

A Fragile Change

Reporting monitoring data for **The Pēpi-Pod® Programme** from Jan 2019-Nov 2020

Introduction: The Pēpi-Pod® Programme (PPP) was developed by Change for our Children (CCL) to decouple the ‘smoking + bedsharing’ risk¹, support wahakura, and help reduce preventable sleep-related infant deaths. It progressed from an emergency response to the Christchurch earthquakes² in 2011, through scaled supply to an increasing number of district health boards (DHB), and since 2017 the supply of portable sleep spaces (PSS) to more vulnerable infants has become a national health-funded norm.

With this latest change came a change to data collection expectations of DHBs by the Ministry of Health (MOH), beginning January 2019. To support DHBs in this transition from a previously coordinated approach to developing their own systems, CCL provided a data support service, so that clinically relevant monitoring of PSS services could continue as a quality driver, at least for those DHBs opting to use the service.

This report is of data entered into the PPP database between Jan 2019 and Nov 2020.

Aim: To describe the supply of PSS in New Zealand during a transition period from development as a stand-alone programme to integration into the infant health service.

Method: The methods and methodology of the PPP have been described previously.³ Data were entered by DHB personnel themselves into a simplified on-line PPP database that was adapted to be a one-stop shop and enable entry of MOH-required data, too. Distribution and impact data entered between 1st January 2019 and 1st Nov 2020, were analysed by frequency distributions. Where there were missing data, percentages are of total responses.

Main findings: During the 22 months of the study period, 14,000 PSS were supplied to NZ DHBs as well as an unknown number of wahakura and other infant beds. Fifteen DHBs contributed data, 7 of which contributed more than 100 records each. More than half of all records were from two DHBs, Waikato (730) and Whanganui (420).

There were 2198 distribution and 491 follow-up (impact) records entered. The contribution across regions for records entered, decreased from 55% for Midland, 30% for Central, 8% for Northern and 7% for Southern; and reduced over time from 80% during 2019 to 20% during 2020.

Distribution

Of 2198 distribution records, 42 were excluded due to data gaps, leaving 2153 for analysis. Most PSSs distributed were PPs (86%), 14% were wahakura (7 of which were made by a parent), and two were baby boxes. For the 94% with data, all PPs were accepted by families and none were declined. Most (87%) infants were unborn or ≤ 2 weeks of age when they received their PSS.

More PSSs were distributed to infants with older (≥25 years) than younger (<25 years) mothers (61%, 39% respectively), and more to women who were smokefree than who smoked during pregnancy (59%, 41% respectively). Twenty-three percent of infants receiving PPs were born prematurely (<37 weeks gestation), or were of low birthweight (< 2500grams), and 72% had some other type of baby bed. The infant’s ethnicity was reported as ‘Māori’ for 58%, ‘Pacific’ for 11% and ‘Other’ for 31%.

As well, 55% of records describe ‘other’ factors as reasons for distributing PSSs, with ‘household smoking’ the main one (27%), followed by ‘low maternal support’ (11%), ‘infant welfare’ (9%),

'overcrowding' (8%), 'mental health concerns' (6%) and 'regular alcohol and drug use in infant's household' (5%). Considering all the risk factors above there were 10% of PSSs distributed to infants with none of these factors.

Three questions were asked of families about their experience receiving a PSS, to ascertain if core elements of the PPP had been provided at distribution. High levels of inclusion of core elements were reported: a standard safety briefing using the PPP picture card (89%), a demonstration of infant airway protection using a short length of tubing or similar (90%), and whānau encouraged to share their knowledge about safe infant sleep with others (98%).

Impact

Impact data were to be collected when babies were 6-8 weeks old, to assess safe sleep practices at home during the vulnerable age for sudden infant death. Of 491 impact records, 17 were excluded due to insufficient data, leaving 474 for analysis.

Most (76%) infants were aged <13 weeks at follow-up, with ages ranging from 0-8 (52%), 9-16 (29%) and >16 (19%) weeks. Ninety per cent of families took up the peer communicator role, reporting speaking with a collective 1904 'others' about safe infant sleep (\bar{x} = 4.5 others). Bedsharing with infants since getting their PSS was common (64%), with 85% of these infants 'always or usually' in a PSS at the time.

Safe sleep recommendations were evident in practice for most infants, who were: 'always/usually place infant on the back', 'always or usually perform a safe sleep check of the sleeping environment', and 'infant always or usually in the same room as a parent when a parent is also sleeping' (96%, 98%, 97% respectively).

For 80% of infants there was some breastfeeding in the 'past week'. Of these 367 infants, 63% were fully breastfed (only breastmilk, no formula), 23% partially breastfed (mostly breastmilk, some formula) and 14% received some breast milk and mostly formula. For 78 infants, breastfeeding had ceased and 14 infants had never been breastfed.

