



Measuring the effectiveness of the Pēpi-Pod[®] Program in reducing infant mortality in Queensland

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Foreword

To begin, we would like to express, on behalf of the authors, our very sincere condolences to the families and communities who have experienced the death of their infant, whether sudden and expected or not. We acknowledge the enormity of that loss. It is the possibility of preventing future deaths that drives our work.

Sudden Unexpected Death in Infancy (SUDI) is the leading category of infant death after the first four weeks of life. SUDI is a research category which groups together infant deaths from varied causes, but which occur in similar circumstances, namely the death of an infant (aged less than 12 months), that is sudden and unexpected, typically occurs during sleep, and where the cause was not immediately apparent at the time of death.

The Queensland Paediatric Quality Council (QPQC) functions to investigate and monitor trends in the incidence and causes of paediatric mortality and morbidity to identify issues that need action or further study. QPQC reviewed in depth, the SUDI in Queensland for the four years 2013-2016 and confirmed that, like the many published international reports, for the majority of SUDI there were multiple contributory factors, but that sleeping in unsafe circumstances was a factor in almost every case. Improving the safety of the sleeping environment is a key strategy to prevent deaths. The review also confirmed the much higher SUDI rate in Aboriginal and Torres Strait Islander families.

The Pēpi-Pod® Program was introduced to Queensland in early 2011 as a research initiative by University of the Sunshine Coast researchers, to address the need for culturally appropriate support strategies to reduce infant deaths. The Program provides a portable sleep space (Pēpi-Pod®) embedded in safe sleep education, with a family commitment to share learnings about safe sleep within their family and social network.

The research was prioritised in Aboriginal and Torres Strait Islander communities, recognising both the greater need given the disparity in mortality, and also the opportunity to build on the strength of community networks. The Pēpi-Pod® Program has been formally evaluated and has demonstrated a reduction in the proportion of infants sharing a sleep surface in the context of known risk factors. It was also shown to be culturally appropriate, feasible, accessible, and sustainable.

After the conclusion of the research, a number of services continue to deliver the Pēpi-Pod® Program to communities in Queensland, but to date there is not a systematic state-wide approach to delivery of the Program.

This report outlines an important next step, to evaluate the impact on infant mortality in Queensland of the Pēpi-Pod® Program as implemented thus far, and to evaluate the cost of implementing the Pēpi-Pod® Program available to all Queensland families who would benefit. This will set the scene for the next development which will be to develop a framework for statewide implementation.

It has been a privilege for the QPQC Chair and Coordinator to partner with preeminent researchers from the University of the Sunshine Coast and University of Auckland to conceptualise and undertake this research.

Julie McEniery
Co-Chair, QPQC

Executive summary and recommendations

Queensland has a 30 per cent higher rate of Sudden Unexpected Death in Infancy (SUDI) compared with the rest of Australia. Most SUDI occur in the context of unsafe infant sleep environments and/or infant care practices and occur disproportionately in vulnerable population groups. Most deaths are preventable.

The Pēpi-Pod® Program is a portable sleep space embedded in safe sleep education with a family invitation to share what they have learned about protecting babies as they sleep. The program embeds health equity principles which consider the social, cultural and economic determinants of health in order to achieve the key aim of decoupling the interaction between smoking during pregnancy and bed-sharing. The Program has been introduced into certain Queensland communities initially as a research intervention and subsequently as a limited ongoing program. It has been shown by Queensland researchers, and the communities with whom they partnered, to be acceptable, feasible, safe, and culturally appropriate, and has improved the safety of infant sleep practices in those communities.

New Zealand based studies have demonstrated safety, infant physiological stability, and improved breastfeeding outcomes in addition to infant mortality reductions associated with the Pēpi-Pod® Program which is now incorporated as part of New Zealand's national infant mortality reduction strategy.

In this study, "Measuring the effectiveness of the Pēpi-Pod® Program in reducing infant mortality in Queensland", we demonstrated a 75 per cent reduction in the infant mortality (between the ages of 28 days and 6 months) in the Queensland postcode areas where the Pēpi-Pod® Program achieved the highest level of community participation with the target population.

We also demonstrated a 22 per cent significant reduction in the infant mortality rate (between the ages of 28 days and 6 months), in the whole population of Queensland from 2014 onwards which aligns with the phases of research and limited implementation of the Pēpi-Pod® Program. Given that there had been only a gentle decline in infant mortality over the past decade, and no other post-neonatal infant health promotion intervention which provides an explanation, we hypothesise that the Pēpi-Pod® Program is responsible for this reduction in mortality.

We recommend that the Queensland government implements the Pēpi-Pod® Program to priority Queensland populations without delay to address the excess preventable infant mortality due to SUDI. The Program will provide a 'low cost high return on investment' intervention, estimated to save 15 infant lives each year, of approximately AUD \$1.4 to \$ 2.1 million per year (projected cost upscaled over eight years), a fraction of the financial value that the Australian society would place on these lives.

We propose a minimum of an eight year program in the first instance. The first four years will utilise implementation science strategies to embed the Program into existing maternity and postnatal care support programs in an incremental expansion. The following four years will evaluate the mortality benefit and process outcomes within the established Pēpi-Pod® Program.

This plan directly addresses priorities identified in the Queensland Family and Child Commission's Safer Pathways Through Childhood strategy 2022-2027 and articulates the intentions of the Making Tracks Together: Queensland's Aboriginal and Torres Strait Islander Health Equity Framework.

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Finally, an acknowledgement to all the service providers who have delivered the Pēpi-Pod® Program across Queensland and the families who have participated in the Program. The data you have provided and collected as part of the Program has been crucial to the evaluations and recommendations contained in this report.

Context

Sudden unexpected deaths in infants

Infant mortality in Queensland

Children are more likely to die in infancy (0-12 months) than at any other time in childhood.⁽¹⁾ (Figure 1) Queensland has an approximately 30 per cent higher infant mortality and post-neonatal infant death rate (age 28 -364 days) than the rest of Australia (Figure 1 & 2). The measurement of infant mortality in populations (Infant Mortality Rate [IMR]) is considered a core indicator to describe population health and the effectiveness of health systems.⁽²⁾ The Queensland Government has announced its vision to be amongst the healthiest people in the world by 2026;⁽³⁾ this will not be achieved if the high IMR continues.

Queensland has a 30% higher infant mortality and post-neonatal infant death rate than the rest of Australia.

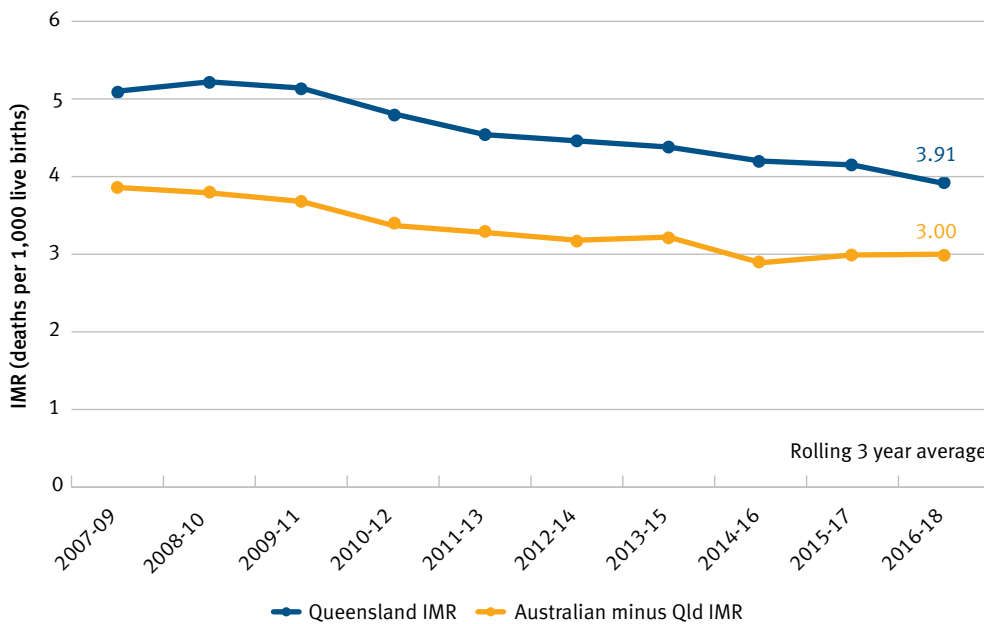


Figure 1. All Infants, Queensland vs rest of Australia (A-Q) IMR

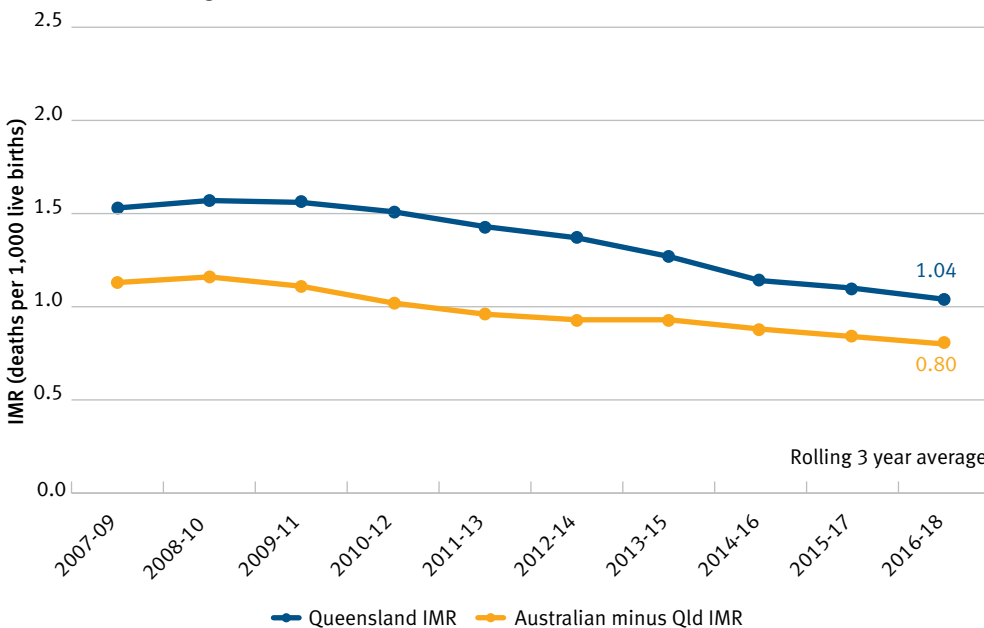


Figure 2. Post neonatal infants, Queensland vs rest of Australia (A-Q) IMR

Queensland Paediatric Quality Council – sudden unexpected death in infancy review

The Queensland Paediatric Quality Council (QPQC) convened an Infant Mortality Expert Panel in 2015 to examine Queensland’s high IMR. QPQC’s focus has been on the subgroup of post-neonatal infant deaths (death at age 28-364 days), for which the QPQC Infant Mortality Expert Panel members have expertise in general paediatrics, community child health, midwifery and neonatal nursing, critical care, neonatology, forensic paediatrics, forensic and specialist pathology, academic research on infant deaths, and non-government service provision. Detailed reviews are conducted to identify modifiable risk factors which, if addressed, may reduce some of the excess infant mortality.

The QPQC Expert Panel has reviewed all post-neonatal infant deaths (death at age 28-364 days) in Queensland between 1 January, 2013 to 31 December, 2015 (n= 239). The results of these reviews show that half of all infant deaths were unexpected and not immediately explained by medical or external causes. Known as Sudden Unexpected Death(s) in Infancy (SUDI), these deaths comprise a research category used to describe the death of an infant (aged under one year) which is sudden and unexpected, usually occurs during sleep, and with no immediately obvious cause.⁽⁴⁾ SUDI does not correspond to any one cause of death category.

Categories of SUDI

Figure 3 illustrates how SUDI may be categorised after investigation. Following a thorough investigation, a single underlying cause of death may be evident in a small number of the deaths. In contrast, for most deaths no single cause that sufficiently explains the death is identified, and the death remains unexplained. Unexplained deaths may be coded as Sudden Infant Death Syndrome (SIDS) following a comprehensive investigation and meeting specific criteria, or remain as an Unexplained Sudden Infant Death (USID) if the investigation is incomplete, or insufficient detail is available to be certain about a cause which appears likely (for example a fatal sleep accident) or if the investigation reveals several factors which, whilst insufficient to cause death on their own, are considered contributory and the balance of contribution is uncertain.

The QPQC multidisciplinary expert panel reviews post-neonatal infant deaths (28-364 days).

Sudden Unexpected Death in Infancy (SUDI) is a research category used to describe the

- death of an infant (aged under one year)
- which is sudden and unexpected
- usually occurs during sleep
- and with no immediately obvious cause.

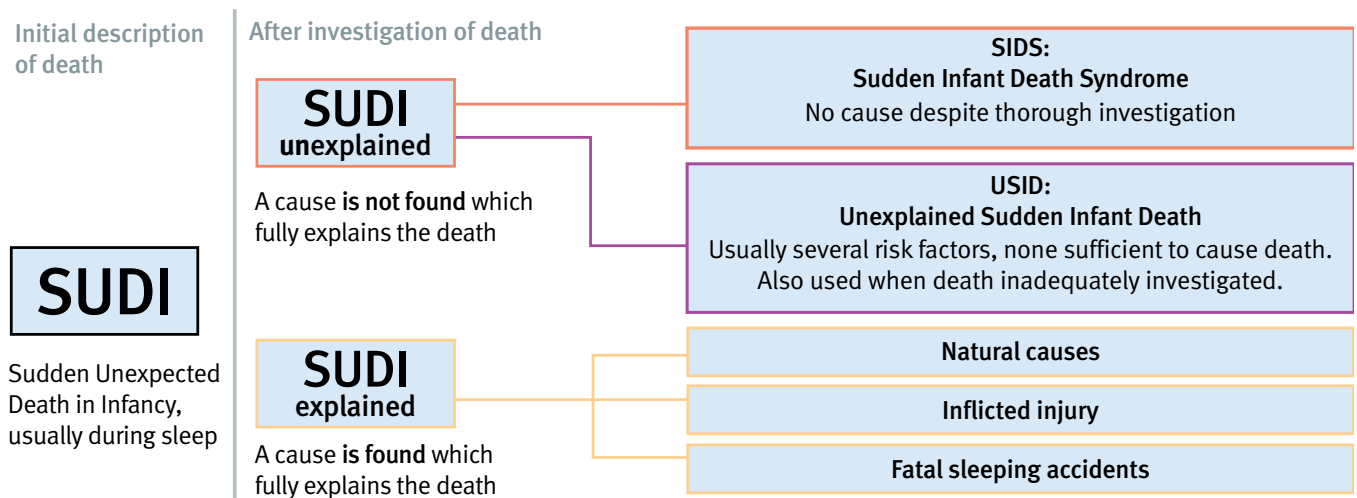


Figure 3. Illustration of SUDI categorisation after investigation

The QPQC Expert Panel reviewed SUDI in Queensland for the years 2013-2015, finding that the group of Unexplained SUDI (68 per cent) contributed to a greater proportion of sudden infant deaths than explained SUDI (32 per cent). For nearly all Unexplained SUDI, multiple contributing factors were documented.⁽⁴⁾ The presence of multiple factors has been widely reported by other researchers and is best explained by the “Triple Risk Model” for SUDI.⁽⁵⁴⁾ This Model proposes interactions between: a critical period of infant development; infant vulnerability (eg. after preterm birth, or maternal smoking in pregnancy); and external stressors (eg. a hazardous sleep environment or infection) which may lead to sudden and unexpected death.

