Databases searched included Ovid Medline, Embase, Scopus, Kiwi Research Information Service, Cochrane, Index New Zealand, Pubmed, Google Scholar, ProQuest, ABI Inform, INNZ, grey sources such as .government websites, as well as medical and research organisations. Searches were limited to English language only.

While the focus of the search was on New Zealand, we also searched for papers from countries with similarities to New Zealand (e.g. America, the United States, Australia, and Canada).

See Appendix 1 for examples of the types of search terms used.

We also conducted interviews with three[1] leading research experts in the SUDI field.

1.3 Definitions

SUDI refers to deaths of infants aged under one year, which are initially unexplained.[2] It is a broader term that includes deaths that can be explained after investigation, such as accidental asphyxiation.

Sudden Infant Death Syndrome (SIDS) refers to a subset of these cases, in which the death remains unexplained after a full investigation.[3] SIDS cases are included in SUDI case numbers.

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1 We invited five research experts to participate, but as yet have managed to only reach three.

2 BPAC. (2016). *Upfront – Sudden unexpected death in infancy: Where are we now?* Retrieved from http://www.bpac.org.nz/BPJ/2013/November/infant-death.aspx#2

3 Task Force on Sudden Infant Death Syndrome. (2011). SIDS and other sleep-related infant deaths: Expansion of recommendations for a safe infant sleeping environment. *Paediatrics, 128*(5):1341–67. Retrieved from http://pediatrics.aappublications.org/content/early/2011/10/12/peds.2011-2284

1.4 Risk factors

1.4.1 Risk factors

There are certain factors that increase the risk of SIDS. Risk factors are organised into 'modifiable' (meaning you can take measures to change them) and 'non-modifiable'. The strength of evidence behind each risk factor varies. Table 1 lists the known risk factors behind SIDS.

Table 1 Risk factors

Modifiable	Non-modifiable
• Sleeping position • Smoking • Bed sharing • Temperature • Bedding and mattresses • Drug/alcohol use • Post-natal depression[4] • Room sharing • Breastfeeding • Pacifier use • Immunisation	• Gender – more common in boys • Age range • Prematurity • Multiple birth • Small for gestational age • Sick with a mild infection • Time, e.g. season – more common in winter • Socioeconomic status of parent/caregiver[5]

Source: Created by Sapere from various sources

American Academy of Paediatrics (AAP) recommendations for a Safe Sleep Environment

In 2011, the AAP Taskforce on Sudden Infant Death Syndrome published a technical report and policy statement of safe infant sleeping environment recommendations (the previous one was published in 1992). The recommendations described in this report include supine positioning, use of a firm sleep surface, breastfeeding, room sharing without bed sharing, routine immunization, consideration of a pacifier, avoidance of soft bedding, overheating, and exposure to tobacco smoke, alcohol, and illicit drugs.

In 2016, the AAP updated its advice to include new evidence and rationale for recommendations for skin-to-skin care for new-born infants, use of bedside and in-bed sleepers (insufficient evidence), sleeping on couches/armchairs and in sitting devices, and

4 Amenable to treatment; therefore, in the 'modifiable' column.

5 Note: this factor was debated by hui participants. Many felt that NZ Government has the ability to modify this.

use of soft bedding. The updated recommendations emphasised that couches and armchairs can be very dangerous places for babies.

Bed sharing as a risk factor by itself

Bed sharing of an infant with a sleeping parent or caregiver is controversial. Mitchell et al (2015) states that bed sharing is associated with an increased risk of SUDI; however, advocates for bed sharing suggest it promotes a closer emotional bond with the infant and that bed sharing is also associated with increased duration of breastfeeding.

A meta-analysis by Vennemann et al (2012) on the relationship between bed sharing and SIDS included 11 studies and found the combined Odds Ratio for SIDS in all bed sharing vs non-bed sharing was 2.89 (95% CI, 1.99-4.18). The OR in infants <12 weeks old was 10.37; 95% CI, 4.44-24.21).

Carpenter et al (2013) conducted an analysis of 1472 SIDS cases and 4679 controls across multiple countries and found an Adjusted Odds Ratio (AOR) for bed sharing of 2.7 (95% CI 1.4 to 5.3), p=0.0027, for breastfed infants across all ages with no other risk factors (e.g. smoking or alcohol use). For infants under three months, the AOR was 5.1 (95% CI 2.3 – 11.4, p=0.00006). For infants three months and over, the authors found no increased risk in bed sharing for breastfed infants with no other risk factors (AOR = 1.0, 95% CI 0.3-3.1). They state that their analysis suggests that about 90% of bed sharing SIDS deaths would not occur in the absence of bed sharing.

However, another paper found no significant relationship between bed sharing and SIDS in the absence of other risk factors. Blair et al (2014) quantified the risk of SIDS among UK infants who co-sleep with and without other risk factors, such as smoking, alcohol consumption, and age of infant. The authors found that the risk associated with bed sharing in the absence of smoking, sofa-sharing and alcohol consumption was not significant overall (OR = 1.1 [95% CI: 0.6–2.0]), neither was it significant for infants less than three months old (OR = 1.6 [95% CI: 0.96–2.7]).

The AAP review of evidence found ORs of between 4.7 and 10.4 in infants younger than four months of age, regardless of parental smoking status (Moon and AAP, 2016).

Regarding the promotion of bed sharing for enhanced bonding, Mitchell et al (2015) recently evaluated the association between bed sharing and maternal bonding in Auckland mothers (8.8% identifying as Māori or Pacific) and found an inverse association between bed sharing and maternal-infant bonding, contrary to the often expressed belief that bed sharing enhances maternal-infant bonding.

Interaction between risk factors

A meta-analysis by Vennemann et al (2012) on the relationship between bed sharing and SIDS included 11 studies and found the combined Odds Ratio for infants of smoking mothers was 6.27; 95% CI, 3.94-9.99.

Blair et al (2014) quantified the risk of SIDS among UK infants who co-sleep with other risk factors, such as smoking and alcohol consumption. The multivariable risk associated with co-sleeping on a sofa (OR = 18.3, 95% CI: 7.1–47.4) or next to a parent who drank more than two units of alcohol (OR = 18.3, 95% CI: 7.7–43.5) was very high and significant for infants of all ages. The risk associated with co-sleeping next to someone who smoked was significant

for infants under three months old (OR = 8.9, 95% CI: 5.3–15.1), but not for older infants (OR = 1.4, 95% CI: 0.7–2.8).