Families were invited to rate how well their PSS had supported them in various ways, on a scale of 1-9 with 1=low and 9=high. High ratings were defined as a score of 7-9 out of 9. High ratings were given for safety (95%), improved maternal sleep (82%), and breastfeeding (68% of the 398 infants who were breastfed). There were ninety-eight responses describing 'other' ways their PSS had been supportive, many of which related to portability, convenience, proximity, closeness, travelling ease, safety and peace of mind. A selection of responses to illustrate these, follows:

"The pod is portable. I can pick it up and put it anywhere."

"It's been really handy when I bring him into our bed at night when he is unsettled and just wants to be near me."

"Can move sleeping baby to different rooms with me."

"The Pepi-Pod has reassured me and allowed me to bond with my baby."

"Being able to stay away from home and know baby has a safe place to sleep."

"Stops him rolling off the bed and couch."

"Didn't have to worry about rolling on baby and this gave peace of mind."

"I quite like it. It helps me. I like how it's clear and I can see my baby."

Most parents had plans for a 'next bed' when their infants had outgrown their PSS, and for 95% this was a cot or porta-cot. Fourteen parents planned to bedshare directly with their infants and 9 had no plans at the time.

At the follow-up session, families were invited to offer a free comment on their experiences using PSSs and 253 (53%) did so, with 211 comments from PP, and 42 from wahakura, users. Many comments were general in nature e.g. 'great', 'awesome', 'excellent', 'handy', 'useful', 'loved it', 'thank you', 'terrific', 'beautiful'. Others were more specific, and a selection of these follows:

"Thank you for the opportunity to have a wahakura. He sleeps in it during the day and in his bassinet at night. Before I had the wahakura he was sleeping on a bean bag during the day. The wahakura is much safer."

"It's been absolutely amazing. I shared information about the Pēpi-Pod and safe sleep on social media."

"It's cool as. When we travel we take the Pēpi-Pod for baby. It's easy to carry around. We use the Pēpi-Pod when we sleep on a mattress in the lounge. I tell everyone about safe sleeping."

"Awesome resource. Very grateful, but if given the choice, I would prefer to weave my own wahakura vs being given one."

"Liked the sheets - they're nice and soft."

"Would recommend it to pregnant women."

"Used it a lot more than I thought I would."

"Really happy with Pēpi-Pod, and baby is now sleeping in her cot, with the Pēpi-Pod being passed to another mum who is using it."

"I just think having a Pēpi-Pod is a nice worry-free safe sleeping space. Even took it to the beach."

There were 14 (5%) of the general comments expressing difficulties, dislikes or disappointments as shown in the selected responses below:

"I've tried to talk to my family about safe sleeping, but they've got their own ideas. The pod is really good, everyone should get one, it's safe and easy to use."

"Tried for a week didn't work out."

"I got a Pēpi-Pod and a wahakura., the Pēpi-Pod is at his father's place. I can't get it back because we've broken up, but I've got the wahakura. I prefer the Pēpi-Pod, the sides are stronger than the wahakura. The wahakura was good in the beginning, but now the sides have got wide and the mattress doesn't fit as well anymore".

"Pēpi-Pod is a bit wide to fit on our bed."

"Pēpi-Pod was not wide enough as baby can hit hands on the edges."

"Parents have struggling to get baby to settle anywhere else but on either of them, so now baby is too large for the Pēpi-Pod and will probably co-share unless they can settle baby in the cot."

Discussion: There are obvious limitations in reporting monitoring data. It is not evaluation. The purpose of monitoring is to keep track of the process of an intervention, whereas that of evaluation is to estimate its value.

Results presented here need to be treated with caution and not generalised beyond this study group to the wider population of infants receiving PSSs. Data are not representative of that group, nor of DHB processes overall. However, in the absence of any other monitoring information for this critical period of transition, the report offers the chance to ask questions, check processes and make course adjustments as may be required, for tracking a reliable pathway to effective outcomes for infants.

The main question this report highlights is: ***'Were PSSs being supplied to appropriate infants?'*** An appropriate infant is a new-born exposed to smoking in pregnancy, because the point of a PSS intervention is to decouple the alarmingly high risk of death for such an infant when they also share their parents' beds (multivariable OR 32.8 compared to 1.91 for just smoking in pregnancy¹). Recent alcohol use by the bed-sharing adult magnifies this risk further.