The QPQC has developed a response model for SUDI to encompass prevention, improved investigation, and better support for bereaved families.⁽⁵⁾ Two key findings in particular have led to this examination of the potential role of the Pēpi-Pod® Program in Queensland in preventing SUDI.

1. Our First Nations families bear an unequal burden of SUDI

The first of these findings by QPQC confirms the well documented high rate of Aboriginal and Torres Strait Islander SUDI in Queensland. This has been reported by the Queensland Family and Child Commission as 3.4 times higher than the non-Indigenous rate.⁽⁶⁾ The QPQC review found that 26.4 per cent of post neonatal SUDI in Queensland were of Aboriginal and Torres Strait Islander infants (a rate of 2.1 SUDI per 1,000 live births), which was 3.9 times higher than the rate of SUDI of 0.5 per 1,000 non-Indigenous births in those years.⁽⁷⁾

This aligns with a more recently published analysis of infant deaths occurring in Queensland during 2010-2014 which also highlighted that the true magnitude of the disparity is restricted by under-identification of Indigenous status in death records.⁽⁸⁾ That study, for the first time, applied the algorithm proposed by the ‘Getting our Story Right’ cross agency data linkage project (GOSR algorithm) to improve Indigenous identification in both cases of SUDI (numerator) and infant population data (denominator). The Indigenous SUDI rate increased from 1.38 per 1000 live births to 2.12 per 1000 live births following application of the algorithm to numerator and denominator data; representing a rate increase of 0.75 per 1000 live births, an increase of 54.3 per cent.⁽⁸⁾

The reasons for this disparity are complex. Many infant, parental, environmental and socio-economic factors associated with health inequities are prevalent within Aboriginal and Torres Strait Islander peoples and are known to contribute to an increased vulnerability for infants, as well as being recognised as risk factors for SUDI.⁽⁸⁾ However, it is also recognised that there are protective factors in many Aboriginal and Torres Strait Islander families including strong community networks and good breastfeeding rates, especially relevant for SUDI prevention.

Multiple unsafe sleep factors were documented in nearly all unexplained infant deaths reviewed by the QPQC.

SUDI rates are more than 3 times higher in Aboriginal and Torres Strait Islander infants.

2. Unsafe infant sleep practices and unsafe sleep environments are risk factors for SUDI

Currently, smoking in pregnancy is the most significant modifiable risk factor for SUDI. The interaction with this risk factor and certain sleep environments, such as shared sleep has been reported to increase the risk of SUDI by as much as 32 times in a recent New Zealand study.⁽⁵⁵⁾ Approximately half of the SUDI reviewed by the QPQC occurred in a setting of shared sleep and smoking in pregnancy had occurred in 80% of these cases. Shared sleep refers to an infant sharing a surface during sleep with another person, whether or not this was intentional. The term shared sleeping encompasses the commonly used terms of co-sleeping and bed sharing and often occurs with parents, siblings and sometimes pets.

Shared sleeping is a common practice particularly when mothers are breastfeeding. It is the cultural norm in many Indigenous communities and is also valued by many non-Indigenous families. A recent study of infant care practices in Queensland (n=3,341 families) found that 76.9 per cent of parents of infants aged approximately 3 months reported that they had shared a sleep surface with their baby at some time since birth; while 49.6 per cent had shared a sleep surface in the last two weeks.⁽¹⁰⁾ For 57.3 per cent of families, shared sleeping had not been planned.

Whilst sharing a sleep surface is often associated with SUDI, current evidence suggests that it is not sharing the sleep surface per se that increases the risk; but rather the context in which it occurs.⁽¹¹⁻¹³⁾ Certain shared sleeping contexts have been found to increase the likelihood that SUDI may occur. Some infants are more vulnerable to risks to their breathing in a shared sleep environment. This includes infants who were exposed to tobacco smoking during pregnancy, or exposed to smoking within the household, and infants of low birth weight or those born prematurely.⁽¹³⁾ Infants are also vulnerable when sleeping with adults who have used substances that impair arousal from sleep including consumption of alcohol prior to sleep, and infants who share a sofa or armchair with an adult.^(11, 12, 13, 14-16) In addition to these cautions, the Australian national advocacy organisation for SUDI, Red Nose, does not recommend sharing a sleep surface when the mother/carer is overly tired or unwell.

The research team who trialled the Pēpi-Pod® Program (a portable sleep space embedded in safe sleep education) in Queensland in selected health services, identified the potential for the Pēpi-Pod® Program to decouple the interaction between shared sleeping and maternal smoking, and hence to decrease the risk of SUDI, however further analysis was needed to demonstrate any mortality benefit. The research did show that the Pēpi-Pod® Program is culturally appropriate and respectful of traditional infant care practices in Queensland. The Pēpi-Pod® provides families with a safe sleep space for their infant which can be used in a shared sleep setting.^(17, 18)

The following section outlines the history of the Pēpi-Pod® Program and its implementation within Queensland to date.

Shared sleeping is a common and valued infant care practice for many families.

Shared sleep in the context of maternal smoking and other known SUDI risk.

The Pēpi-Pod® Program

First Nations - innovations in infant care practices

To begin with, it is important to acknowledge that devices to carry and sleep infants have been part of Aboriginal and Torres Strait Islander culture for thousands of years. Baskets, sometimes woven from pandanus or palm leaf and most often used to carry food, were also used for sleeping infants. In some parts of Australia, including Queensland, carved wooden vessels known as Coolamon (also known as Lanturrji or Pitchi) were used for carrying infants and settling them to sleep.^(19, 20) Similarly the pōrakaraka, a woven flax basket, was used in New Zealand by Māori cultures to sleep and carry babies in pre-European times.^(20, 21)

New Zealand beginnings

The Pēpi-Pod® Program was developed in New Zealand in 2010 by Change for our Children. It followed the introduction of the Wahakura safe sleep basket into Māori communities in 2006.⁽²¹⁾ Wahakura means ‘holder of that which is precious’ and is a Māori innovation based on traditional baskets (pōrakaraka) which were hand woven from flax. Infants sharing a bed with caregivers is a valued Māori cultural practice, and the Wahakura allowed families to bring the infant into the parental bed within their own separate sleep space. Wahakura are also woven, for and by, Māori families with safe sleeping messages incorporated into family support.⁽²¹⁾

Whilst effective, the Wahakura are time intensive to produce and a more cost-effective option was needed to allow wider access to this preventive intervention. In collaboration with the Māori SIDS team led by Dr David Tipene-Leach, Stephanie Cowan, Director, Change for our Children New Zealand investigated more cost effective options during the period 2009-2010.

The Pēpi-Pod® sleep space began as a simple storage container decked out as an infant bed intending to support Wahakura. The 2011 Christchurch Earthquakes led to the distribution of 1000 Pēpi-Pod® sleep spaces as an emergency response supported by community action. This was quickly followed by requests from health services, especially in regions with high Māori birth rates, and enabled further development and evaluation of the program of agreements, accountability, systems and education in which the sleep space itself is embedded.

New Zealand’s Safe Sleep Program has been associated with recent reductions in New Zealand’s infant mortality and to the closing gap between Māori-non-Māori infant mortality, since program inception in 2011.⁽²²⁾ Sleep space programs are considered to be a major contributor to this, and have been incorporated into New Zealand’s national strategy to reduce the risk of SUDI.⁽²³⁾

The Pēpi-Pod® Program in Queensland

The research phase

The Pēpi-Pod® Program was introduced to Queensland in early 2011 by Professor Jeanine Young and her team through discussions with Aboriginal and Torres Strait Islander groups and communities as part of a safe sleep health promotion program. Young and Cowan formed a Australian-New Zealand collaboration and during 2011-2012 Young and Craigie (Indigenous Project Officer) consulted with key stakeholders (Aboriginal and Torres Strait Islander elders, Office of Fair Trading - Department of Product Safety, Kidsafe Queensland



The Coolamon was used for carrying infants and settling them to sleep. Model baby in a traditional coolamon, Photo with permission, Jeanine Young



Wahakura means ‘holder of that which is precious’ and is a Māori innovation based on traditional baskets hand woven from flax

*Health Navigator New Zealand
<https://www.healthnavigator.org.nz/healthy-living/c/co-sleeping/>*

New Zealand’s Pēpi-Pod® and Wahakura Programs are recognised as major contributors to recent reductions in New Zealand’s infant mortality.

former Commission for Children, Young People and Child Guardian (CCYPCG), Office of the State Coroner, Queensland Health, and Red Nose (formerly SIDS and Kids) to introduce the program to Queensland⁽²⁴⁾. Ethical permission was secured to pilot the Program with five families in Queensland in 2012.^(18, 25)

A larger study (target n=300 families) was implemented during 2013-2016.⁽²⁶⁾ The need to identify culturally appropriate support strategies to reduce infant deaths in the context of shared sleeping had been identified.⁽²⁷⁾ Queensland Aboriginal and Torres Strait Islander people identified this program as a priority for investigation. The University of the Sunshine Coast led research study identified the Pēpi-Pod[®] Program (portable sleep space embedded in safe sleep education, with a family commitment to share learnings about safe sleep within their family and social network) to be culturally appropriate and respectful of traditional infant care practices. It aligned with translational research pathways by moving safe sleep advice to safe sleep action through family engagement, working with local health services trusted by families, and building workforce and community capacity around practical implementation.^(17, 25, 26)



The Pēpi-Pod[®] sleep space
Health Navigator New Zealand <https://www.healthnavigator.org.nz/healthy-living/c/co-sleeping/>

The Pēpi-Pod[®] sleep space and Program

The trademarked Pēpi-Pod[®] Program has three core elements for effective distribution to families:

- a dedicated portable sleep space made from 100% virgin polypropylene that is supplied with a firm and fitting mattress, quality bedding and information resources
- personalised education about infant breathing and how to protect it, guided by a picture card and using a tube to demonstrate, that is delivered by a trained distributor
- role of communicator whereby families are encouraged to share what they have learned about infant breathing and safe sleep within their social networks

The Queensland Pēpi-Pod® Research Study targeted high-priority families, most of whom had two or more risk factors for SUDI identified by their health service provider.⁽²⁶⁾ The study was undertaken in a staggered sequential way to selected communities, mainly Indigenous, usually remotely located and with socio-economic disadvantage, through community organisations such as Aboriginal Medical Services, the Royal Flying Doctor Service, and Primary Health Networks with some Queensland Health maternal and child service involvement.

The study evaluation highlighted that parent and health carer responses have been positive, and the Program was associated with a reduction in the proportion of babies sharing a sleep surface in the context of known risk factors including smoke exposure, prematurity, low birth weight, parental substance and alcohol use, and multiple bed-sharers. Health professional feedback relating to implementation indicated that the Pēpi-Pod® Program was culturally appropriate, feasible, accessible, sustainable, and built local workforce capacity with integration into current service models.^(17, 26)

Data from the research study was recorded in the Queensland Pēpi-Pod® Program Research Database managed by the University of the Sunshine Coast with Young as Principal Investigator. The program was supported during the period 2013-2016 by competitive research grants (National Partnership Agreement on Indigenous Early Childhood Development 2013-2014, Perpetual Philanthropy) and nongovernment support (Red Nose, Rural Doctors Association of Queensland Foundation). Project sites grew with health service providers actively seeking participation in the Program (5 to 13 services during the research study which extended to approximately 27 sites/organisations by the end of the implementation phase); ethical and site specific approvals were obtained where required, in addition to memorandums of understanding with non-Queensland Health sites.⁽²⁶⁾

The post research phase

– ongoing Implementation in some Queensland locations

Following this research study (pilot 2012-2013; main study 2013-2016) together with effective lobbying by the research group and participating services during early 2017, an ‘implementation phase’ commenced in July 2017 with the Pēpi-Pod® Program being delivered to 600 families within Queensland areas identified with higher infant mortality. During the interim period 2016-2017, funding from the Rural Doctors Association of Queensland Foundation facilitated continuity for the program, and provided a further 100 families with the opportunity to participate during January-June 2017.

The extension program was funded by the former Department of Communities, Child Safety and Disability (DCCSD) (now Department of Children, Youth Justice and Multicultural Affairs), during the period July 2017-June 2018. The Program was provided to Aboriginal and Torres Strait Islander communities previously participating in the research component who wished to continue, with some new non-Aboriginal and Torres Strait Islander individuals and communities located within DCCSD priority areas. This post-research service implementation phase was less structured compared to the research project period, influenced by variable resourcing within participating health services. Data collection has been ongoing since 2017, however was revised to a mutually agreed minimum Australia-New Zealand dataset, consistent with the New Zealand data collection. Deidentified data is stored on the Pēpi-Pod® Program database managed by Change for our Children, with Australian reports for data entry generated on request.⁽²⁸⁾

Queensland researchers found that the Pēpi-Pod® Program was:

- culturally appropriate
- feasible
- accessible
- sustainable
- integrated into current service models.

Continued data collection

During the period 2018- September 2020 several Queensland-based health services participating in the original research program (2013-2016) and the ‘implementation’ component (July 2017-June 2018) have continued participation in the program where the service was able to source internal and/or external funding. During the period July 2018-September 2020, 289 de-identified records relating to the Queensland Program have been entered into the Pēpi-Pod® Program database however this is likely to reflect only a small proportion of Pēpi-Pods provided to families as part of the program (estimated to be approximately 900 based on purchase of Pēpi-Pod® from known services with continued participation), due to several services embedding the program into service delivery and only keeping their own records, and/or lack of funding to ensure data follow-up from participating services. Of the services participating in the implementation phase, 100 per cent of participants providing feedback stated that the Pēpi-Pod® Program should be continued in their service.⁽²⁸⁾

Current status of the Pēpi-Pod® Program

There is a growing evidence base for the introduction of culturally appropriate sleep spaces to assist families with identified risks in creating a safe sleep space for their baby. New Zealand based studies have demonstrated safety, infant physiological stability, and improved breastfeeding outcomes in addition to infant mortality reductions associated with Pēpi-Pod® and Wahakura Programs. These programs are now part of New Zealand’s national infant mortality reduction strategy.⁽²³⁾

Queensland-based studies have identified that the use of a Pēpi-Pod® reduced the prevalence of smoking and direct bed-sharing by 57 per cent (a major risk factor for SUDI)^(26, 28); while parent feedback identified the program was practical and culturally appropriate as it addressed family and cultural preference for infant care within shared sleep environments. Health professional feedback supported continuation of the program as a maternal and child health service for Aboriginal and Torres Strait Islander families, and for it to be expanded for families with social vulnerabilities, where similar risk factors are present which place infants at a higher risk for SUDI.^(17, 26, 28)

The Program to date has relied on a combination of competitive research funding and philanthropic support provided through nongovernmental agencies that promote the wellbeing and safety of infants and families, and in particular, support rural and remote families to achieve improved health outcomes. To achieve further reductions in infant mortality associated with SUDI, and in particular reduce the disparity between Indigenous and non-Indigenous infant mortality⁽⁸⁾, a systematic, state-wide approach to promoting safe sleep environments and supporting families with social vulnerabilities is required in Queensland. Programs to date have been designed to measure safety, cultural acceptability within a priority population, and feasibility and sustainability within contemporary health service delivery models.

