**Validation of SmartSnugg Infant Sleeping Bags**

**Background:**

Since the introduction of public health programmes promoting ‘back-to-sleep’ to reduce the risk of Sudden Unexpected Death in Infancy (SUDI) including Sudden Infant Death Syndrome (SIDS) and fatal sleeping accidents, there has been a significant reduction in the number of babies dying suddenly and unexpectedly (Tursan d'Espaignet et al., 2008). However, tragically, around 120 babies die suddenly and unexpectedly every year in Australia (Australian Bureau of Statistics, 2013) and it is important for parents to keep following evidence-based recommendations on ways to avoid risk factors related to baby’s sleep environment (International Society for the Prevention of Perinatal and Infant Death, 2013, Mitchell and Blair, 2012).

The association between overheating and SIDS has been known for several years particularly if baby’s head is covered (Fleming et al., 1990, Ponsonby et al., 1993, Ponsonby et al., 1992, Stanton, 1984). Current research confirms that if a baby becomes too hot, the risk of SUDI is increased (Kinney and Thach, 2009). Overheating can be caused by room heating, high body temperature, excessive clothing or bedding and head covering (Byard et al., 2001). To reduce the risk of this, Red Nose recommends that parents and carers use their own judgement, taking into account factors such as where you live (climate, whether it is summer or winter), whether you have heating in the house, and whether baby has a cold or minor illness (which may cause their temperature to rise).

A useful guide is to dress baby as you would dress yourself: to be comfortable, neither too hot nor too cold. If baby has a minor illness and has a temperature it is common for parents or carers to overdress baby for sleep (Rognum, 2001) but in fact, fewer bedclothes should be used or, at times, none at all. If parents or carers are worried that baby is ill they should talk to their baby’s doctor and have the baby assessed.

Both hyperthermia (unusually high body temperature) and hypothermia (unusually low body temperature) are important to avoid during infancy (Stanton, 1984).

Baby’s face and head should always remain uncovered. A baby’s head (particularly the face) is the main route for heat loss (Joseph et al., 2007). Overheating has been found to be related to SUDI and the risk of overheating is increased if the baby is sleeping on the tummy (Fleming et al., 1990). This is especially dangerous if the baby is under heavy bedding as, if baby should roll over onto the tummy, then the risk of overheating is even further increased. In fact, research has shown that babies sleeping on the tummy are at ten-fold the risk of SUDI while sleeping in a heated room (Ponsonby et al., 1992).

Increased temperature alters infant physiology by increasing respiratory and heart rate and in some studies the frequency of central apnoeas. Increased temperature, whether due to head covering or by increasing room temperature depresses arousal responses and reduces autonomic control of heart rate (Franco et al., 2000, Franco et al., 2001, Franco et al., 2002, Franco et al., 2003). Both impaired arousal from sleep and autonomic cardiovascular control have been implicated in the final mechanism of SIDS (Harper, 2000).

Sleeping babies in a safe baby sleeping bag, one designed especially for baby, with fitted neck and armholes and no hood, has a number of features that help baby sleep safely. Research has shown that sleeping bag use reduces the risk of bedclothes covering the baby’s face, and delays the baby rolling onto the tummy during sleep until baby is past the age of peak risk of SUDI. Supine sleep is also promoted when the zipper is opened to the front (L'Hoir et al., 1998) and will keep the baby’s temperature at a more constant level while sleeping at home (Sauseng et al., 2011).

This study will validate a new product the SmartSnugg Baby Sleeping Bag that records the baby’s temperature and sleeping position while asleep and displays this for parents to check. The SmartSnugg uses a “pebble” which is contained in a pouch and is removable so it can be used in different sleeping bags and also for washing of the sleeping bag. The pebble incorporates an ambient temperate sensor, accelerometer and Ultra Low Power Bluetooth transmitter that communicates with a WIFI bridge in the child’s room. The WIFI bridge also incorporates an ambient temperature sensor so that the child’s room temperature can be monitored. The information captured from the pebble and bridge (temperature, movement, position) are received and routed from the SmartSnugg bridge through the users home WIFI network before being stored and analysed in the cloud. The information is then displayed to parents and caregivers on their mobile phone or tablet.



The validation study will record temperature from accurate temperature sensors placed on the abdomen and limbs while the baby sleeps and compare these measurements to the output of the SmartSnugg. Sleep position and room temperature will also be confirmed.

**Recruitment:** The study will be advertised on Monash University and Monash Health Newsletters and to local Maternal and Child Health Centre and Crèches. Parents of healthy babies aged 3 and 6 months will be invited to participate. Parents will contact Prof Horne and after discussion of the time commitments and methods to be used in the study she will email or post the parent information sheet. If parents agree to the research study a suitable time for the study will be scheduled. Parents will sign the parent information and consent form before the study commences. 20 healthy infants born at term will be recruited and studied at 3 months (n=10) and 6 months (n=10) of age.

**Methods:** Infants will be studied in a quiet room at the Monash Children’s Hospital.

Four different SmartSnugg Infant Sleeping Bags will be tested:

1. 0-3 month 1 tog

2. 0-3 month 2.5 tog

3. 3-12 month 1 tog

4. 3-12 month 2.5 tog.

Infants will sleep for 1-2 hours in each thickness of sleeping bag. Studies will last 5-6 hours.

Sleep state will be recorded using behavioural observations of eye movements and breathing and heart rate patterns as active sleep (AS) or quiet sleep (QS). Chest and abdominal wall motion (ProTech z-RIP belts, Pro-Tech Services, Inc. Mukilteo, WA, USA), pulse oxygen saturation (Masimo Radical, Masimo Corporation, CA, USA), oronasal airflow and nasal pressure (Compumedics, Melbourne, Vic, Australia) will be recorded to assess breathing patterns. Skin temperature will be recorded from the trunk and limbs (4 probes in total) (ADInstruments, Sydney, NSW, Australia). All signals will be recorded onto and E-series Sleep System (Compumedics, Melbourne, Vic, Australia).

All studies will be transferred via EDF format to specialised analysis software PowerLab (Chart, ADInstruments, Sydney, NSW, Australia). Sleep state in infants will be scored as AS or QS according to standard criteria for infants. Apnoeas will be defined as those respiratory events lasting ≥3 s and will be classified as central, obstructive, or mixed apnoeas, central or obstructive hypopnoea. Periodic breathing episodes will be defined as 3 or more sequential central apnoeas lasting ≥3 s interrupted by breathing lasting ≤20 s.

Total sleep time, sleep epoch lengths and the frequency of sleep state changes will be documented. Sleep position will be recorded. Infant skin temperature will be compared with the temperature recorded by the SmartSnugg with paired Student’s T-Tests. Data will be presented as mean ± SEM with a p value <0.05 take as being statistically significant.

Baby weight will be recorded from infant health book.

**Expected Outcomes**

We expect that the temperature recorded by the SmartSnugg will not differ from that recorded from the infant.

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