Carpenter et al (2013) conducted an analysis of 1472 SIDS cases and 4679 controls across multiple countries in an attempt to identify the interaction between risk factors such as breastfeeding, infant age, and smoking in relation to bed sharing and SIDS. The following table from the authors shows the additive effects of bed sharing combined with smoking or alcohol use. The table shows that the interaction, first of smoking and then of parental smoking plus maternal alcohol with bed sharing, greatly enhances the risk associated with bed sharing.

Figure 1 Average AORs for smoking and maternal alcohol when room sharing and bed sharing with the multiplicative increase in risk due to bed sharing

Age group	Risk factors		Room sharing		Bed sharing		Increase when bed sharing	
	Smoking	Alcohol	AOR	95% CI	AOR	95% CI	Multiplier	95% CI
<3 month	No	No	1	–	5.1	2.3 to 11.4	5.1	2.3 to 11.4
	Partner	No	0.7	0.5 to 1.1	7.8	3.6 to 17.2	11.2	5.0 to 25.1
	Mother	No	1.3	0.8 to 2.2	20.3	7.4 to 56.4	15.2	5.3 to 43.4
	Both	No	2.9	2.0 to 4.2	21.6	11.1 to 42.3	7.5	3.9 to 14.6
	Both	Yes	13.7	5.5 to 34.4	151.0	50.2 to 448.4	10.8	3.0 to 39.2
3 months and over	No	No	1	–	1.0	0.3 to 3.1	1.0	0.3 to 3.1
	Partner	No	1.2	0.9 to 1.7	3.0	1.2 to 7.5	2.5	1.0 to 6.3
	Mother	No	1.7	1.2 to 2.4	6.1	1.7 to 22.6	3.6*	0.9 to 13.9
	Both	No	3.0	2.3 to 4.0	13.7	6.1 to 31.0	4.6	2.0 to 10.3
	Both	Yes	15.7	8.1 to 30.4	243.8	76.1 to 781.4	15.6	4.2 to 57.4

*This multiplier is significant at p=0.062.
The AORs are adjusted for all other factors in the table, any drug use by the mother since birth, bottle feeding, sex, whether matched or unmatched, race, birth weight group, mother's age group, number of live births (grouped), mother single and where slept.
AOR, Adjusted OR.

Source: Carpenter et al (2013)

The AAP review of evidence found enhanced risks when an infant was bed sharing combined with either smoking (pre- and post-natal), age (younger than four months), preterm/low birthweight, excessively soft or small surfaces (e.g. waterbeds or sofas), the use of soft bedding (e.g. pillows or blankets), when there are multiple bed sharers, when the parent has consumed alcohol or illicit drugs, or where the infant was bed sharing with someone who is not a parent (Moon and AAP, 2016).

1.4.2 The triple risk model

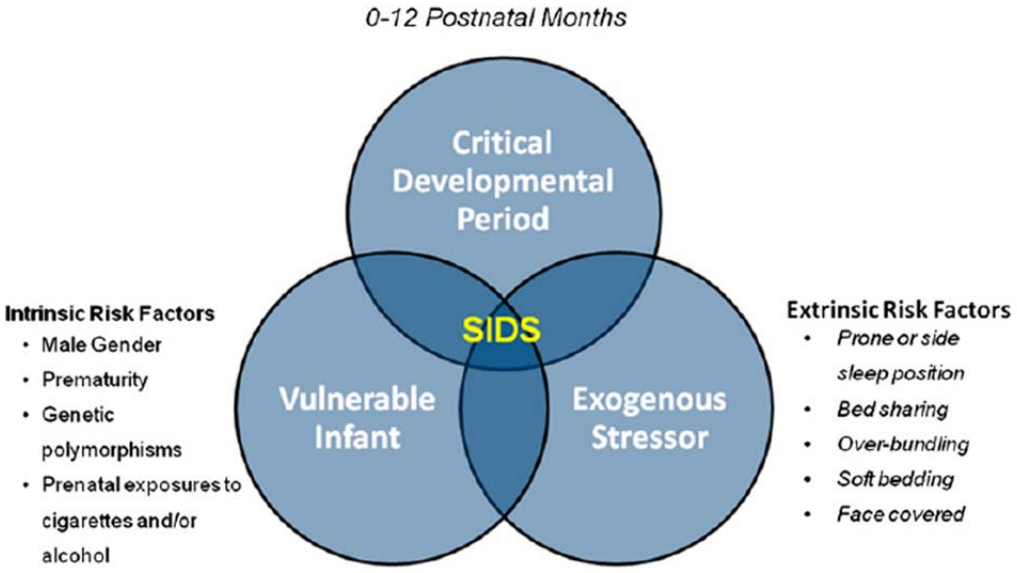
In 1994, a 'triple risk model' was presented by Filiano et al to describe the simultaneous occurrence of multiple events that takes place when a baby dies of SIDS. The model contains three elements:

(1) A vulnerable infant with an underlying susceptibility;

(2) An exogenous stressor at the time of death, and

(3) The critical developmental period.

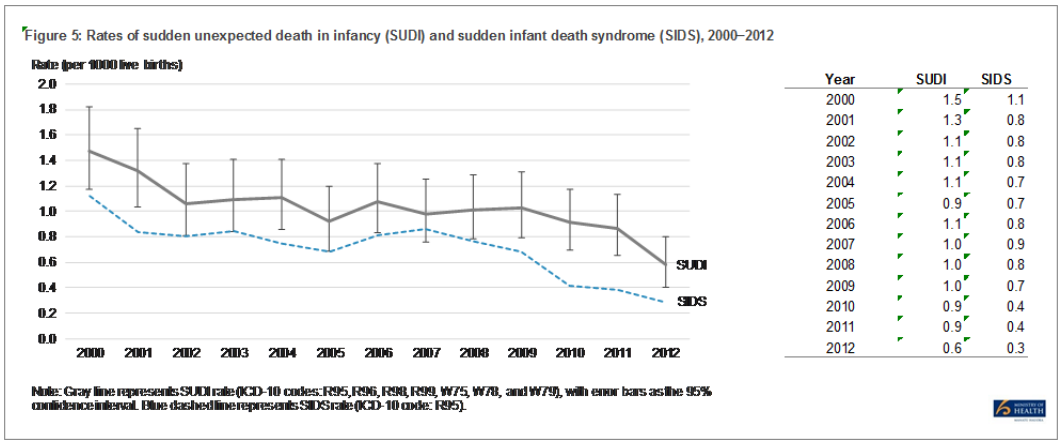
Figure 2 Triple Risk Model (from Trachtenburg et al 2012)



1.5 New Zealand rates

From the most recent statistics published by the Ministry of Health (MoH) in 2015 (Fetal and Infant Deaths 2012, where infant death was defined as from birth up to 12 months of age), following a relatively stable period, the rates of SUDI and SIDS are falling over the past five years (see Figure 3).