The outcome of the Pēpi-Pod® Program on the primary outcome of interest - infant mortality - had not yet been measured in the Australian context.

All participants providing feedback wanted the Pēpi-Pod® Program to continue in their service.

The Queensland based studies identified that use of a Pēpi-Pod® reduced the prevalence of smoking and direct bed-sharing by 57%.

Spotlight on Apunipima - Baby One Program



“Baby One is a term used by Aboriginal women from Cape York when referring to their youngest child.”

Baby One Program

Apunipima Cape York Health Council’s Baby One Program (BOP) aims to strengthen the social and emotional well-being of the family, increase the cultural acceptance of health promotion/education programs, and provide tools to support health promotion within the clinical model of the Maternal and Child Health team. The Pēpi-Pod® Program was introduced to communities in 2013 as part of a Research study and incorporated in the Baby One Program. A total of over 900 families have participated in the Pēpi-Pod® Program so far. Parent and health carer responses have been positive, and the Program has been associated with a reduction in the proportion of babies’ bed-sharing in the context of smoke exposure and other known risk factors including prematurity, low birth weight, parental substance and alcohol use, and multiple bed-sharers.



Photo courtesy Johanna Hunt, Apunipima Cape York Health Council

The Pēpi-Pod® Program in Queensland

Evaluation of impact on infant mortality

Introduction

Background

Following the successful implementation of the Pēpi-Pod® Program in Queensland as a staged research intervention to certain communities, there has been considerable interest in further implementation.⁽²⁸⁾ Pilot projects based on the resources developed between Change for our Children and the Queensland Pēpi-Pod® Program have commenced in all state and territory jurisdictions. However the impact of the program on the primary outcome of infant mortality needs to be established.^(29, 30)

At the time of this analysis, there has not been a known death of an infant (aged up to six months), from this target population of infants with known risk factors for SUDI, during their participation in the Queensland Pēpi-Pod® Program. Whilst this is reassuring, there has not been a population study of this intervention in Queensland to examine whether participation in the Pēpi-Pod® Program is associated with a reduction in infant mortality. Given the high burden of mortality on specific population groups who experience higher rates of SUDI, there is urgency to undertake this evaluation.

A reduction in the all-cause Infant Mortality Rate (IMR) has been demonstrated in New Zealand, temporally in association with the use of targeted safe sleeping interventions including the use of portable sleep spaces, particularly amongst the Māori population.^(22, 31, 32)

Possible benefits, in addition to saving lives, include reducing the social and economic impact of infant death on the community. The impact of infant death on the immediate and extended family is considerable with significant long-term outcomes reported.⁽³³⁾ The economic effect is also considerable and measures such as “Quality-adjusted life years saved” (for an average life expectancy of 80 years) are appropriate.⁽³⁴⁾ The reduction in economic cost can be assessed against the cost of implementation of the Pēpi-Pod® Program.⁽²⁸⁾

Finally, understanding where the locations of high need exist, based on Infant Mortality Rate and risk factor profile, will inform an implementation plan that, if successfully implemented, will have the most impact.

Aims

This study uses a retrospective design to identify whether a reduction in all-cause postneonatal infant mortality up to six months of age can be demonstrated in relation to the introduction of the Pēpi-Pod® infant sleep space to various discrete communities in Queensland. The cost of implementation of the Program will be evaluated based on the expected number of participants in the Pēpi-Pod® Program required to reduce one infant death. Results will inform decisions to extend this practical intervention to promote infant survival for vulnerable families in Queensland and will be of relevance around Australia.

There have been no known deaths up to 6 months of age of any infants with known risk factors who were participants in the Pēpi-Pod® Program in Queensland.

Aim: to identify whether a reduction in all-cause postneonatal infant mortality (up to 6 months of age) can be demonstrated in relation to the introduction of the Pēpi-Pod® Program.

Methods

Participants and study population – the study postcode subgroups

Data on all Pēpi-Pod[®] Program participants enrolled up to March 2019 (“participants”) were included in this study, including those participants involved in the original research project (2013-2017), and those participating in ongoing implementation (2017–2019). De-identified data were provided by the Queensland Pēpi-Pod[®] Program researcher team. We used postcode of participant residence as a proxy descriptor of the communities they live in, as this was the geographic variable available (“participant postcodes”).

These “participant postcodes” were used to define the study populations for analysis. We assumed *a priori* that the impact on infant mortality at the population level for each postcode would be related to the proportion of participants in that postcode, given the design of the program included a commitment from each participant to share safe sleep learning with their wider family and social network. A review of the Pēpi-Pod[®] Program participant data revealed that of the 110 participant postcodes, different communities had very different levels of participation within their community, often related to health service delivery models or population eligible for participation. We determined that a stratified approach to the analysis of population mortality was needed to account for this heterogeneity of community participation: infant mortality analysis of every participant postcode population would not provide meaningful results for the many postcode populations with small participant numbers (most frequently related to health service delivery to target population eligible for participation) and a lack of statistical power, but combining all participant postcodes populations together would pool communities which were too dissimilar in terms of proportion of participants.

After review of the participant frequency per postcode, (whilst blinded to outcome) a pattern emerged of higher versus lower participant numbers per postcode. Additionally, a measure of the Aboriginal and Torres Strait Islander (Indigenous) infant participation was also used, based on numbers of Indigenous infant participants as a proportion of the Indigenous population per postcode, using data available from the Australian Census 2016 population data. Details of the ABS reference sources and population used in this study can be found in Appendix 1. Based on these research population characteristics, the postcodes of the Research phase participants fell into three groups described below, and the post-Research Implementation phase participants were grouped as a fourth subgroup.

Subgroup 1: Research project postcodes with ≥ 15 participants per postcode and where participants comprised ≥ 15 per cent or more of the Indigenous infant population for that postcode.

Subgroup 2: Research project postcodes with < 15 participants per postcode and where participants comprised ≥ 15 per cent or more of the Indigenous infant population for that postcode.

Subgroup 3: Research project postcodes with < 15 participants per postcode and participants comprised < 15 per cent of the Indigenous infant population for that postcode.

Subgroup 4: Ongoing implementation phase (post-research) postcodes, each with < 15 participants per postcode and participants comprised < 15 per cent of the Indigenous infant population for that postcode.

Subgroup 1 included postcodes with ≥ 15 participants and $\geq 15\%$ of the Indigenous infant population (research phase)

Subgroup 2 included postcodes with < 15 participants and $\geq 15\%$ of the Indigenous infant population (research phase)

Subgroup 3 included postcodes with < 15 participants and $< 15\%$ of the Indigenous infant population (research phase)

Subgroup 4 included postcodes with < 15 participants and $< 15\%$ of the Indigenous infant population (implementation phase)

Data variables

Participant variables

Individual participant data variables were provided (de-identified) from the original research data base (Queensland Pēpi-Pod[®] Program Research Database) and the Pēpi-Pod[®] Program research data base (described in Context) by the University of Sunshine Coast via a Collaborative Research Agreement. Data provided included:

- infant month and year of birth
- maternal age (categorised in five-year intervals)
- maternal Indigenous status (two categories, “Aboriginal and or Torres Strait Islander” or “not Indigenous”)
- infant Indigenous status (also two categories)
- infant sex (not available for participants in the ongoing implementation phase)
- infant birth order
- mother cigarette smoking during pregnancy status (yes/no)
- mother use of alcohol or illicit drugs (yes/no)
- infant birthweight (two categories <2500g and ≥2500g)
- infant gestation (two categories <37weeks and ≥37 weeks), (birthweight and gestation available as a single combined variable with two categories “either or both” or “neither” for participants in the ongoing implementation phase)
- infant outcome at 6 months (lived or died)
- postcode of residence
- Australian Remoteness Category allocated by postcode of residence, collapsed to four categories; Remote/Very Remote, Outer Regional, Inner Regional, Major Cities)⁽³⁵⁾
- Australian Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) which is one of the Australian Socio-Economic Indexes for Areas (SEIFA), which is a measure of socioeconomic status based on area of residence (Deciles are available for postcode of residence and were summarised to Quintiles for this study)⁽³⁶⁾
- Four characteristics which have reported association with SUDI (Sudden Unexpected Death in Infancy); maternal age less than 20 years, combined low birthweight/or preterm, SEIFA Quintile One (most disadvantaged), and maternal smoking during pregnancy) were summed to provide a summary “Pēpi-Pod[®] Program prioritisation factor score” out of a possible total of four.

Postcode denominator variables

For Subgroups 1, 2 and 3, de-identified individual linked infant and mother variables for all births in each postcode were provided for the years 2010-2018, by the Statistical Services Branch of Queensland Health (SSB QH), from two linked administrative data sources: the Perinatal Data Collection (PDC) and the Queensland Registry of Births, Deaths and Marriages (RBDM). The PDC includes data variables for all live births, and stillbirths of at least 20 weeks gestation and/or at least 400 grams in weight, born in Queensland.⁽³⁷⁾ The PDC data is collected by the birth attendant (midwife or physician) from a structured interview of the mother and the maternal hospital record. The Queensland RBDM dataset contains details of all deaths, including live born and stillborn infants. The SSB QH maintains these databases and their linkage.

Data for the project were obtained from Statistical Services Branch, Queensland Health and the University of the Sunshine Coast.

The individual level data for each postcode population (Subgroups 1-3) included the same variables as collected for the participants, where possible. Some variables not available for the postcode population were: month of infant birth, maternal use of alcohol or illicit drugs, and infant birth order (as these variables are not collected routinely as part of the PDC).

Infant deaths

Data for all infant deaths which occurred between the age 28 days and 183 days in each postcode (Subgroups 1-3) included: infant age at death, text cause of death from death certificate, ICD-10 (International Classification of Disease) code where available, whether reported to Coroner, and a linkage key to match the record with birth data.

The cause of death text variable was categorized prior to record linkage into one of three categories: perinatal cause (related to pregnancy and birth events), congenital and genetic cause (intrinsic to the infant); and acquired and ill-defined cause (acquired after birth including external, morbid, and “SUDI ICD-10 codes” (R95 Sudden Infant Death Syndrome, R99 “undetermined” deaths, and W75 “Accidental suffocation and strangulation in bed”). Report of the death to the Coroner was a requirement for the death to be identified as a SUDI. This category was used for a subset analysis of mortality.

Queensland State denominator variables

Queensland state population data were provided by SSB QH and did not include individual level variables. Calendar year live births and infant deaths between the ages 28 days and 183 days were provided for the following Queensland populations:

- whole of Queensland population
- Aboriginal and Torres Strait Islander population
- SEIFA Quintile one population.

Ten years of data for the period 2010-2019 were requested; only nine years of data (2010 to 2018) were able to be supplied as data for the 2019 year had not been finalised.

Outcome

The primary outcome was all-cause mortality rate, defined in this report as infants dying between the ages of 28 days and 183 days (six months) per 1,000 live births, called “Study IMR”. This mortality age range was chosen to encompass the expected duration of an infant sleeping in a Pēpi-Pod® (most infants outgrow the Pēpi-Pod® sleep space by 5-6 months or when they begin to roll) and to exclude the neonatal period where other causes of infant death are much higher than sleep related deaths.

Study IMR was examined using three comparison strategies:

1. retrospective Subgroup mortality comparison for each Subgroup population before and after the Pēpi-Pod® Program
2. contemporaneous Subgroup mortality comparison between each Subgroup
3. a retrospective time series mortality comparison of the whole of Queensland state population for the years before and after the Pēpi-Pod® Program.

The primary outcome used was all-cause mortality rate for infants dying between the ages of 28 days and 183 days per 1,000 live births.

Comparison 1: Retrospective Subgroup mortality comparisons

Pre- and post- intervention years were defined for each postcode. When participant postcode data (deaths and births) were combined in a research subgroup for analysis, the individual postcode pre-intervention data were summed for analysis, as were the post-intervention data, to calculate Subgroup totals. Details of the postcode time considerations can be found in Appendix 1.

Comparison 2: Contemporaneous subgroup comparisons

Study IMR of Subgroup 1 was compared with Subgroup 2 and with Subgroup 3. This methodology leveraged the assumed similarity in higher SUDI risk of all original research communities, regardless of the uptake of the Pēpi-Pod® Program in that community / postcode and compared Subgroup 1 with a higher number of participants, with Subgroups 2 and 3 which had a lower number of participants. Comparisons between pre-and post-intervention years were made for each subgroup.

Comparison 3: Retrospective time series mortality comparison for the Queensland state population

Study IMR was examined for the whole of Queensland state population over the years 2010 to 2018, and for the low SEIFA and Indigenous populations.

Secondary Outcome

Need and cost of the Pēpi-Pod® Program

The secondary outcome of this study was to establish the need and cost of the Pēpi-Pod® program. The economic impact of future priority population-based implementation of the Pēpi-Pod® Program in Queensland was derived according to the principle of proportionate universalism espoused by the Public Health Association of Australia, to target the population most at risk.⁽³⁸⁾

The size of the population most vulnerable in Queensland was estimated referencing the New Zealand Safe Sleep Program infant vulnerability factors available for Queensland^(26, 28, 39); which were smoking in pregnancy, young maternal age (<25 years, preterm birth or low birth weight (<37 weeks or <2,500 grams) and low income, for which the equivalent variable available in Queensland is residence in a SEIFA IRSAD Quintile One area. Information on some of these characteristics was provided with the data for this study and supplemented by summary data from the recent Queensland Maternity and Perinatal Quality Council report.⁽⁴⁰⁾

The following factors were estimated:

- the number of potential lives saved was estimated from the mortality analysis
- the cost of implementation of the Pēpi-Pod® Program per participant was extrapolated from the Pēpi-Pod® Program Research phase, and from the New Zealand “Change for our Children Ltd” Safe Sleep program.⁽⁴¹⁾
- the cost offset by the expected reduction in mortality was given a monetary value by referencing the Australian Government best practice guidance on the Value of a Statistical Life.⁽⁴²⁾

The project compared Study IMR :

- within postcode subgroups (pre- and post-)
- between postcode subgroups
- whole of Queensland over the years of the intervention.