Given that more PSSs went to smokefree infants and infants with older mothers, than to infants smoke-exposed in pregnancy and with younger (<25 years) mothers, the answer to the above question is ***'Not enough PSSs were supplied to appropriate infants.'*** Unless of course, there were sufficient PSSs distributed to saturate the high-risk need, but that is unlikely given the volumes of PSSs supplied. What is more likely is that too many high-risk infants are missing out on access to a PSS.

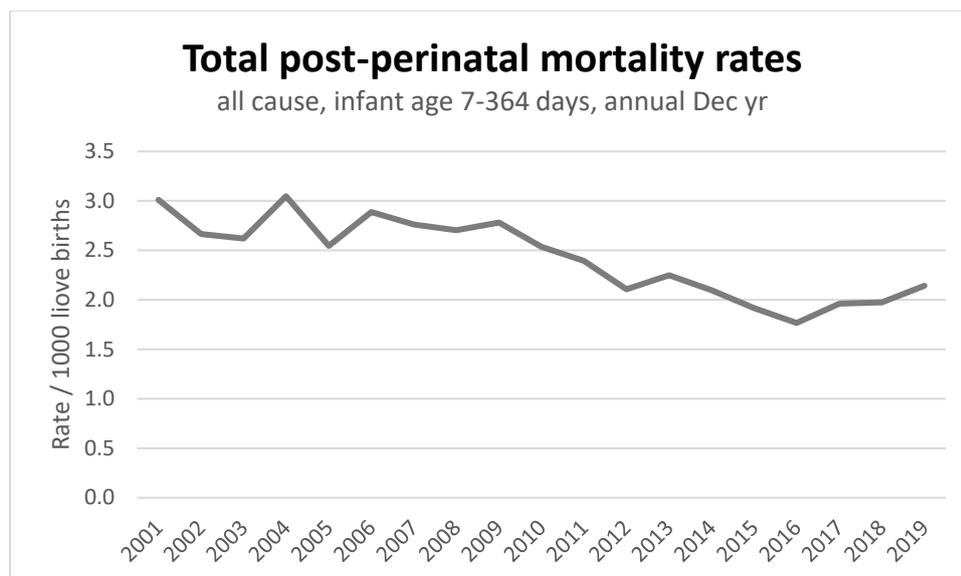
This loosening of criteria for who gets PSSs has changed over time. Comparing current distribution statistics with those described for the first three years of the PPP, between 2012-2014³, current supply of PSSs includes more non-Māori infants (74% vs 58%), more smokefree infants (59% vs 23%), and more infants of older mothers (≥ 25years) (46% vs 39%) than was reported for the early years of the PPP. While there may well be benefits other than safety in the use of PSSs, imprecise targeting of a resource intended for a specific purpose, in this case reduced infant deaths, is likely to weaken impact.

What has increased between the periods 2012-2014 and 2019-20, is that now, more infants are getting their PSSs before they are born (28% vs 11%), and overall, before two weeks of age (87% vs 64%). Early distribution offers families an opportunity to lengthen the duration for protection from PSS use and, in this way, strengthens the potential impact of the intervention.

Another question we must ask is, ***"Have infant death rates reduced since the change to a MOH-led service?"*** An important part of monitoring the PPP, in the past, has been also to monitor and report on infant death rates. Post-perinatal mortality (PPNM) rates have been used as a marker of preventable deaths. PPNM includes all deaths of infants aged between 7 and 364 days, whatever the cause. Any significant change to preventable deaths, is likely to show in PPNM rates. PPNM statistics are provided quarterly as a special report to Change for our Children by Statistics New Zealand.

The answer to the above question is ***"No, infant death rates have actually increased since 2016."***

Figure 1, below, tracks PPNM rates in New Zealand this century. For the first ten years, rates plateaued between 3.0 and 2.5 / 1000 live births. From 2010 to 2016, they reduced by 36% from 2.5 to 1.8 / 1000 live births. The Safe Sleep Programme, which included the scaled supply of PSSs, that was implemented in NZ from 2009 through this period of falling PPNM rates, has been described in full elsewhere⁴. In the three years from 2016 to 2019, PPNM rates have increased by 14%.



This increase in infant deaths was unexpected, is concerning and needs to be addressed as a matter of urgency. What was expected, given the intervention's strong basis in science and six years of falling PPNM rates, was that dedicated and reliable resourcing from Vote Health would enable continuing reductions in infant deaths, and at the very least a new lower plateau to lock in the gains made and enable greater focus on protecting infants with more complex risk profiles. The next and most important questions for the sector now are **“Why has this increase happened and how must we reverse this trend?”**

Any intervention that has been effective in one context and then applied in another, cannot expect a similar impact if core elements (content, methods, dosage, and tools) of the approach are misunderstood, weakened or lost in the process of adapting to that new context. Finding a good fit for an effective programme in a new environment is a balancing act. A review⁵ of the literature on this topic concluded that *“science and experience say that maximum success requires attention to both fidelity and adaptation”*, and an implementation guide⁶ published by Washington State University in 2019, explains how to achieve such a balance.