Figure 3 SUDI and SIDS rates in New Zealand 2000-2012



Year	SUDI	SIDS
2000	1.5	1.1
2001	1.3	0.8
2002	1.1	0.8
2003	1.1	0.8
2004	1.1	0.7
2005	0.9	0.7
2006	1.1	0.8
2007	1.0	0.9
2008	1.0	0.8
2009	1.0	0.7
2010	0.9	0.4
2011	0.9	0.4
2012	0.6	0.3

Source: Ministry of Health, 2015

According to more recent (unpublished) figures provided by MoH, the numbers of SUDI cases has stayed in line with the 2012 total of 36, with 37 cases in 2013 and 35 cases in 2014.[6]

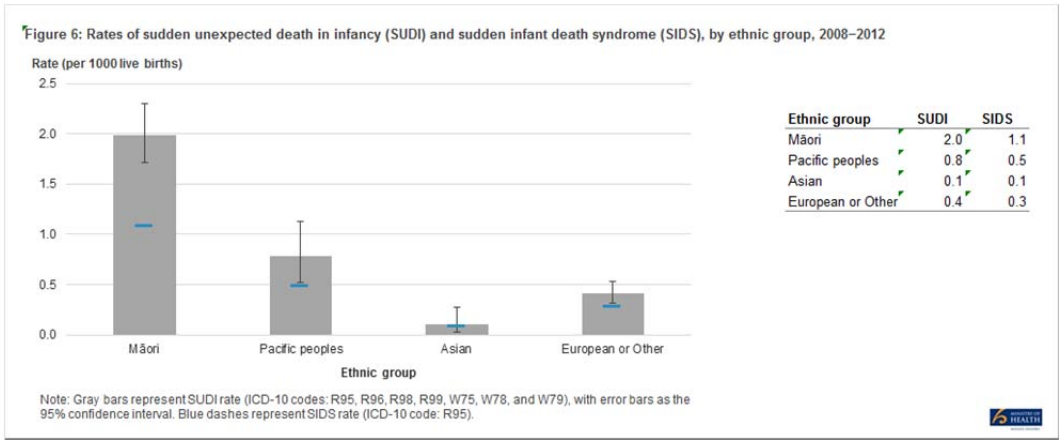
In specific populations

From the Ministry of Health statistics:

- The 2012 SUDI rate per 1000 is 2.0 in Māori, 0.8 in Pacific peoples, 0.1 in Asian, and 0.4 in European or other.
- In 2012, the most deprived population (quintile 5) rate is 1.7 per 1000, compared with 0.3 in the least deprived quintile.

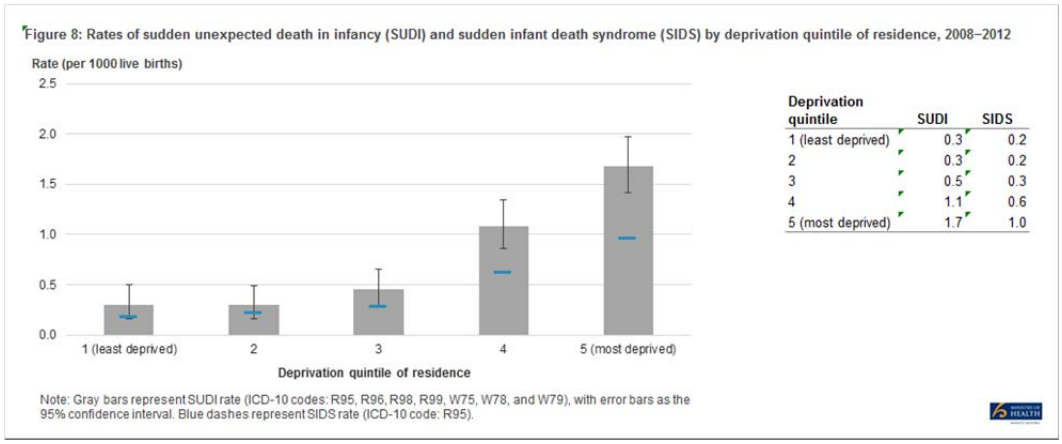
Figure 4 and Figure 5 show the aggregate rates over 2008-2012 by ethnicity and deprivation.

Figure 4 SUDI and SIDS rates in New Zealand by ethnicity



Ethnic group	SUDI	SIDS
Māori	2.0	1.1
Pacific peoples	0.8	0.5
Asian	0.1	0.1
European or Other	0.4	0.3

Figure 5 SUDI and SIDS rates in New Zealand by deprivation quintile



Deprivation quintile	SUDI	SIDS
1 (least deprived)	0.3	0.2
2	0.3	0.2
3	0.5	0.3
4	1.1	0.6
5 (most deprived)	1.7	1.0

6 Personal communication with Portfolio Manager, National Services Purchasing, and Ministry of Health in October 2016.

In relation to risk factors

Those where the mother was recorded as being a tobacco user at the birth event accounted for 14.9% of the group and 45.6% of the SUDI in the group (30.7% and 51.7% respectively for Māori). Escott et al (2009) described the factors associated with SUDI cases referred to the Wellington Coroner from 1997-2006 (64 deaths, 54 without a clear medical diagnosis). Of the 54 deaths, 28% were NZ European, 46% were Māori, 22% were Pacific, and 4% 'other'. Overall, 50% of infants had been placed to sleep in a non-recommended sleep position and 38% usually slept in a non-recommended location. Bed sharing was associated with 53.7% of deaths. There was a significant association between bed sharing and being found dead on a Sunday morning (p=0.04).

Galland et al (2014) conducted a prospective study of 209 New Zealand infants and found five independent predictors of a high SUDI risk score: higher parity (P =0.028), inverse correlation with maternal age (P =0.030), not working or not caring for other children (P =0.031), higher depression scores antenatally (P =0.036), and lower education (P =0.042).

2. Interventions

The classic approach to preventing SIDS deaths has been to define the risk factors, devise the appropriate messages, and then design and implement an information-sharing health promotion campaign (Abel and Tipene-Leach, 2013).