Analysis

Analyses were performed using the statistics program SAS[®] version 9.4 (SAS Institute Inc., Cary, NC, USA), and the Open Source Epidemiologic Statistics for Public Health Program (http://www.openepi.com/Menu/OE_Menu.htm). The Study IMRs were compared using Rate Ratios with 95 per cent confidence intervals and associated p values.

Ethics and research governance

This research was approved by the Health Research Ethics Committee (HREC) of the Children's Health Queensland Hospital and Health Service (LNR/19/QCHC/49899) and the University of the Sunshine Coast (A191270). Each participant family had consented for their data to be used in a de-identified manner for further research (ie. this current research project). The de-identified data were provided from USC to the QPQC following an executed Research Collaborative Agreement.



Results

Participant and population characteristics

There were 671 participants in the research and post-research implementation phases of the Pēpi-Pod® Program up to March 2019, in 110 postcodes in Queensland (Table 1). The number of postcodes included in research subgroup 1 was small, however comprises the largest number of research phase participants. Research subgroups 2 and 3 each included a larger number of postcodes with fewer research participants which reflects the grouping criteria based on a smaller percentage of participants per postcode population. The post-implementation Subgroup 4 reflected the less structured recruitment of participants influenced by variable funding and resourcing and by the local implementation focus within health services.

There were 671 participants from 110 postcodes.

Table 1. Summary of subgroups and number of participants and postcodes

		Participants N (%)	As % of Indigenous infants in postcodes	As % of all infants in postcodes	Postcodes (number)
Research phase	Subgroup 1	265 (39.4)	23.8	10.8	8
	Subgroup 2	43 (6.4)	17.9	6.8	11
	Subgroup 3	91 (13.6)	4.6	0.5	34
Implementation	Subgroup 4	272 (40.5)	n/a *	n/a*	83**
Total		671			110

* Postcode total births and Indigenous births for Subgroup 4 were not provided.

** Some 'implementation phase' participants lived in postcodes which were also part of the original research phase

Subgroup research phase and implementation participants had higher rates of young maternal age, maternal smoking, remote residence, low birthweight and preterm birth and Aboriginal and Torres Strait Islander identification, than the Subgroup postcode populations. Subgroup 4 did not have data provided for all of the postcode populations; the Queensland Indigenous and Queensland total populations profiles are therefore provided for comparison (Figures 4, 5, 6, 7).

Subgroup 1

265 participants / 8 postcodes



Mothers age
<20 years
15.8%

Postcode population¹ 10%

Statewide²⁻⁵ 3.9%



Smoked during
pregnancy
42.6%

Postcode population¹ 32.8%

Statewide²⁻⁵ 10%



Gestation
<37 weeks
15.5%

Postcode population¹ 11.5%

Statewide²⁻⁵ 9.1%



Birth weight
<2500g
12.8%

Postcode population¹ 10.3%

Statewide²⁻⁵ 8.2%



SEIFA
Quintile 1
74.3%

Postcode population¹ 63.8%

Statewide²⁻⁵ 21%



ARIA Remote/
Very Remote
94.3%

Postcode population¹ 51.3%

Statewide²⁻⁵ 3.3%

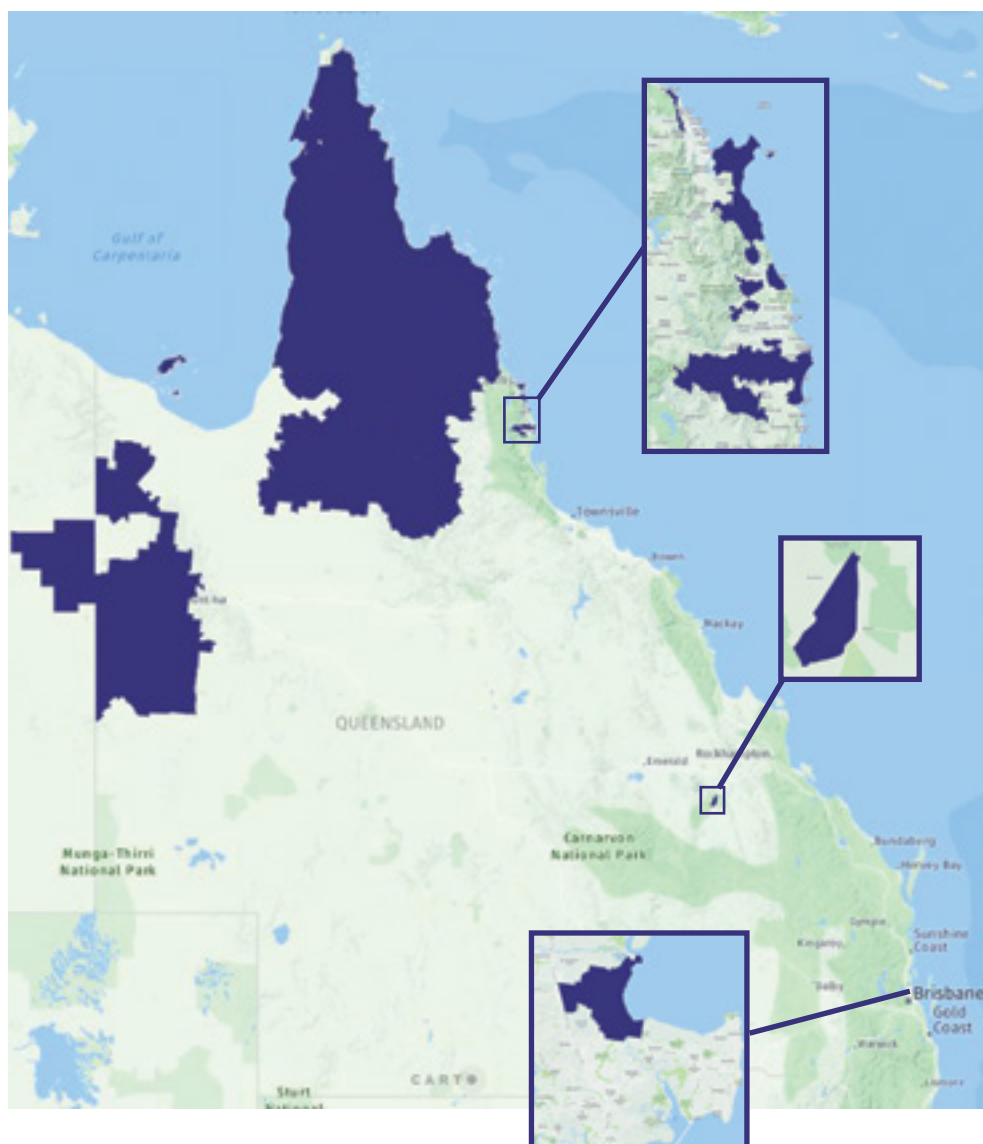


Indigenous
infants
90.6%

Postcode population¹ 45.6%

Statewide²⁻⁵ 6.5%

Figure 4. Participants vs Populations for Subgroup 1



Subgroup 2

43 participants / 8 postcodes



Mothers age
<20 years
16.3%

Postcode population¹ 3.6%
Statewide²⁻⁵ 3.9%



Smoked during
pregnancy
48.8%

Postcode population¹ 12.5%
Statewide²⁻⁵ 10%



Gestation
<37 weeks
20.9%

Postcode population¹ 9.3%
Statewide²⁻⁵ 9.1%



Birth weight
<2500g
23.3%

Postcode population¹ 7.7%
Statewide²⁻⁵ 8.2%



SEIFA
Quintile 1
16.3%

Postcode population¹ 21.4%
Statewide²⁻⁵ 21%



ARIA Remote/
Very Remote
2.3%

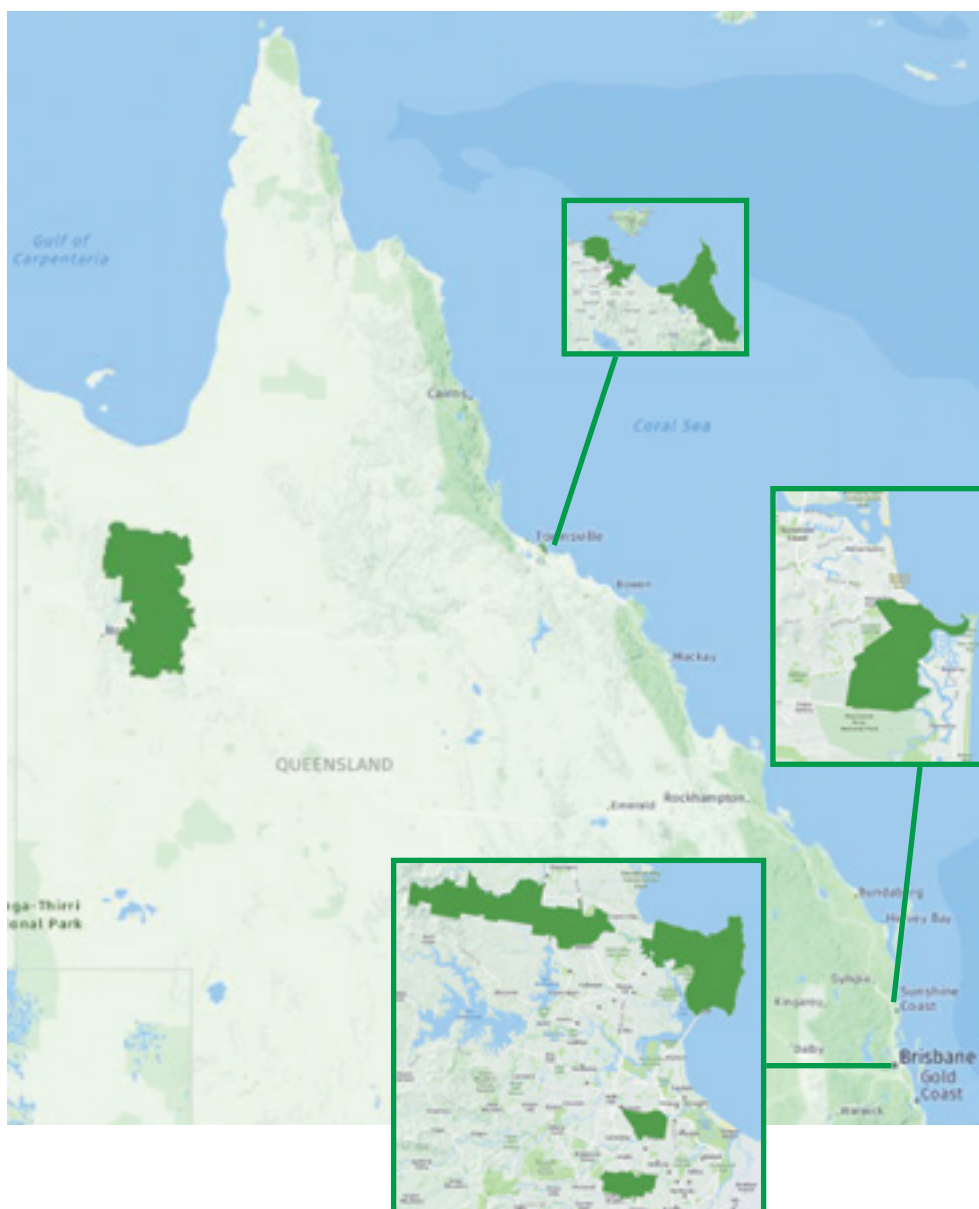
Postcode population¹ 2%
Statewide²⁻⁵ 3.3%



Indigenous
infants
88.4%

Postcode population¹ 8.1%
Statewide²⁻⁵ 6.5%

Figure 5. Participants vs Populations for Subgroup 2



Subgroup 3

91 participants / 34 postcodes



Mothers age <20 years
12.1%

Postcode population¹ 5%
Statewide²⁻⁵ 3.9%



Smoked during pregnancy
50.5%

Postcode population¹ 14.8%
Statewide²⁻⁵ 10%



Gestation <37 weeks
8.8%

Postcode population¹ 9%
Statewide²⁻⁵ 9.1%



Birth weight <2500g
9.9%

Postcode population¹ 6.9%
Statewide²⁻⁵ 8.2%



SEIFA Quintile 1
37.4%

Postcode population¹ 29.4%
Statewide²⁻⁵ 21%



**ARIA Remote/
Very Remote**
19.8%

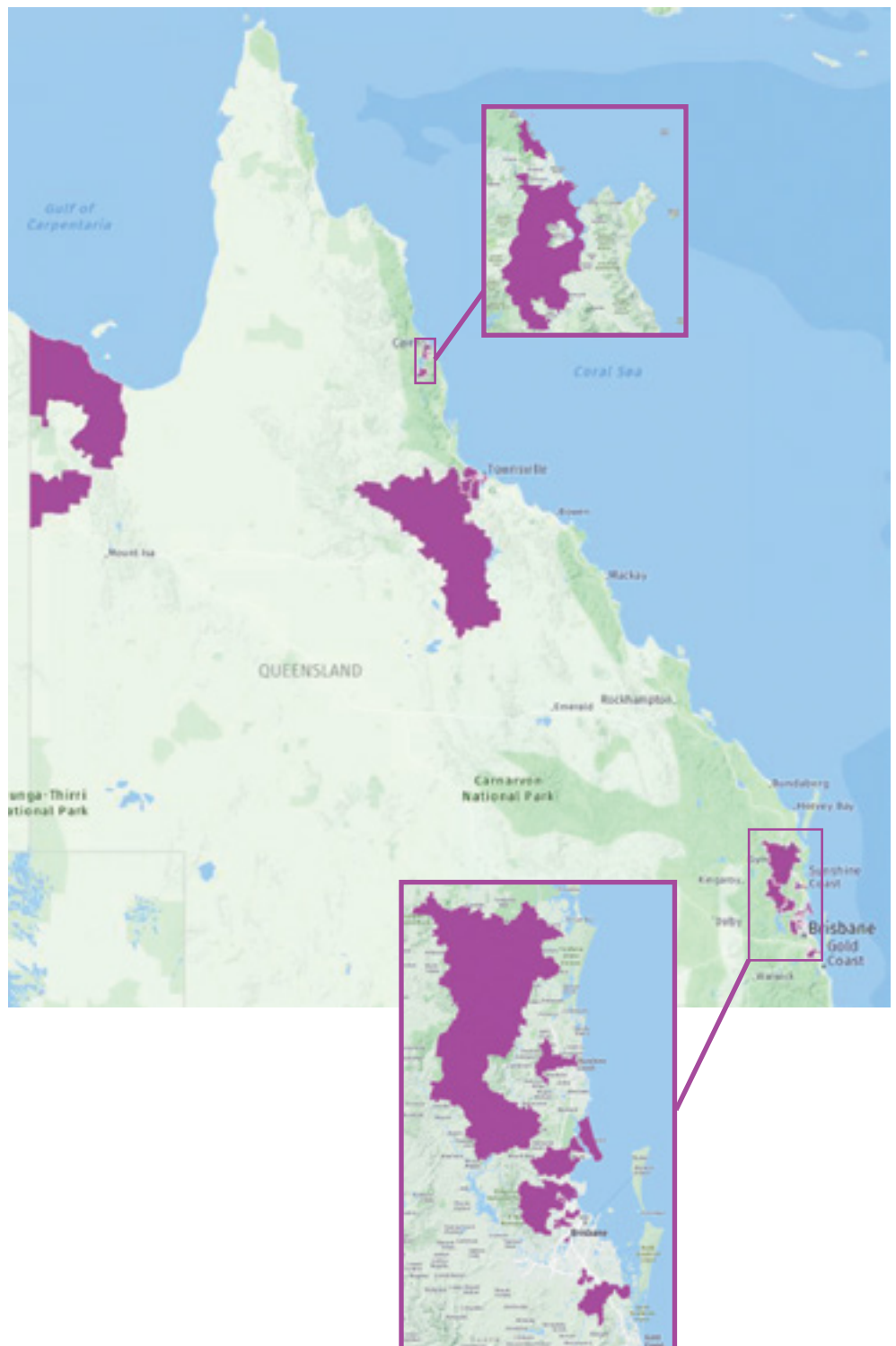
Postcode population¹ 0.4%
Statewide²⁻⁵ 3.3%