Attention to this balance is needed in New Zealand. A key principle of the PPP is that the product (PP) is not the intervention. It is but a component of a comprehensive suite of principles, agreements, systems, processes, and tools that together are the intervention, and together have likely contributed to reducing infant deaths between 2010 and 2016. The intervention is the less-visible programme and not just the more-visible product.

Much has been lost, diluted, or changed since 2016 and these adaptations may be part of the reason for reduced effectiveness that we currently see. The PPP is no longer formally coordinated as it was in the past. There is general SUDI prevention training available online, but no longer is there training for dedicated distributor roles.

Another core element that has been dropped from the adapted approach, is the nation-wide monitoring of clinically relevant data, collected at distribution and follow-up contacts. Lost with it, are the quarterly reports back to services, to enable them to keep their interventions on track. The data that is nationally coordinated and required, is not clinically relevant, nor is it reported, so DHBs have lost a significant feedback loop for quality improvements. This is like operating in the dark. There may be some local data collection happening outside of what we report here, but what is

being collected, how it is being used and who it is for is unknown. Monitoring and feedback are essential quality tools for any intervention and especially through a change of context for delivery.

Conclusion: Data presented here described a situation where more PSSs were being distributed to smokefree infants than to infants exposed to smoking in pregnancy, more were distributed to non-Māori than was the case in the early years of the PPP, and post-perinatal death rates have increased by 14% since 2016.

Programme fidelity has been undermined in the process of adapting to a Ministry of Health led service, most concerningly in relation to national coordination, the monitoring and feedback of clinically relevant data, and dedicated training for the role of distributing PSSs.

There is an urgent need for more precision in targeting resources to infants most at risk of death due to the interaction of 'smoking in pregnancy' and 'sharing beds with parents', and for more balance between fidelity to the methodology of the Pēpi-Pod® Sleep Space Programme and its adaptation to a nationally embedded infant health intervention.

References:

1. Mitchell, Edwin A., et al. "The combination of bed sharing and maternal smoking leads to a greatly increased risk of sudden unexpected death in infancy: the New Zealand SUDI Nationwide Case Control Study." *NZ Med J* 130.1456 (2017): 52.
2. Cowan, Stephanie, et al. "An evaluation of portable sleeping spaces for babies following the Christchurch earthquake of February 2011." *Journal of Paediatrics and Child Health* 49.5 (2013): 364-368.
3. Cowan, S. Their first 500 sleeps – Pepi-Pod Report: 2012-2014. Change for our Children (2015) (Available at :<http://www.changeforourchildren.nz/files/docs/pepi-pod%20programme/their%20first%20500%20sleeps.pdf> (downloaded 1/12/2020))
4. Mitchell EA, Cowan S, Tipene-Leach D (2016) The recent fall in postperinatal mortality in New Zealand and the Safe Sleep programme. *Acta Paediatrica* (Oslo, Norway : 1992) 105, 1312–1320.
5. Backer, Thomas E. "Finding the balance: Program fidelity and adaptation in substance abuse prevention: A state-of-the-art review." Rockville, MD: Center for Substance Abuse Prevention (2001).
6. Parker, Louise, AnaMaria Diaz Martinez, and Brittany Rhoades Cooper. "Balancing fidelity and adaptation: a guide for evidence-based program implementation." *Washing State Universities Extensions* (2019).

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Disclosure:

To ensure transparency, we declare associations which may be perceived by others as a competing interest in promoting protection for infants.

- Change for our Children Limited supplies the Pēpi-Pod® Programme on a cost recovery basis and as a social business. As such, the commercial activities involved in purchasing component parts and selling goods constitutes a commercial interest.

- Change for our Children Limited owns the intellectual property and service mark of the Pēpi-Pod[®] Programme which constitutes a professional interest. The intention of the mark is to assure the public of a standard experience when receiving a Pēpi-Pod[®] sleep space.
- Stephanie Cowan developed the Pēpi-Pod[®] Programme, is Director of Change for our Children Limited and as such has a professional interest in the reputation of the programme.
- The sole source of funds for providing the Pēpi-Pod[®] Programme comes from the sale of goods and services associated with it. There is no funding from any other source.
- Change for our Children Limited offers the approach developed as the Pēpi-Pod[®] Programme to the distribution of wahakura and any other portable infant bed, on a good-will basis, but has no mandate to discuss wahakura.
- Change for our Children Limited supplies infant bedding for use with wahakura as requested and on a cost recovery basis.

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