The major advance in the early 1990s was the identification of 'modifiable' risk factors, such as prone sleeping position. The reduction in the prevalence of infants sleeping prone, following the recommendation to place infants to sleep on their backs ('Back to Sleep' or 'Reduce the Risk' campaigns), resulted in a dramatic decline in SIDS mortality from 6.2 per 1,000 in 1986 to 3.6 per 1,000 in 1992. In Māori, the rates dropped from 9.7 to 9.1 per 1,000 and for non-Māori, the rates dropped from 5.7 to 2.8 per 1,000 (Mitchell and Krous, 2015 and Mitchell et al, 1994).

When considering the effectiveness of interventions, we need to bear in mind that increased knowledge does not always lead to a change in behaviour. Moon et al (2016) states that attitudes and intentions may not be predictive of actual behaviour because of unanticipated barriers. A parent, after participating in a safe sleep discussion, may know that they should place the infant on the back and may intend to do that, but opposition from a partner or mother may prevent changing behaviour. Thus, measurements of attitudes and intentions may not correlate well with actual behaviour.

From the researcher interviews, we also heard that for some families life is complex and that they have many competing priorities, so messages regarding safe sleep interventions may be more difficult to reach them and/or for them to adopt them for a range of reasons.

Moon et al (2016) used a model that outlines barriers and incentives that should be considered when trying to change behaviour.

Figure 6 Barrier and incentives for behaviour change

Level	Barriers/Incentives	Examples of barriers specific to infant sleep practices
Innovation	Advantages in practice, feasibility, credibility, accessibility, attractiveness, personal relevance	• Parents do not understand rationale for back sleep position • Parents feel that infant is "immune" to SIDS • Parents believe that recommended sleep practices will place baby at risk (e.g., choking)
Individual professional (Healthcare provider)	Awareness, knowledge, attitude, motivation to change, behavioral routines	• Healthcare provider does not believe that babies should sleep supine • No standard of care for infant sleep practices in hospital or daycare center
Breaking down barriers (Infant caregiver)	Knowledge, skills, attitude, compliance	• No money to buy crib • Concern that infant will be uncomfortable without blankets • Maternal smoking during and after pregnancy
Culture and tradition (Social context)	Opinion of colleagues, cultural norms, collaboration, leadership	• Bedsharing is family or cultural norm • Elder family members are trusted sources of information and may encourage prone positioning • Parents often receive unsafe bedding as gifts for baby
Legislation and regulation (Organizational, economic, and political context)	Organization of care processes, staff, capacities, resources, structures; financial arrangements, regulations, policies	• No safe sleep regulations in child care • No safe sleep education given at birth hospitals

Source: Moon et al 2016 (adapted from Grol et al 2004)

It is also important to note that, while education may improve knowledge, surveys often test that knowledge soon after the education was delivered. Therefore, it is often not known if the educational intervention leads to sustained knowledge.

2.1 Education and promotion

Public health and health promotion programmes based around the modifiable risk factors (prone infant sleeping, maternal tobacco smoking in pregnancy, breast feeding, and not bed sharing if the mother smoked in pregnancy) have brought dramatic reductions in the numbers of cases (McManus et al, 2010).

Hutchison et al (2015) evaluated 172 mothers' knowledge of, and practices related to, risk factors for SUDI. They compared the results to a similar survey conducted in 2005. Compared with 2005, more women in the current survey cited avoiding bed sharing, keeping the face clear, avoiding soft bedding, and room sharing as SUDI prevention factors. More mothers usually used the supine sleep position and shared the parental bedroom, while fewer mothers reported smoking. Eight percent said the infant usually shared a bed, down from 15% in 2005. Of the five main protective factors promoted by New Zealand's Ministry of Health (supine sleep, own bed, room sharing, smoke free, breastfeeding), 43% were implementing all of these practices. However, the majority of the respondents were New Zealand European, so the findings may not be representative of the whole of New Zealand. These findings suggest that the education and promotion activities in New Zealand over the last decade were successful in increasing knowledge and behaviour, particularly in New Zealand European women.

In comparison, a randomised controlled trial in New Zealand (conference proceedings, Galland et al, 2012) aimed to determine whether extra education on safe sleep practices effectively influenced practices of the parent(s). The extra education was given both antenatally and postnatally and was aimed at aiding healthy sleep, including information on safe sleeping practices. The authors found no significant differences in safe sleep practices between groups who received extra education and those that did not.

Salm Ward and Balfour (2015) conducted a systematic literature review of safe sleep interventions and included 29 articles (majority were from the US, one New Zealand study was included – Cowan et al 2013b, discussed here). Studies focused on interventions targeted at infants' caregivers, health care professionals, peers, and childcare professionals. They found that most articles described multi-faceted interventions. The authors suggest that future studies should incorporate rigorous evaluation plans, utilize comparison groups, and collect demographic and follow-up data. The authors emphasised the need for multi-pronged, consistent messaging across multiple levels.

Most articles reported some degree of success in changing some of the targeted behaviours. Of the 20 studies that measures changes in infant sleep position, 12 significantly change the rates of intention or use of the supine sleep position. Of the 11 studies that measures change in knowledge about safe infant sleep practices, nine found significant changes in scores. Of the 12 studies that measured changes in sleep location, four concluded their interventions were successful in significantly increasing rates of intention to, or self-report of, using a crib (vs. bed sharing or other sleep locations). Of the 10 studies that measured changes in practices regarding unsafe items in the crib, four concluded their interventions were successful in significantly changing practices or intentions.

There has been a recent and as yet non-peer reviewed and unpublished, randomised controlled trial of 240 of Māori and Pacific Island families in South Auckland (McIntosh and Trenholme, Vogel and Stewart 2016). In this study, the Safe sleep programme with Pepi-pod was provided to the entire intervention group and nearly all families took up an offer of a portable cot. Interviews of the study participants revealed that the pepi-pods were well received. They found that of high-risk families[7], one quarter did not have a baby bed at the time of birth of the baby. The pepi-pods were used by half the families at two months post-intervention, but only by 16% at four months. A quarter of families continued to bed share in both intervention and control. In summary, overall SUDI knowledge for both groups improved with no apparent change in behaviour.