Indigenous infants
96.7%

Postcode population¹ 10.2%
Statewide²⁻⁵ 6.5%

Figure 6. Participants vs Populations for Subgroup 3



Subgroup 4

272 participants / 83 postcodes



Mothers age
<20 years
19.9%

Statewide²⁻⁵ 3.9%



Smoked during
pregnancy
47.1%

Statewide²⁻⁵ 10%



Gestation
<37 weeks
18%

Statewide²⁻⁵ 9.1%



Birth weight
<2500g
18%

Statewide²⁻⁵ 8.2%



SEIFA
Quintile 1
44.9%

Statewide²⁻⁵ 21%



ARIA Remote/
Very Remote
30.9%

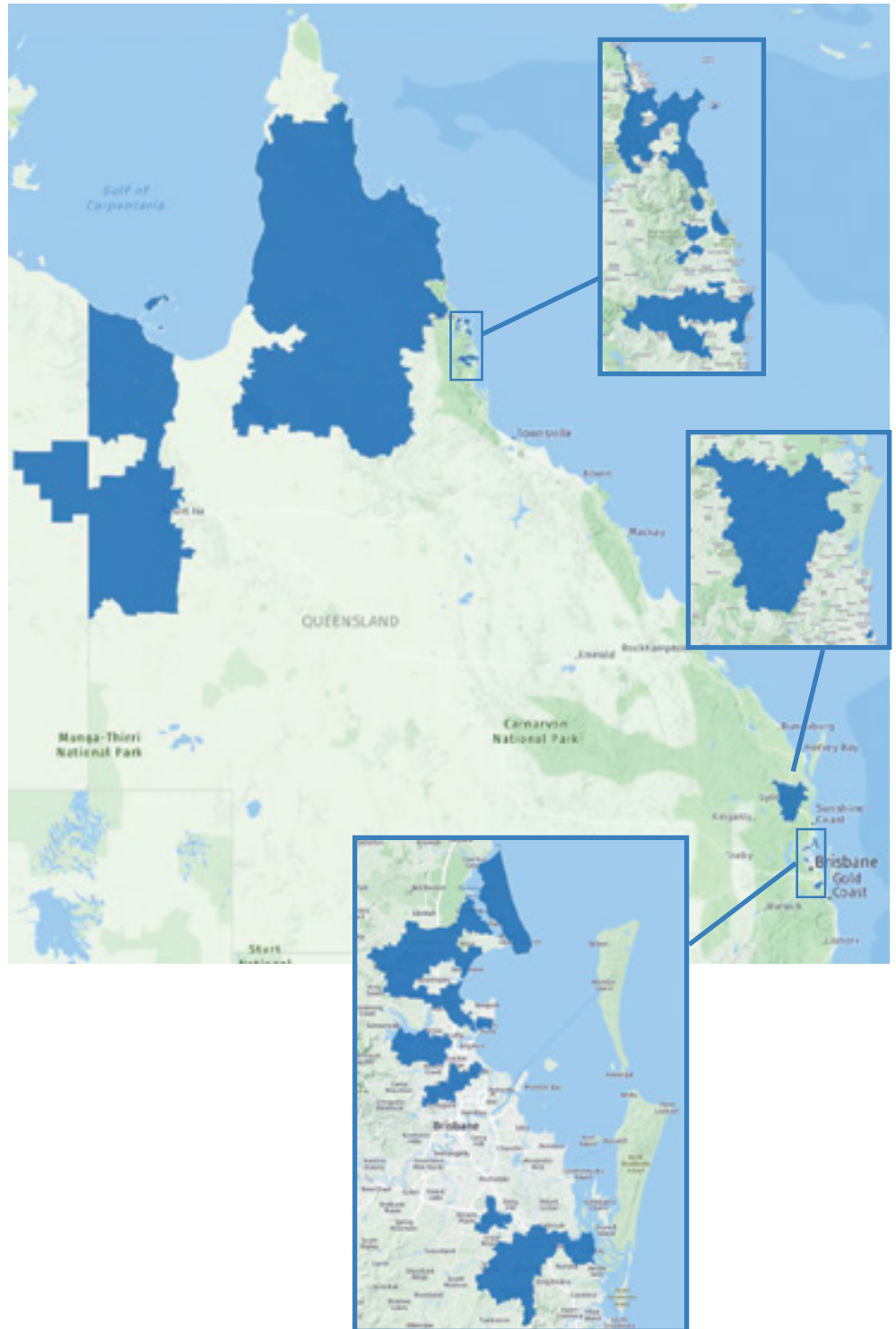
Statewide²⁻⁵ 3.3%



Indigenous
infants
75%

Statewide²⁻⁵ 6.5%

Figure 7. Participants vs Queensland for Subgroup 4



Subgroup characteristics are summarised and compared across subgroups in Figures 8 and 9 with details available in Tables 6 to 9 in Appendix 2, Results: Characteristics of Study Population subgroups. Two or more Pēpi-Pod® Prioritisation factors (maternal age less than 20 years, low birthweight/ preterm, SEIFA Quintile One, maternal smoking during pregnancy) were present in 60.0 per cent of Subgroup 1 participants and more than a third of all infants in the postcode population for this subgroup.

Fewer Subgroup 2 (34.9 per cent) and Subgroup 3 (41.8 per cent) participants had two or more Pēpi-Pod® Prioritisation factors (Chi-square 16.82, $p < 0.001$). Subgroups also differed somewhat in area of residence socio-economic and remoteness characteristics.

- Subgroup 1**
higher % of:
- participants
 - Indigenous infants
 - remote
 - disadvantage
 - young mothers
 - smoking during pregnancy

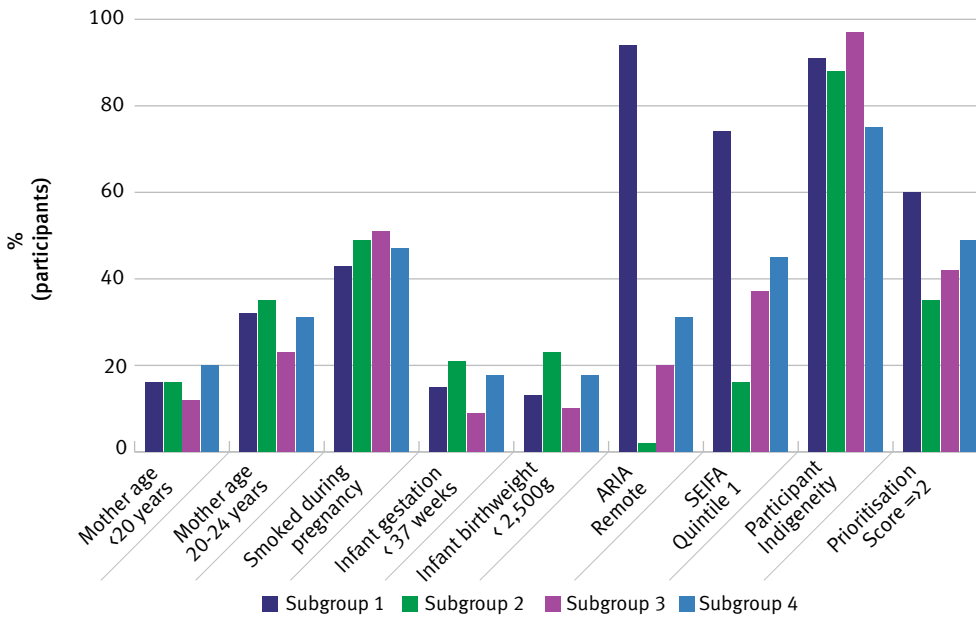


Figure 8. Comparing Participants of each Subgroup (total n=671)

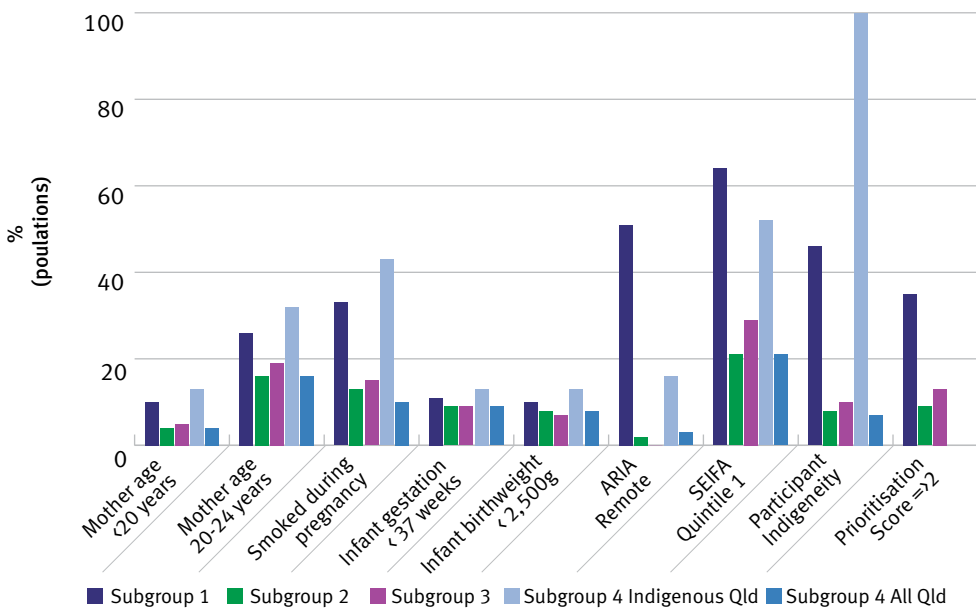


Figure 9. Comparing Subgroup Populations with Queensland total and Indigenous populations (total n=671)

Mortality Comparisons, Subgroups 1, 2 and 3 Populations before and after the intervention

Subgroups 1, 2, and 3 postcode populations had similar patterns of cause of death. The ill-defined subcategory accounted for approximately half of all deaths in each subgroup population with no significant differences between groups (Chi-square 6.65, $p=0.1554$) (Table 2).

Table 2. Pattern of cause of death of each subgroup

Postcode population deaths N (%)	Perinatal cause of death	Congenital cause of death	Acquired Cause of death	*Subcategory "SUDI"
Subgroup 1	4 (22)	4 (22)	10 (56)	9 (50)*
Subgroup 2	0	7 (47)	8 (53)	7 (47)*
Subgroup 3	25 (23)	24 (22)	58 (54)	54 (50)*

The three categories of Perinatal, Congenital and Acquired Causes of death account for 100% of deaths.

*"SUDI" is a subcategory of Acquired Cause, displayed in italics.

Acquired causes were the most common category of death in each subgroup.

The Study IMR for Subgroup 1 fell after the Pēpi-Pod® Program intervention to 25 per cent of the pre-intervention rate, but did not reach statistical significance due to the small numbers of deaths (Table 3, Figure 10). The Study IMR for Subgroup 2 did not significantly change post-intervention and there was a modest fall in Study IMR for Subgroup 3 post-intervention which did not reach statistical significance. Pre-intervention, the Study IMR for Subgroup 1 was significantly higher and more than double that of Subgroups 2 and 3. Post-intervention, the Study IMR of Subgroup 1 was lower than Subgroups 2 (but not statistically significantly lower).

The pattern was similar for the subset of ill-defined deaths (the majority of which are SUDI), with Subgroups 1 and 3 Study IMR falling post intervention. The numbers were smaller and did not reach statistical significance. As for all deaths, the Study IMR for ill-defined deaths for Subgroup 1 was significantly higher and more than double that of Subgroups 2 and 3. Post-intervention, the Study IMR of Subgroup 1 was lower than Subgroups 2 and 3 (Table 10, Appendix 2).

Table 3. Study IMR comparisons between subgroup communities deaths between age 28-183 days, per 1,000 live births

	Population Pre-intervention	Population Post-intervention	Rate Ratio Pre vs Post (95% CI)
Subgroup 1: N deaths / births	15 / 6,522	2 / 3,528	
Study MR (95% CI)	2.30 (1.36, 3.83)	0.57 (0.01, 2.22)	0.25 (0.06, 1.08)
p value			p =0.08
Subgroup 2: N deaths / births	9 / 9,630	7 / 6,491	
Study MR (95% CI)	0.93 (0.46, 1.81)	1.08 (0.47, 2.27)	1.15 (0.43, 3.10)
p value			p =0.98
Subgroup 3: N deaths / births	57 / 54,825	35 / 44,061	
Study MR (95% CI)	1.04 (0.80, 1.35)	0.79 (0.57, 1.11)	0.76 (0.50, 1.16)
p value			p =0.21
Subgroup 1 vs Subgroup 2 Rate Ratio (95% CI)	2.46 (1.08, 5.61)	0.53 (0.11, 2.53)	
	p = 0.03	p = 0.64	
Subgroup 1 vs Subgroup 3 Rate Ratio (95% CI)	2.21 (1.25, 3.90)	0.71 (0.17, 2.97)	
	p =0.005	p =0.88	

Study IMR fell in Subgroups 1 and 3 after the Pēpi-Pod® intervention. Small study numbers meant that statistical significance was not reached.