Cowan et al (2013b) evaluated the use of an online education tool for preventing SUDI. Content was designed to align current knowledge, attitudes, and actions. The tool was promoted across the country. Between November 2009 and December 2011, 3286 sessions were completed. Usage reached across regions, ethnic groups, and roles. On completion of the course, most rated highly (7-9/9) (68.8%) their 'increased confidence' to discuss infant sleep safety with others. A high increased confidence rating was significantly influenced by spending more time per slide ($p < 0.05$).

Two of the researchers interviewed noted that some Māori families they had interviewed suggested a sustained TV campaign with safe sleep messages would be useful. An in-depth review on evidence for the effectiveness of social marketing was not within the scope of this rapid evidence review. A review of the available evidence would be required before making any recommendation on a particular approach.

2.2 Safe Sleep Spaces

2.2.1 What are they?

There has been a recent focus on the infant safe sleep environment as a way to increase the infant sleep environment safety without necessarily banning bed sharing. There are two main interventions in New Zealand, both of which allow for the baby to share the bed with the parent/caregiver: wahakura and pepi-pods.

The wahakura was designed to provide a safe sleep place for infants, especially when bed sharing. The wahakura ('waha' to carry, 'kura' precious little object) is a bassinet-like object woven from harakeke (New Zealand flax). It comes with a foam mattress and a set of rules to promote back sleeping: keeping the wahakura free of pillows, loose blankets, or toys, keeping the baby's environment smoke-free, and banning the proximity of tired or inebriated adults. It also promotes an 'every time, every place, every sleep' usage, a return to the wahakura after feeding, and sharing the 'rules' with every possible caregiver (Abel and Tipene-Leach, 2013).

[7] Inclusion criteria for 'high-risk' were: infants born to Māori or Pacific mothers, aged less than two weeks of age and with a history of smoke exposure in utero, and/or smoke exposure in the environment, and/or low birth weight, congenital airway problem or family history of SUDI.

The pepi-pod is a plastic container that comes with a mattress and a sheet/merino blanket set, along with comprehensive safe sleep education resources and instruction. It is cheaper than the wahakura (Abel and Tipene-Leach, 2013). The pepi-pod gained popularity because of a response to the February 2011 earthquake (it was available prior to this, but in lower numbers), which saw increased risks to infants from disturbed living and sleeping conditions.

2.2.2 Evidence review

Effectiveness

The recent 2016 technical report from the AAP stated that there is insufficient evidence to recommend for or against the use of devices promoted making bed sharing "safe." The AAP cited the fact that there were no studies examining the association between these products and SIDS or unintentional injury and death, including suffocation.

Mitchell et al (2016) described the efforts of the Safe Sleep Programme in New Zealand. Participation in the nationwide education 'blitz' by health professionals exceeded one in 23 live births, distribution of Safe Sleep leaflets exceeded two for every live birth, and over 16,500 wahakura/pepi-pods were distributed to vulnerable infants. The authors linked this programme with a fall in post-perinatal mortality (note: this is wider than SUDI/SIDS) of 29% from 2009 to 2015 (2.8 to 2.0/1000 live births). The fall was greatest for Māori and in regions with the most intensive programmes. Note that it was not possible to separate out the effects of the education and the provision of the wahakura/pepi-pods, so any drop in mortality cannot be solely attributed to the provision of safe sleep devices.

Due to the relatively new focus on wahakura and pepi-pods, there are not yet any published papers directly focusing on whether these interventions affect SUDI/SIDS rates. In addition, there is a significant time lag for mortality data (the most recent published data available as at October 2016 is for 2012).

It would not be ethical to perform a randomised controlled trial (considered the 'gold standard' of evidence) on safe sleep spaces vs non-safe sleep spaces (i.e. a pepi-pod or wahakura vs bed sharing without a pepi-pod/wahakura). In any case, if the ultimate outcome measure is an event that occurs infrequently in the population (such as SIDS, with rates in developed countries ranging from 0.2-1.0/1000 live births), a randomised controlled trial would require an impractically large sample size (Moon et al 2016).

Any effectiveness study would be observational, and therefore it is difficult to ascribe causality. Studies would not be directly able to attribute safe sleep spaces to falls in rates, as there will be other influencers in play, e.g. education. Safe sleep devices are always issued alongside education in formal distribution channels. However, there may be informal channels for wahakura or pepi-pods, and secondary reuse that may not include concurrent education.

Behaviour change

A pilot in Northland District Health Board (Kiwikiwi Research and Evaluation Services, 2013) was evaluated by a survey of caregivers whose infants received a wahakura or pepi-pod as part of the pilot programme during the period 1st April 2013 to 31st July 2013. Participants were identified using defined criteria (ethnicity, young maternal age, smoking status, pre-term or low birth weight infant, maternal alcohol or substance abuse, family violence, housing, no

antenatal care or GP, previous SUDI, maternal mental health). There were 45 caregivers who responded to the follow-up interview, 96% reported their infant's ethnicity as Māori. Sixty per cent of survey respondents were smokers before pregnancy, and 53% smoked during pregnancy.

The follow-up interview revealed that only 22% of infants (10/45) were sleeping in their wahakura or pepi-pod for all of most sleeps. Sixty per cent of the infants were sleeping either solely or additionally in an alternative baby bed such as a bassinette or a cot. A small number of infants (six) were bed sharing without the wahakura or pepi-pod. When asked if the baby ever sleeps in a bed with another person while that person is also sleeping, 44% said yes. When asked if the infant was always in their wahakura or pepi-pod when bed sharing with another person who is also asleep, 50% said yes.

There is a new New Zealand paper about to be published (McIntosh and Trenholme, 2016). This study is the result of a randomised control trial in South Auckland from 2012 to 2014. The researchers randomised high-risk families to pepi-pods vs no pepi-pods (along with, for everyone, a cot and an intensive appropriate education on safe sleep practices as well as the five major risk factors for infant death) and followed them up two and four months later. They found essentially no difference in bed sharing behaviour between the group given pepi-pods and those not given pepi-pods.

As an example of spreading knowledge throughout the community, Cowan et al (2013) evaluated the distribution of pepi-pods to victims of the Christchurch earthquake. As part of receiving a pepi-pod, there was an expectation that recipients share what they had learned in the briefing with people in their networks. Each recipient drew an average 3.5 'others' into conversations about safe sleep conditions for babies, making it a most cost-effective and targeted approach to preventing sudden infant death.

Safety

From the pilot programme in Northland DHB, there were eight incidents reported (seven with a wahakura, and one with a pepi-pod). Most of the accidents related to toddlers wanting to get close to the baby in the wahakura or pepi-pod.

There were two presentations (Taylor et al and Baddock et al) at the Australasian Sleep Association Conference in Perth in October 2014 (Sleep and Biological Rhythms), comparing wahakura and bassinets from preliminary results of a randomised controlled trial. Baddock et al found no different between overnight oxygen saturation and thermal temperature for wahakura and bassinets. Taylor et al found no difference between infant sleep position, maternal sleep quantity and quality.

Cowan et al (2013) evaluated the distribution of pepi-pods to victims of the Christchurch earthquake. There were no reported accidents when babies were in the pepi-pods; although, there were three incidents: one mattress went mouldy, one cracked around the moulded handle, and an unidentified object fell into another.

Acceptability

Abel et al (2015) conducted a qualitative study on 12 Māori mothers' and 10 key informants' views and experiences of the wahakura. From a mother's perspective, the appeal of the wahakura related to its portability, the enabling of bed sharing, and easier breastfeeding. Health professionals found it useful for engaging Māori women antenatally. From a cultural

perspective, the native flax composition and the traditional origins meant that the wahakura held considerable cultural and spiritual appeal.

Cowan et al (2013) evaluated the distribution of pepi-pods to victims of the Christchurch earthquake. The pepi-pods were distributed with educational material and a safety briefing. They were used even though most families (96%) also had a cot or bassinet. They were used for same-bed co-sleeping by 87% of respondents. Features most appreciated were 'having baby close' (90%), 'peace of mind' (88%), and portability (74%).

From the pilot programme in Northland DHB, participants had a choice between pepi-pods and wahakura. Those who chose wahakura most commonly cited the look of it, the fact that it resonated with them culturally, that it was made of a natural fibre, and provided good airflow. Those respondents who chose a pepi-pod said they did so because of their strength, stability, additional safety, superior look, and longevity. Caregiver feedback on the use of both wahakura and pepi-pods was equally positive with all respondents stating they would recommend them to others. Both wahakura and pepi-pod users said these baby beds supported them with safety and convenience.

Amongst respondents who reported their infant had stopped sleeping in the wahakura or pepi-pod, all but two had stopped between the infant age of four and 16 weeks. The most common reason given was that the baby had grown too big.

2.3 Smoking

Smoking (both during and after pregnancy) is considered a major risk factor for SUDI. Smoking is more common in more deprived areas, and in those of Māori ethnicity.

Humphrey et al (2016) analysed data from the antenatal period of the Growing Up in New Zealand cohort (an ongoing longitudinal study). The authors found that 20% of mothers reporting smoking before pregnancy and 9.9% of mothers continued during pregnancy. This was more pronounced in younger women ($p<0.0001$), with lower education achievement ($p<0.001$) and of Māori ethnic group ($p<0.001$). 46.8% of Māori women smoked before pregnancy, and 31.6% smoked during, compared with 15.5% of NZ Europeans smoking before pregnancy and 6.8% during. Thirty-four per cent of pregnant women in the most deprived quintile reported smoking before pregnancy, and 19.5% during, compared with 9.7% (before pregnancy) and 3.3% (during pregnancy) in the least deprived quintile.

2.3.1 Reasons why women continue to smoke while pregnant

Glover and Kira (2011) interviewed 60 pregnant Māori women to investigate the reasons behind why they continue smoking during their pregnancy. Of the main reasons given for smoking, 50% of participants said they smoked because of habit, 30% due to stress, 25% due to addiction, and 23% because it calms and relaxes the person (women could provide more than one answer). Most of the participants (92%) had thought about quitting and 78% had tried to quit. Stopping for their baby's health was the number one reason motivating the women to stop smoking. However, many believed that the effects of smoking during pregnancy on children are short-lived and that the child will overcome the damage.

The authors stated that the findings are consistent with the results from international studies which found that pregnant women who smoke do not fully understand the harms of smoking, large proportions of their social circle smoke, and that they smoke to alleviate stress and cope with stressful life circumstances. However, the authors noted that the findings contrast with the general population of smokers' reasons for smoking, which are enjoyment, stress-relief, and weight-control. All the women interviewed lived with other smokers. Thirty-three per cent of participants agreed that they might as well keep smoking themselves as they were exposed to so much smoke from others. The authors suggested that cessation interventions need to be extended to include the whole family. They also suggested educating the community surrounding pregnant women about the effect of their smoking on pregnant women.

Hoek et al (2014) conducted a study that tested different cessation messages with women who were smoking (or had smoked) while pregnant. The majority of women participating were Māori or Pacific. As part of that study, the authors asked women their reasons for smoking. Participants often described it as a choice and only a minority acknowledged their smoking was controlled by an addiction. Despite recognising smoking as harmful and despite nearly all having attempted to quit, participants still asserted that smoking is a choice. Choosing to smoke implied control and power, participants sought this status as it maintained their belief they could also choose to quit.

2.3.2 Interventions

Hill et al (2014) conducted a review of evidence on the impact of tobacco control interventions on socioeconomic inequalities of smoking (all populations, not just pregnant women). Seventy-seven primary studies and seven reviews were included. The authors found strong evidence that increases in tobacco price have a pro-equity effect on socioeconomic disparities in smoking. Evidence on the equity impact of other interventions was inconclusive, with the exception of non-targeted smoking cessation programmes, which had a negative equity impact due to higher quit rates among more advantaged smokers.

Chamberlain et al (2013) conducted a Cochrane systematic literature review on psychosocial interventions for supporting women to stop smoking in pregnancy. The review included 86 randomised controlled trials. Two studies were from New Zealand (Dixon et al 2009 and McLeod et al 2004). The intervention that supported the most women to stop smoking in pregnancy appeared to be providing incentives. However, these results are based on only four trials with a small number of women (all in the US), and they only seemed to help women stop smoking when provided intensively (three trials). Counselling also appeared to be effective in supporting women to quit, but only when combined with other strategies (27 trials). The effectiveness of counselling was less clear when women in the control group received a less intensive smoking intervention (16 trials). Feedback also appeared to help women quit, but only when compared with usual care and combined with other strategies (two studies). It was unclear whether health education alone helped women quit, but the numbers of women involved in these trials were comparatively small. The evidence for social support was mixed; for instance, targeted peer support appeared to help women quit (five trials), but in one trial partner support did not. Women also reported that peer and partner support could be both helpful and unhelpful.