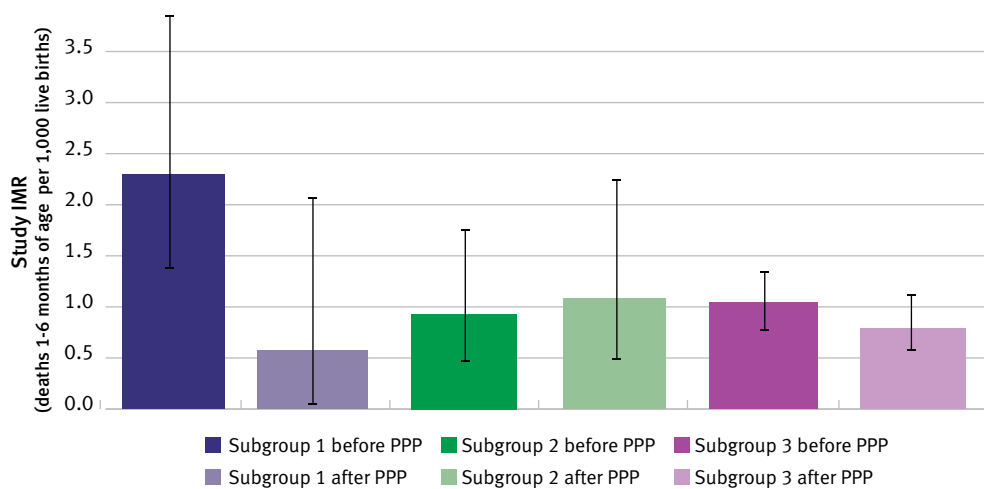


Figure 10. Comparison Study Mortality Rate Research Subgroups

Mortality comparisons for the whole of Queensland infant population over this time period

Over the 9 years 2010-2018, the Study IMR of the Queensland population has changed with a steady fall after 2013 (Figure 8). Linear regression analysis shows this is a significant decrease of 0.048/1,000 population per year ($p=0.029$). The fall was evident for non-Indigenous infant Study IMR, a decrease of 0.038/1,000 population per year ($p=0.048$). The fall was more pronounced for Indigenous infants (decrease 0.215/1,000 births per year ($p=0.073$), but due to the smaller sample size did not reach statistical significance. The fall was also evident for those infants who lived in SEIFA Quintile 1 areas and was more apparent from 2014 onwards (Figures 11, 12, 13).

Between 2010 and 2018 the study IMR of the Queensland population has significantly decreased, but the mortality disadvantage persists for Indigenous infants.

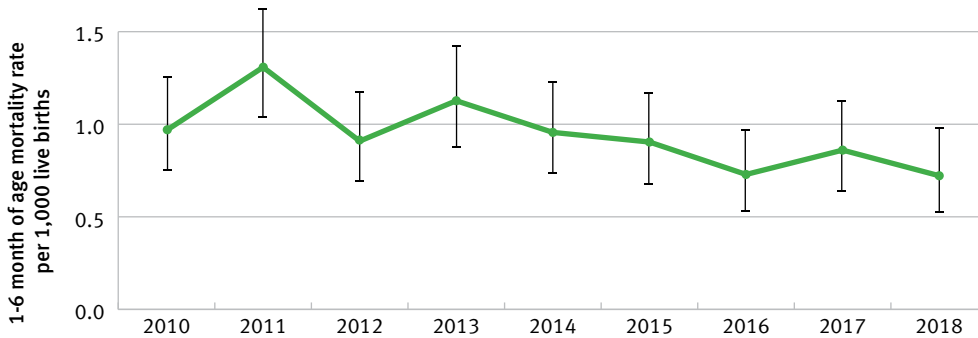


Figure 11. Calendar Year Study IMR, All Queensland Population

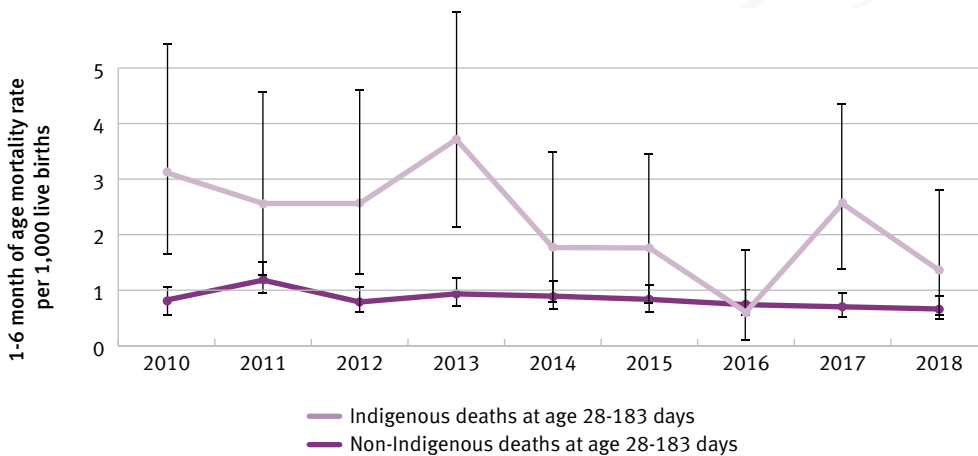


Figure 12. Calendar Year Study IMR, Queensland Population, comparing Indigenous and non-Indigenous infant populations

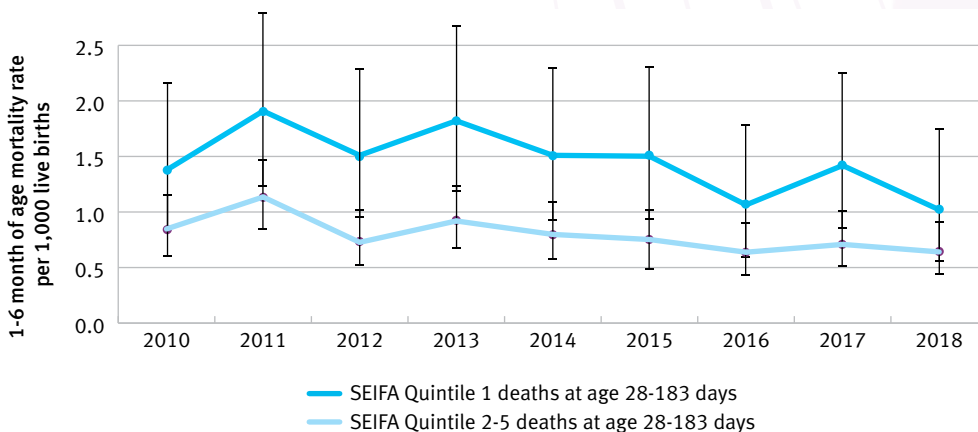


Figure 13. Calendar Year Study IMR, Queensland Population, SEIFA Quintile comparison

Queensland population Study IMR was further analysed by comparing the time periods before and after the Pēpi-Pod® Program intervention. The year 2014 was determined to be the most appropriate year to separate the pre- and post-intervention time periods, given the staged implementation in the communities starting in 2013. Study IMR post-implementation (2014-2018) was significantly lower than pre-implementation IMR (2010-2013) for the whole Queensland population (Rate Ratio (RR) 0.78, 95% Confidence Interval (CI) 0.65, 0.92), and in both the Aboriginal and Torres Strait Islander population (RR 0.53, CI 0.35, 0.81) and non-Indigenous population (RR 0.82, CI 0.68, 0.99). There was also a fall in Study IMR for the population of infants who live in areas of the most severe socioeconomic disadvantage (SEIFA Quintile 1, RR 0.85, CI 0.63, 1.14), but this did not reach statistical significance (Table 4).

The Aboriginal and Torres Strait Islander population Study IMR fell by 46 per cent. The mortality gap between Indigenous and non-Indigenous infants, fell post-implementation from 3.2 times the rate to 2.1 times the rate; however a significant gap between Indigenous and non-Indigenous Study IMR remained (Figure 14). If Queensland had the same Study IMR in 2014-2018, as it had in 2013-2014, 328 infant deaths would have been expected instead of the 254 which occurred, a saving of 74 infant lives over 5 years, or 15 fewer deaths per year.

Study IMR post implementation (2014-2018) was significantly lower than pre-implementation IMR (2010-2013) for the whole Queensland population and in both the Aboriginal and Torres Strait Islander population and non-Indigenous population.

Table 4. Queensland population Study IMR comparing two phases before and after the Pēpi-Pod® Program

	Population Pre-intervention	Population Post-intervention	Rate Ratio Pre vs Post (95% CI)
All of Qld: N deaths / births	266 / 247,051	254 / 304,202	
Study IMR (95% CI)	1.08 (0.95, 1.21)	0.84 (0.74, 0.94)	0.78 (0.65, 0.92)
p value			p=0.004
Indigenous: N deaths / births	50 / 16,628	39 / 24,254	
Study IMR (95% CI)	3.01 (2.27, 3.97)	1.61 (1.17, 2.20)	0.53 (0.35, 0.81)
p value			p=0.003
Non-Indigenous: N death/birth	216 / 230,423	215 / 279,948	
Study IMR (95% CI)	0.94 (0.82, 1.07)	0.77 (0.67, 0.88)	0.82 (0.68, 0.99)
p value			p=0.038
SEIFA Q1: N deaths / births	93 / 60,402	86 / 65,799	
Study IMR (95% CI)	1.54 (1.26, 1.89)	1.31 (1.06, 1.62)	0.85 (0.63, 1.14)
p value			p=0.27

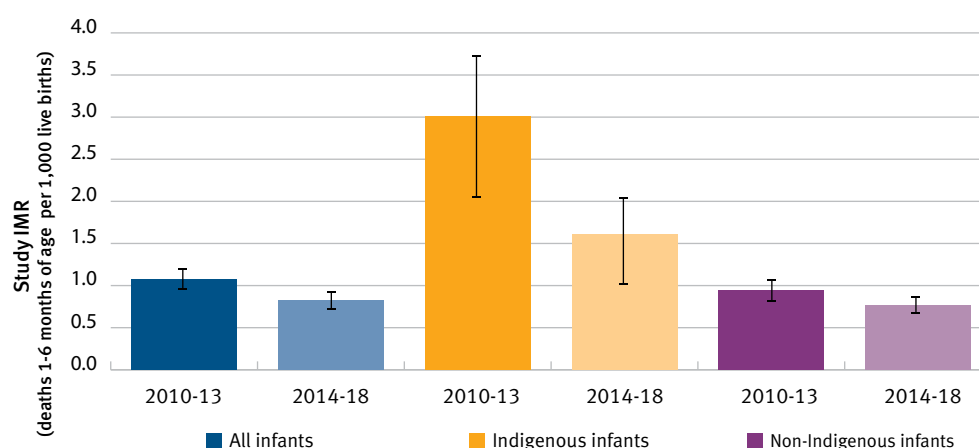


Figure 14. Queensland population Study IMR comparing two phases before and after the Pēpi-Pod® Program

The Queensland population Study IMR was also analysed over three time periods, 2010-2012 pre-Pēpi-Pod® Program intervention, 2013-2016 research project years (the last infant participant was enrolled in June 2017), and 2017-2018 post- implementation phase.

A reduction in Study IMR in the whole population comparing pre- with during- the research intervention was identified. The reductions did not reach statistical significance. Study IMR continued to fall in the whole and non-Indigenous populations comparing post- with during- the research intervention, again not reaching significance. In contrast there was no further reduction in Aboriginal and Torres Strait Islander infant population Study IMR comparing post- with during- the research intervention. The mortality gap between Indigenous and non-Indigenous infants narrowed somewhat during the research phase but widened again in the post implementation phase (Table 9, Figure 15).

The mortality gap between Indigenous and non-Indigenous infants narrowed somewhat during the research phase but widened again in the post implementation phase.

Table 5. Queensland population Study IMR comparing three phases: before the Pēpi-Pod® Program, during the research phase, and the after implementation phase.

	Pre-intervention 2010-2012	During research 2013-2016	Post implementation 2017-2018
All of Queensland: N deaths / births Study MR (95% CI)	196 / 194,912 1.06 (0.92, 1.22)	230 / 247,403 0.93 (0.82, 1.01)	94 / 118,838 0.79 (0.64, 0.96)
Rate Ratio (95% CI) p value	During: Pre 0.88 (0.73, 1.06) p=0.18	Post: During 0.85 (0.67, 1.08) p=0.19	
Indigenous QLD: N deaths/births Study MR (95% CI)	34 / 12,320 2.76 (1.94, 3.81)	35 / 18,315 1.91 (1.35, 2.63)	20 / 10,247 1.95 (1.23, 2.96)
Rate Ratio (95% CI) p value	During: Pre 0.69 (0.43, 1.11) p=0.12	Post: During 1.02 (0.59, 1.77) p=0.94	
Non-Indigenous Queensland: N deaths/births Study MR (95% CI)	162 / 172,592 0.94 (0.80, 1.09)	195 / 229,178 0.850 (0.74, 0.98)	74 / 108,601 0.68 (0.54, 0.85)
Rate Ratio (95% CI) p value	During: Pre 0.91 (0.74, 1.12) p=0.36	Post: During 0.80 (0.61, 1.05) p=0.10	
Indigenous vs Non-indigenous Rate Ratio (95% CI) p value	2.94 (2.03, 4.25) p <0.001	2.25 (1.57, 3.22) p <0.001	2.86 (1.75, 4.69) p <0.001

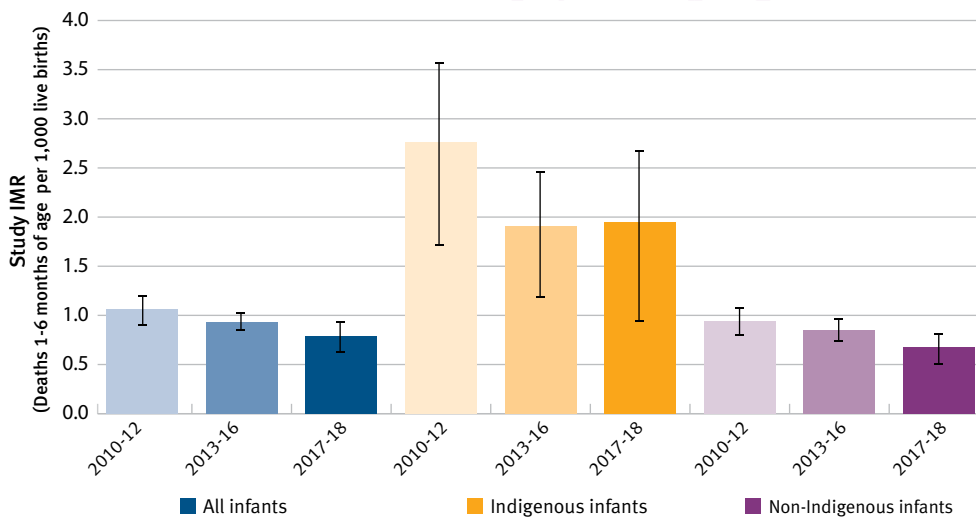


Figure 15. Queensland population Study IMR comparing three phases: before the Pēpi-Pod® Program, during the research phase, and the after implementation phase

Economic evaluation of the implementation of the Pēpi-Pod® Program to all priority mother-infant dyads in Queensland

This study reported on the mortality outcome associated with 671 participants enrolled over 6 years, an average of 100 participants per year which is a very small proportion of the potential priority population. Specific data to accurately estimate the size of the priority population for Queensland were not obtained as part of the data provided for this study, but some published data are available. Details are provided in Table 11, Appendix 2.

Given the importance of maternal smoking, a conservative estimate of the annual population of mother-infant dyads who had the two risk factors of young maternal age (<20 years) and smoking in pregnancy, is 3,397, approximately 5.7 percent of Queensland's annual births using the 2017 data in Table 11. This number of 3,400 was used as one estimate of the cost of a statewide priority population Pēpi-Pod® Program. Another estimate of the priority population could be to include all Indigenous infants, and the priority group of non-Indigenous infants with the two risk factors of young maternal age (<20 years) and smoking. The estimate for 2017 was 7,229 infants.