Increasing the frequency and duration of the intervention did not appear to increase the effectiveness. Interventions appeared to be as effective for women who were poor, as those

who were not, but there is insufficient evidence that the interventions were effective for ethnic (five trials) and aboriginal women (two trials). Trials where the interventions became part of routine pregnancy care did not appear to help more women to quit, which suggests there are challenges to translating this evidence into practice.

Glover et al (2015) undertook a small feasibility study on the effectiveness of an incentives-based cessation trial among pregnant Māori smokers (usual cessation support plus voucher or product valued at $25 for each 'abstinent from smoking' week for eight weeks). Twenty-four women were recruited (eight control, eight voucher, and eight product). Overall, 21% (n = 5) of the women were abstinent from smoking for at least six weeks of the eight, one from the control, six from the product, and three from the voucher. The authors suggest that incentives, in particular a choice of products, may be an effective addition to usual care.

GP and midwife smoking cessation knowledge and practices

One of the identified issues with cessation support provided by GPs and midwives is that it waits for pregnant women to come into contact with the health system. However, Māori women tend to register with an LMC later in their pregnancy than New Zealand Europeans.

Glover et al (2008) surveyed general practitioners and midwives on their smoking cessation knowledge and the support they offered to pregnant women who smoke (147 GPs and 203 midwives responded). Almost all respondents saw it as part of their role to ask about smoking in pregnant patients. Seventy-one per cent of GPs reported usually advising pregnant women who smoke to abstain completely, and only 11% of midwives said they do this (RR 6.50, 95% CI 4.32–9.77). Midwives were much more likely to advise cutting down on smoking. Over 60% of participants said they usually provide cessation counselling to pregnant women. Reported recommendation of nicotine replacement therapy (NRT) was low. Only 34% of GPs and 31% of midwives were likely to recommend nicotine gum. Almost all GPs indicated that they were involved in confirming pregnancy during the first trimester, compared with only 55% of midwives. The authors suggest that this means GPs are in a pivotal position to offer stop smoking advice at the time of confirmation of pregnancy, when the motivation to quit is highest.

Flemming et al (2016) conducted a systematic review of qualitative research on health professionals' perceptions of barriers and facilitators to providing smoking cessation advice to women in pregnancy and during the post-partum period. Nine papers were included, one of which was from New Zealand (McLeod et al 2003). Health professionals identified the association between maternal smoking and social disadvantage as a barrier to addressing and supporting smoking cessation. Regarding barriers, of particular note were perceived gaps around effective interventions for women in disadvantaged circumstances and around the prescribing of NRT. Procedures and time pressures that resulted in 'tick box' approaches to smoking were also cited as particular barriers. The authors noted that professionals need ways of addressing smoking without a perceived risk to their relationship with the woman.

Content of smoking cessation messages

In the study discussed above, Hoek et al (2014) developed and tested different cessation messages with women who were smoking (or had smoked) while pregnant to examine the perceived effectiveness of the messages. Cessation messages that evoked strong affective responses capitalise on the dissonance many women feel when smoking while pregnant and stimulate stronger consideration of quitting.

The authors suggested that future campaigns could make greater use of emotional appeals and place less emphasis on informational approaches, which often prompt counter-arguments. They note that generating affective, rather than cognitive, dissonance appears to have a stronger cut-through than informational or didactic messages. The authors highlighted that framing smoking not as an assertion of women's choices, but as a behaviour that deprives children of the freedom to make choices, could offer a new approach to promoting cessation to pregnant women. The study did not involve an actual intervention, so the behavioural effects of the messages were not studied.

3. Expert interviews

The interviews with four New Zealand research experts in general reinforced the themes and consensus of the literature.

The recent, as yet unpublished research from South Auckland,[8] showed that 25% of families did not have a sleeping surface for the baby to come home to.

In addition, a portable cot was offered to the families in both the intervention and control group. An offer of a portable cot was taken up by nearly all families.

There has been a recent and as yet non-peer reviewed and unpublished, randomised controlled trial of 240 of Māori and Pacific Island families in South Auckland (McIntosh and Trenholme, Vogel and Stewart 2016). In this study, the Safe sleep programme with Pepi-pod was provided to the entire intervention group and nearly all families took up an offer of a portable cot. The pepi-pods were well received. They found that of high-risk families, one quarter did not have a baby bed at the time of birth of the baby. The pepi-pods were used by half the families at two months post intervention, but only by 16% at four months. A quarter of families continued to bed share in both intervention and control.

In summary, overall SUDI knowledge for both groups improved with no apparent change in behaviour.

From the interviews, there were various and non-research based "anecdotal" comments, particularly around change in safe sleep practices from families. A take away message was that for many families there is a combination of issues and complexities in their lives, which mean the safe sleep messages may not be a priority for them.

[8] Note: we have been granted permission to quote this research.

4. Populations

4.1.1 Harder to reach populations in New Zealand

During the hui, there was much discussion on whether the populations are harder to reach or are the professionals/services not doing their jobs as well as they could. Consensus was that it is not the issue of the families "being hard to reach".

Groups most at risk of SUDI may be labelled 'hard to reach', yet it may be that the delivery of the messages and the modes are not accessible or acceptable for parts of the population. It has been noted that these at times harder to reach parts of the population can include Māori, disadvantaged families, and women who smoked during pregnancy and bed share with their infants (Mitchell et al 2016).

The education to change from prone to back sleeping position was associated with a large decrease in post-neonatal death in the 1990s. It worked well in mainly middle class, white communities (Abel and Tipene-Leach, 2013). However, the messaging was not as effective amongst Māori, whose babies are now significantly over-represented. This is because the primary risk factor for SIDS is now maternal smoking in pregnancy where the infant co-sleeps with an adult. Half of Māori mothers are smokers, many of whom sleep with their infants (Tipene-Leach and Abel 2010).

Tipene-Leach et al 2010 conducted a survey to determine what Māori mothers know about SIDS prevention, and to determine their SIDS-related childcare practices. They found that knowledge of Māori mothers was lower than European mothers. More Māori infants slept prone and Māori mothers stopped breastfeeding significantly earlier. Researchers McIntosh and Trenholme are seeking to replicate this study in the near future. There is a hypothesis that the wider environment and messaging has changed (i.e. improved safe sleep knowledge overall) and they want to test this.

Haereroa (2015) asked young Māori mothers why they bed-shared with their infant. Their justification for this practice related to reasons of convenience, ease of access, emotional connection and bond between mother and infant, and belief of safety with the infant being in close proximity. However, the author noted that all the mothers were aware of the perceived dangers of bed sharing, but the mothers gave reasons for bed sharing that took precedence.