The cost of the Pēpi-Pod® Program per participant was estimated at AUD\$170 per device. The health promotion and support aspects of the program are integral, but flexible delivery within existing health service models is possible. Essential aspects include antenatal (preferably) and postnatal contact for family education, and a follow-up session at 6-8 weeks. This can be delivered by any health care worker who has engaged with the family and who has done the Pēpi-Pod® Program competency training. Approximately 5 hours contact time has been estimated for the purpose of the evaluation, equating to a cost of approximately AUD \$300 per participant. The total cost of the program for each participant is \$410.

Multiplied by the number of participants, this provides an estimate of annual cost in order to achieve an annual mortality reduction estimated as 15 fewer deaths (as estimated by the limited nature of the intervention in selected Queensland services, described in this study).

Using the Australian Government Value of a Statistical Life (AUD \$4.656 million per life, adjusted to this report year 2020); \$69.84 million per annum is the financial value our society places on saving 15 infant lives per year, which is the estimate of lives saved by the intervention. This compares with an annual cost of a Pēpi-Pod® Program of 3,400 participants costing an estimated \$1.394 million (3,400 infants multiplied by \$410 per infant), or \$2.9 million of the larger estimate of approximately 7,200 at risk infants, approximately 12% of the birthing population.

Almost \$70 million per annum is the financial value our society places on saving 15 infant lives per year. This compares with an estimated \$1.5 million to \$3 million annual cost if the Pēpi-Pod® Program were delivered to targeted families in Queensland.

Discussion

Mortality reduction in Subgroup 1

There was a 75 per cent reduction in the Study infant mortality rate (age 28 days to six months) in the population of the Subgroup 1 postcodes, after the Pēpi-Pod® Program research intervention. The reduction was not statistically significant at the 5 per cent level ($p=0.08$) due to small numbers. Whilst it is possible that this fall occurred due to other factors, we hypothesise that the Pēpi-Pod® Program is responsible for this notable reduction in mortality given that the Program and the intervention specifically targeted safer infant sleeping. “Ill-defined deaths” including SIDS deaths from unknown cause are strongly associated with unsafe sleeping environments and practices, and comprise a large proportion of infant deaths in this age group. The reduction in mortality was also seen for the subset of “Ill defined” deaths of which SUDI are the majority and the pattern supports our hypothesis that the intervention was the reason the mortality fell.

Subgroup 1 was defined by its high level of community participation (24 per cent of Indigenous infants, 11 per cent of all infants). The postcode population characteristics were associated with a high risk of SUDI, and this was reflected in the significantly higher Study IMR for Subgroup 1 compared with Subgroups 2 or 3, before the intervention. There was no other systemic, targeted safe sleep intervention in the Subgroup 1 population to have influenced mortality in this age group of infants during this time, no changes in safe sleeping guidelines or their implementation; nor child safety programs. One participant service serving remote Indigenous communities in the Cape York region which contributed to Subgroup 1, developed and implemented a child health support program based on the “First 1000 days strategy” which incorporated the Pēpi-Pod® Program and safe sleep education as one of its key strategies to improve maternal and child health.⁽⁴³⁾ The majority of communities in the Subgroup 1 postcodes were remote and small; often the whole community was involved in the intervention with considerable uptake by the priority population, and there was usually a single or collaborative health service provider of the Pēpi-Pod® Program. The original research team noted that there was considerable consistency in messaging and program delivery; these factors may be important contributors to the outcome.

Outcomes for Subgroups 2 and 3

The pattern of mortality change was different in Subgroups 2 and 3. All the subgroups were artificial constructs created for the study analysis – an attempt to group communities of similar characteristics (which were identified by postcode) to manage the issue of heterogeneity of community participation in the research and implementation phases. Both Subgroups 2 and 3 had high rates of young and smoking mothers, and a high proportion of Indigenous participation. Some characteristics of Subgroups 2 and 3 differed from Subgroup 1, and differed from each other, having smaller participant numbers, a smaller proportion of community participation, different profiles of socioeconomic vulnerability and remoteness, and lower rates of SUDI risk factors in their communities / postcodes. Subgroup 2 had more participant infants of low birth weight or preterm gestation, and fewer residing in low socioeconomic or remote areas.

There was a 75% reduction in Study IMR in Subgroup 1 after the Pēpi-Pod Program Research intervention. We hypothesise that the Pēpi-Pod® Program is responsible for this reduction in mortality.

Although Study IMR also decreased in Subgroups 2 and 3, the pattern of mortality change was different.

The lack of a demonstrated significant mortality benefit may have been an artefact of the construct of the Subgroups 2 and 3, however other explanations may also be considered. The participants and communities were at lower risk to start with: it is possible that the incidence of shared sleeping with risk factors was also lower so the potential benefit might have been expected to have been lower. Perhaps the outcome was also influenced by, or related to, small numbers. Subgroup 3 did have a 21 per cent mortality reduction which did not reach statistical significance; and both Subgroups had a reduction in the ill-defined mortality rate, but the numbers were very small and the results did not reach statistical significance.

There may, however, be a lesson in how the intervention was implemented as the participants were more dispersed within communities: perhaps there was lack of a “critical mass” of within-community knowledge and interaction between participant families and their social networks of influence. Different communities had very different levels of participation within their community.

State population mortality reduction

There was a 22 per cent significant reduction in the Study IMR (infant mortality rate between the ages of 28 days and 6 months), in the whole population of Queensland from 2014 onwards. Whilst it is possible that this fall occurred due to other factors, we hypothesise that the Pēpi-Pod[®] Program is responsible for this reduction in mortality, given there has been only a gentle decline in IMR over the past decade, and no other post-neonatal infant health promotion intervention identifiable which might have been responsible. This population study also included the influence of the later phases of the Pēpi-Pod[®] Program; the post research implementation phase which, whilst more scattered, reached an expanded number of areas. The ongoing influence of the research program in the original communities, where Pēpi-Pods sleep spaces and associated safe sleep messaging were shared within and between families and communities are likely to be retained.

Study Subgroup 1, with its high level of community and large reduction in Study IMR, suggests what might be achievable if the Pēpi-Pod[®] Program were to be implemented to that degree in all Queensland priority populations. New Zealand described a 29 per cent reduction in post-neonatal infant mortality in 2016 coinciding with implementation of their Safe Sleep Program which involved a “blitz approach to SUDI education”, consistent health policy across all health districts, and targeted provision of portable sleep devices (the Pēpi-Pod[®]).⁽²²⁾

The fall in the Queensland population Study IMR was most marked for the Indigenous population – a fall of 47 per cent; these infants have a higher incidence of SUDI than non-Indigenous infants.⁽⁶⁾ The Pēpi-Pod[®] Program prioritised participation by Indigenous infants and families so this greater fall is not surprising and supports our hypothesis.

The Study IMR also fell significantly for the non-Indigenous Queensland population mortality. Non-Indigenous infants and families were prioritised for participation in the Program by health services using eligibility criteria based on the presence of risk factors and recruited at a lower rate than Indigenous families. The estimate of the mortality benefit on the non-Indigenous population may be an overestimate as there is likely to have been some under-identification of Indigenous infants.⁽⁸⁾

The lack of change in infant mortality in the low SEIFA group was not expected given the vulnerability to SUDI of low socioeconomic families.^(44, 45) In this study, this result may reflect the lack of utility of the area-of-residence measure to characterise the highly complex social vulnerabilities of high-risk families.⁽⁴⁶⁾ It may also reflect the challenges in identifying this vulnerable subpopulation with complex needs.

There was a 22% statistically significant reduction in the Study IMR in the whole population of Queensland from 2014 onwards. We hypothesise that the Program is responsible for this reduction.

A closer look at discrete time periods which reflect more closely the phases of the Pēpi-Pod® Program research phase and the post implementation phase, shows some interesting patterns. There was a greater fall in Indigenous Study IMR during the earlier years of the research program, and since then, no ongoing reductions. This is difficult to explain if due to other factors. Instead, it may reflect variations in the intervention: the Authors are aware that during the research years, the intervention was more structured with program integrity tightly maintained (ie. awareness of safe sleep messages shared with families and community networks). After the research finished, the postimplementation phase (without research administrative support at service levels), has been less structured and with the resulting residual impact potentially less protective.

A different explanation may be that the mortality reduction measured was the maximal effect achievable with the Pēpi-Pod® Program and is being maintained in the post intervention phase. The steady reduction in Indigenous Study IMR over 2014-2016 was reversed in 2017 where Study IMR rose, before falling again in 2018. Anecdotally, the research team have highlighted that almost no Pēpi-Pod® sleep spaces were distributed from August 2016 through December 2017 following completion of the research project. In addition to those services which had purchased their own Pēpi-Pod® sleep spaces, the program was supported by a generous donation from a rural medical foundation to purchase a small number of Pēpi-Pod sleep spaces (n=100) which allowed some service continuity, until government funding (Department of Child Safety) was secured for a post-implementation phase (July 2017-June 2018).

There is a different pattern for the non-Indigenous Study IMR (which influences the whole of Queensland pattern given the high proportion of non-Indigenous infants), where an ongoing fall has continued through the post implementation phase. Whilst this may reflect other factors, it may reflect the Pēpi-Pod® Program enrolment pattern for the non-Indigenous population; less enrolment (10 per cent) in research phase and more enrolment (25 per cent) in post implementation phase: the ongoing fall in Study IMR may suggest that the maximum benefit is not yet achieved.

An important question for Queensland is whether there are further mortality benefits to be gained. The New Zealand experience suggests that the benefit diminishes if the Pēpi-Pod® Program uncouples the actual sleeping device from the intensive health promotion program. In 2018, New Zealand experienced a rise in post-neonatal mortality rate, following a sustained period of lowered infant mortality.⁽⁴⁶⁾ While no inferences can be made from this ‘all cause’ infant mortality data, a temporal association can be observed with the change in the original Pēpi-Pod® Program developed by New Zealand’s Change for our Children Pēpi-Pod® Program being replaced by a national sleep space service coordinated by the Ministry of Health.⁽⁴⁷⁾ Unfortunately, a weakening of the Program-specific education, coordination and quality processes that were core to Program effectiveness has been noted, as the emphasis was placed on supply of devices to families with risks. An intervention such as the Pēpi-Pod® Program that is effective in one context will not be effective in another if core components are not included in delivery.⁽⁴⁸⁾ The safety briefing, the “Rules of Protection, the Safe to Breathe resource”, and strengths-based language used in safe sleep education were designed to help parents to understand the factors which protect babies as they sleep and to value the practical strategies that they can put in place for their baby to create a safe sleep environment.⁽⁴⁹⁾

Effective and sustainable implementation that achieves the program aims requires measures of implementation integrity, which contribute to the understanding of program performance and outcomes.^(48, 50) These elements were beyond the scope and resources of the original research project which aimed to establish acceptability, feasibility and safety of the Pēpi-Pod[®] Program in Aboriginal and Torres Strait Islander communities.⁽²⁶⁾ Recommendations for future evaluations of the program's impact include embedding the principles of implementation science.^(26, 28, 48, 50) This includes the tracking and reporting of implementation strategies, to help us understand when, where, why and how incorporated program implementation strategies improve program effectiveness and ultimately infant health outcomes. Key to future evaluations, is the inclusion of health service professional and parent consumer perspectives of the program elements which are the most engaging, useful and effective for families.⁽¹⁷⁾

Economic evaluation of the Pēpi-Pod[®] Program

Our cost estimate of providing the Pēpi-Pod[®] Program in a universally proportionate way to the priority families in Queensland, of AUD \$1.4 to \$ 2.1 million per year (projected cost upscaled over eight years), is modest when compared with our modelling using the “value of statistical life” methodology, for the 15 fewer deaths per year observed in this study.

The value of a statistical life is “an estimate of the financial value society places on reducing the average number of deaths by one”.⁽⁴²⁾ The Australian Government Value of a Statistical Life sets a societal benchmark for investment to save a life (AUD \$4.656 million per life, assuming survival for another 40 years, adjusted to the current year 2020). Using the estimate of 15 infant lives saved, our society would place a financial value of \$69.84 million on reducing these lives – 40 times the cost of a Pēpi-Pod[®] Program intervention for the estimated 6 per cent priority families in this example. The Pēpi-Pod[®] Program could be expanded fourfold to 25 per cent of the population and still represent an excellent return on investment.

On average, 51 deaths of infants age 1-6 months continued to occur each year in Queensland so there is the potential for more infant lives to be saved with wider uptake of the Pēpi-Pod[®] Program, assuming the hypothesis is correct that it was responsible for the observed mortality reduction. Given that half the deaths in this age range are “ill defined” and the majority (but not all) of these are associated with unsafe sleeping this potential to save more lives may double or more.

Strengths and limitations of this study

Two aspects of this study enhance generalisability: the whole Queensland population outcome has been studied, and the outcome of all-cause mortality in infants circumvents the problem of misclassification of death from SUDI. By restricting the outcome measure of post-neonatal deaths up to 6 months, we have matched the outcome to the duration of effect of the infant sleeping in the Pēpi-Pod[®] sleep space. A disadvantage of the outcome used is that we have missed the small number of SUDI which occur in the neonatal period (10 per cent in Queensland).⁽⁵¹⁾ Epidemiological studies have demonstrated that infants younger than 12 weeks of age are at a greater risk of SUDI in shared sleep situations in some circumstances, compared with older infants.⁽¹¹⁾

There is the potential for more infant lives to be saved in Queensland with wider uptake of the Pēpi-Pod[®] Program.

This study is limited by the small numbers of deaths in the study period, and smaller numbers when subpopulations are analysed, limiting power to show a difference. We relied on the statistical collections process of identification of Aboriginal and Torres Strait Islander status for the Subgroup and State populations, where under-ascertainment is a reported problem.⁽⁶⁾ Whilst the participant Indigenous status was likely to be more reliable as the data were collected specifically for the research project, the numerator deaths and denominator populations for the Subgroup and State Study IMR would be affected by this misclassification. The apparent mortality benefit in the non-Indigenous population may be a result of the improved mortality of any misclassified Indigenous infants; and if so, the mortality benefit in the Indigenous population is underestimated in this study.

Another challenge was to identify subpopulations (for the mortality analysis) which correlated with the dispersed locations and varying proportions of participants over the phases of the intervention. The research and post-intervention participant locations and times were defined by the participant database, and postcode was the available location variable. Postcodes are not the ideal geographic region for the purpose of population characteristics; the Australian Statistical Geography Standard is preferred because of the more homogeneous and representative nature of the statistical areas.⁽⁵²⁾ Post codes can be very large and characteristics may have not matched the small communities within the postcode where the intervention occurred. The numerator of deaths and denominator of births used in the analysis related to the whole postcode, not the smaller communities in which the intervention occurred. The effect of this would be to dilute the effect of the intervention. Even so, an effect was evident and possibly underestimated. The State population mortality analysis overcame this potential mismatch between participant community and postcode.