Why messages do not get through?

Fleming et al (2016) stated that in the UK, the mothers of the infants at highest risk are "hard to reach". This is largely because of a lack of information on how such mothers make their decisions about childcare practices, and their resistance to the imposition by outsiders of ideas and practices that do not fit easily within their perceptions of how they wish to run their lives.

Safety campaigns have approached bed sharing as a modifiable practice that can be influenced by risk-education and simple recommendations. This fails to recognise the cultural importance of infant sleep location, and such messages are often rejected by their target population (Ball and Volpe 2013).

McManus et al (2010) note that prevention strategies to date have focused on trying to change parents' 'risky' infant raising practices. This has meant that there has been little appreciation of the intimate connection between social environments and behaviour, and its importance in a high SIDS risk context. The authors argue that it is time to challenge the 'non-modifiable' status of these wider determinants of health and look at structural, population-based approaches that work to improve the wider social and physical environments.

Good ways to target

It is extremely important to recognise individual and cultural preferences and design interventions around them. Because of the cultural preference for bed sharing, the wahakura intervention aimed to make the parental bed a safe sleep environment for all infants (rather than to discourage bed sharing). The intervention involved engagement of Māori women in weaving wahakura during their pregnancy. This increases commitment to using the wahakura, and encourages skill-transmission, reviving a tradition of basket weaving for a new purpose. The wahakura also provides a focus for written and verbal transmission of safe sleep education (Ball and Volpe 2013).

Pipi and McKegg (2016) undertook a review of Northland DHB's Kaupapa Māori group-based antenatal education. The programmes involved different combinations of wahakura weaving, advice on safe sleep, smoking cessation, breast-feeding, and drug and alcohol messaging. They found that the programmes were highly acceptable to Māori mothers and whanau, as the programmes are based on a Kaupapa Māori and whanau-friendly approach, and are Marae, Kura, and Māori community based.

In an environment of poor levels of engagement and access by Māori women and their whanau to group-based antenatal education, the programmes showed promise as models to help address the inequity of access. The authors identified that there is a need for 'buy-in' by health professionals, and feedback from participants indicated that many health professionals do not know about the existing Māori programmes.

Cowan et al (2013b) – discussed above – evaluated the use of an online education tool for preventing SUDI. A high increased confidence rating to discuss infant sleep safety with others was significantly influenced by being Māori, Pacific, and Asian or 'other' compared with NZ European ($p < 0.05$).

Expert interview opinions

From interviews with experts in SUDI prevention, one said that they found it very important to not dilute the message and to be bold and upfront. They expressed the idea that agencies need to work closer together, as often these families are visible to many agencies, for example:

- Housing NZ
- CYFS
- Police
- Rheumatic fever nurses
- Well child agencies

It is thought that if any of these agencies are working alongside a family and there is a baby there, then there should be an opportunity to work closer together for the welfare of the baby.

5. Conclusions

Combinations of risk factors multiply risk

There are known modifiable and non-modifiable risk factors for SUDI and today, it is understood the two major modifiable risk factors for SUDI are maternal smoking and bed sharing. It is also known that any combination of more than one risk factor multiplies the risk. The challenge for agencies and health professionals working with families is how to implement effective strategies that will reduce the exposure to and impact of such risks, as was successfully done previously with prone sleeping position messages (Mitchell and Krous, 2015).

Risk screening must be non-judgemental

Risk screening should be undertaken, in a non-judgemental way, to identify those who may most benefit from additional messaging or interventions. This includes needing to be conscious of cultural and family needs. Where family life has a range of complexities, it appears harder to get safe sleep messages through.

Behaviour change is hard to achieve even with effective safe sleep messages

It appears there is no single factor or known way to provide safe sleep messages. Reaching various parts of the population, including those with high risk factors, and promoting behaviour change can be difficult to achieve. Safe sleep messages and/or a programme appear to need a range of modes of delivery. It seems to require both a population approach and that messages and strategies need to target various parts of the population in ways that are meaningful to them.

We note that increased knowledge does not always lead to a change in behaviour. It is also noted that sustained public health and promotion messages appeared to have increased knowledge and behaviour in New Zealand, particularly for New Zealand European women. Once again, this leads to the conclusion that safe sleep messages need to be delivered in a variety of ways. However to promote behaviour change, particularly in target populations, it may be that ongoing follow up is required. It is not clear at this stage as to why behaviour change does not occur even when increased knowledge is evident. Some factors promoted are cultural and family beliefs and norms, and competing messages from others e.g. older family members. In addition, one study notes that there has been little appreciation of the intimate connection between social environments and behaviour.

At this stage, there is no conclusive evidence about use of pepi-pods or wahakura in the reduction of SUDI. However, when the wahakura or pepi-pod is used, it can reduce the risk. The AAP recent technical report also notes that there is insufficient evidence, stating that there are currently no studies examining the association between safe sleep products and SIDS. The challenge is take-up of correct use of them, as well as continuation of use, even when available in the home. Babies' outgrowing them quickly has been one reason cited for discontinuation of use. One interviewer suggested the offer and use of both the pepi-pod and a porta-cot might be the most successful option for safe sleep spaces, as it prepares for the growth issue.

It would seem beneficial to have a national ongoing sustainable safe sleep programme with multiple agencies involved, and get safe sleep messages out in channels or modes that reach

multiple parts of the population. For example, researchers interviewed reported a small (n=16) cohort of Māori families in South Auckland who suggested that to use Māori TV on an ongoing basis for safe sleep messages would be useful.

More research on how to change actual behaviours, within a wider safe sleep programme, is needed.

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Appendix 1 Search terms used

Infant/baby

SUDI/Sudden Unexpected Death in Infancy

SIDS/Sudden Infant Death Syndrome

Cot death/crib death

Non-suspicious unexpected death

Sleep-related death/infant death

Infant mortality

Safe sleep

Sleep safety

Safe infant sleep practices

Risk/factors

Sleep location decision

Co-sleeping

Bed sharing

Supine/back

Prone/front

Smoking

Breastfeeding

Alcohol/drug use

Low birth weight

Age of mother

Single parent

Environmental/accommodation

Pacifier use

Immunisation status

Vulnerable populations

Health inequalities

Social deprivation

Socio-economic

Socio-demographic

Disadvantaged

Vulnerable

Pepi pod, pepi-pod or pēpi pod

Wahakura

Portable sleeping space

ISSD

Prevent*

Behaviour*

Effective*