The method design posed several challenges. The subgroups were artificial constructs created for the study analysis to manage the issue of heterogeneity of community participation in the research and implementation phases. This may have unintentionally separated similar small communities or grouped disparate ones, with artefactual differences or similarities in subgroup comparisons. This issue was countered by the strength of the whole of Queensland population analysis.

A different aspect of the methodology may have caused misclassification, where pre-intervention time periods were defined for each post-code and included a small number of participants born in the second part of the year. This potentially contaminated the pre-intervention phase by some participants and would have reduced the estimate of the difference before and after the intervention. A similar issue is possible in the whole of Queensland analysis, but is somewhat countered by undertaking a two phases and three phases analysis to explore any nuances in the time period comparisons. These methodological issues would tend to cause underestimate of the effect, so that the reductions in mortality shown are likely conservative.

The project limitations should be considered when reviewing results. These include:

- small numbers
- difficulties in identifying subpopulations
- the artificial construct of the Subgroups
- method design challenges.

Conclusion and recommendations

This study shows a significant reduction in infant mortality rates of infants between the ages of 28 days and six months in the Queensland population from 2014 onwards. The mortality rate reduction was particularly marked in the population subgroup which had the highest participation rate in the Pēpi-Pod® Program research conducted from 2013 onwards. Over this time, there have not been other interventions at a population or subpopulation which might have been responsible for improved post-neonatal survival. We suggest this study supports the hypothesis that the Pēpi-Pod® Program is the reason for the mortality reduction.

This study suggests that mortality benefit can be achieved using a proportionate universalism approach where priority populations are identified and targeted. The cost of this intervention is extremely modest compared with what our Australian society has said it is prepared to pay for each life saved.

We recommend that Queensland government implements the Pēpi-Pod® Program to priority Queensland populations without delay.

Key supporting points for the implementation of the Pēpi-Pod® Program in Queensland:

- The Pēpi-Pod® Program represents a practical and tangible solution to Queensland's long standing high infant mortality rates
- With the effectiveness demonstrated in this document, and the validity and acceptability of the Pēpi-Pod® Program having already been evaluated in the Queensland context, this is a program ready for immediate implementation in Queensland
- The Pēpi-Pod® Program has a 'low cost high return on investment' profile, given the high 'value of a statistical life' for each infant saved
- The Pēpi-Pod® Program targets current Queensland Health priority populations including Indigenous infants and their families
- The Pēpi-Pod® Program has a flexible delivery approach enabling the program to be embedded into current models of maternal and child health delivery, in both government and nongovernment organisations within metropolitan, regional and rural/remote settings
- The Pēpi-Pod® Program maximises the resources within communities to achieve outcomes 'close to home' and contributes to building capacity in health services⁽¹⁷⁾
- The Pēpi-Pod® Program leverages other current investments made by the QPQC and Queensland Health in the area of SUDI and infant safe sleep to produce an even greater return on investment (eg. the current development of updated Safe Infant Sleeping Guideline).

This study suggests that mortality benefit can be achieved using a proportionate universalism approach where priority populations are identified and targeted.

Recommended implementation priorities

Queensland Health take a lead role in the implementation

Queensland Health, as the principal public health provider of maternal and postnatal services, is well placed to take a lead role in the implementation of the Pēpi-Pod® Program in Queensland in collaboration with key partners.

Potential exists for collaboration with other key providers of maternal and postnatal services however overarching support and direction are essential to avoid fragmented use of the Pēpi-Pod® Program and avoid inability to achieve the potential reductions on infant mortality that this research has demonstrated. There are lessons to be learned from the New Zealand implementation.

Support implementation of the Pēpi-Pod® Program for a minimum period of 5-8 years

Five to eight years is the minimum timeframe required to establish the program in Queensland, to ensure the outcomes are evaluated and a plan for continuation is developed both within and external to Queensland Health.

This time frame is needed for an implementation science framework to be implemented. This would include tracking and monitoring of implementation strategies and evaluation of process outcomes; and measurement of Infant Mortality before, during and after the period of implementation in each region served by participating services.

Once established, the Pēpi-Pod® Program can be embedded in existing maternity and post-natal care (both within and external to Queensland Health) as part of recommended practice in partnering with families to improve safe sleeping practices.

Target priority populations

Program eligibility should be based on priority populations of interest. This is expected to cover 10-12 per cent of population. Eligibility criteria will be informed by, but not limited to, the following factors:

- Maternal or family smoking
- Mother age <20 years
- Infants who were of low birth weight or born preterm
- Rural or remote residential location
- Experience social vulnerability (alcohol or drug use, mental health, previous child safety involvement, domestic violence, employment instability, criminality).
- Chaotic/transient living circumstances
- No sleep space available for the infant
- Aboriginal and Torres Strait Islander families
- Māori and/or Pacifica families.

Recommended implementation priorities

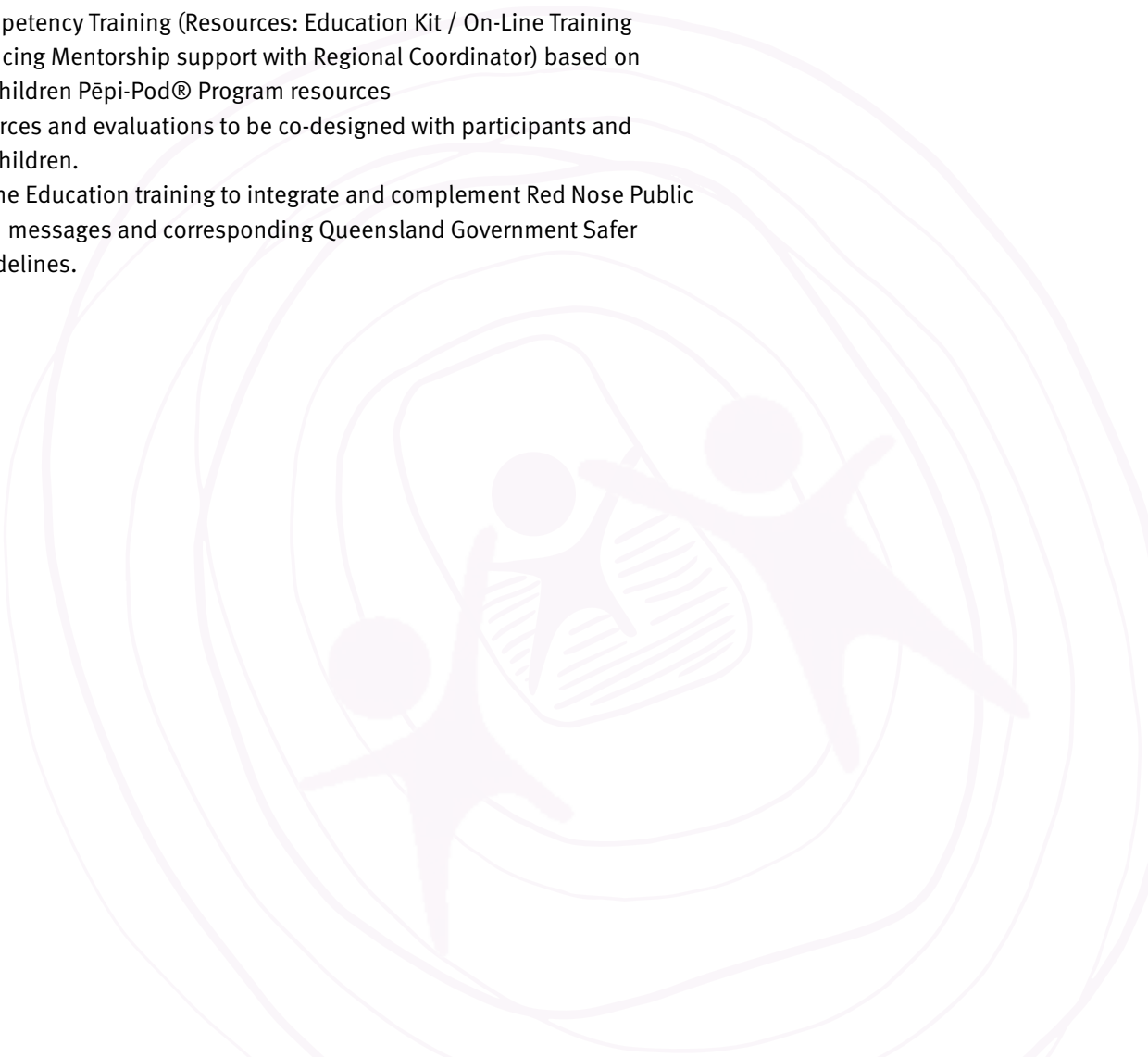
- Queensland Health take a lead role in the implementation
- Support the implementation for a minimum of 5-8 years
- Target priority populations
- Provide financial and service commitment.

Provide financial and service commitment

Whilst developing the details of the implementation were beyond the scope of this project, suggested implementation concepts are presented below. Key financial commitments would be the purchase of the Pēpi-Pod® sleep spaces, a number of core key staff (some with part-time roles) and development of on-line education resources to support health professional and parent education.

The implementation would need to consider the following points:

- Utilisation of existing midwifery and maternal and child health services - government and nongovernment (eg. Aboriginal Health Service controlled), and/or Primary Health Network service providers (program providers can be Indigenous Health Worker, Registered Nurse, Registered Midwife, Child Health Nurses, Paediatricians, General Practitioners)
- Embed the Pepi-Pod Program into an existing intensive support programme which has a successful model of engagement of vulnerable families
- Recruitment of 4-5 key Coordinators for Queensland regions based on population (eg. 15,000/births per coordinator): Cape and North-West to Townsville; Central Queensland, Wide-Bay and West, two for South East Queensland region
- Each Hospital and Health Service (HHS) and participating non-Government Organisation to identify a Safe Sleep Champion; role to provide staff support in their team / HHS
- Provision of Competency Training (Resources: Education Kit / On-Line Training / Video-conferencing Mentorship support with Regional Coordinator) based on Change for our Children Pēpi-Pod® Program resources
- Additional resources and evaluations to be co-designed with participants and Change for our Children.
- Revision of on-line Education training to integrate and complement Red Nose Public health campaign messages and corresponding Queensland Government Safer Infant Sleep Guidelines.



Abbreviations

ABS	Australian Bureau of Statistics
A-Q	Australia minus Queensland (referenced in comparisons of IMR)
AUD	Australian Dollars
BOP	Baby One Program (Apunipima, Queensland)
CI	95% Confidence Interval
CCYPCG	Commission for Children, Young People and the Child Guardian (now Queensland Family and Child Commission)
DCCSD	Department of Communities, Child Safety and Disability (now replaced by Department of Children, Youth Justice and Multicultural Affairs) (Queensland Government)
GOSR	Getting Our Story Right (a cross agency data linkage algorithm to improve Indigenous identification)
HHS	Hospital and Health Service
HREC	Health Research Ethics Committee
ICD-10	International Classification of Disease, Version 10
IMR	Infant Mortality Rate (Infant Deaths age 0-365 days divided by Live Births)
IRSAD	Index of Relative Socio-Economic Advantage and Disadvantage
N	Number
PDC	Perinatal Data Collection (Queensland)
QFCC	Queensland Family and Child Commission (Queensland Government)
QH	Queensland Health
Qld	Queensland
QPQC	Queensland Paediatric Quality Council
RR	Rate Ratio
RBDM	Registry of Births, Deaths and Marriages (Queensland)
SEIFA	Socio-Economic Indexes For Areas
SIDS	Sudden Infant Death Syndrome, a subset of SUDI where death remains unexplained after a thorough investigation
Study IMR	Study Infant Mortality Rate (Infant Deaths age 28-182 days divided by Live Births)
SSB	Statistical Services Branch, Queensland Health
SUDI	Sudden Unexpected Death in Infancy
USC	University of the Sunshine Coast
USID	Unexplained Sudden Infant Death

Appendix 1:

Methods: Technical notes

Stratification of participant postcodes prior to analysis

To classify each postcode into a Study subgroup according to the proportion of the Indigenous infant population who were participants, an approximation of the Indigenous infant population and the total infant population for each postcode was needed prior to the analysis, and prior to the request for the postcode denominator data provided by SSB.

Australian Bureau of Statistics (ABS) population data at the postcode level are available from the Australian Census 2016 resources.⁽⁵³⁾ The total infant and Indigenous infant populations during the Pēpi-Pod® Program in each postcode were estimated, as postcode level age group data, but not births data, were available. The total infant and Indigenous infant populations for each postcode were estimated using the age group 0-4 years (a five year age span) divided by five for an annual population, and then multiplied by the duration of the Program in years, see below.

As outlined in the discussion, this pre-analysis approach was validated, when during the analysis using actual infant population data from SSB, the actual proportions of Indigenous infants reflected the predicted proportions for each subgroup.

Pēpi-Pod® Program in each postcode - time considerations:

Four different time points are relevant in this study.

1. Pre-intervention phase

For the retrospective Subgroup mortality comparisons, identifying the “pre-intervention” phase (the control in the comparison), was done separately for each postcode. This approach was needed given the incremental “roll-out” nature of the research project, starting in different communities / postcodes over several years. For each participant postcode, the “pre-intervention” years were defined as the years prior to the birth year of the first participant (where the birth month was January to June), or including the birth year of the first participant (where the birth month was July to December).

This pragmatic definition introduces the potential for contamination of the pre-intervention phase with the effect of the intervention in those six months. If this occurred, it would tend to lower the estimate of the effect. This is addressed further in the discussion.

2. Intervention Year

An “intervention year” (the year when intervention started) was excluded from the comparison, to allow for the incremental introduction of the Pēpi-Pod® Program into that community / postcode.

3. Post-intervention Phase

“Post-intervention” years were defined as the years after the “intervention year”, rounded to whole years.

4. Duration of the Pēpi-Pod® Program

The duration of the Pēpi-Pod® Program for each study postcode was estimated using the first and last participant enrolment date in that postcode as recorded in the research database. The duration of the Program for each postcode was rounded to whole years.

Appendix 2

Results: Characteristics of Study Population subgroups

Table 6. Characteristics of Subgroup 1
Pēpi-Pod® Program participants and whole postcode communities during years of participation

N (%)		Participants N=265 (%)		All births in those postcodes N=2,444 (%)		Participants as % of population 10.8% overall (%)
Infant male sex		115	(43.4)	1,269	(51.9)	9.1
Infant Indigenous		240	(90.6)	1,068	(43.7)	21.5
Infant gestation	<37 weeks	41	(15.5)	280	(11.5)	14.6
Infant birth weight	<2500g	34	(12.8)	251	(10.3)	13.5
Mother age group	<20 years	42	(15.8)	244	(10.0)	17.2
	20-24 years	85	(32.1)	628	(25.7)	13.5
Mother smoked during pregnancy		113	(42.6)	802	(32.8)	14.1
SEIFA Quintile	1	197	(74.3)	1,559	(63.8)	12.6
	2	16	(6.0)	315	(12.9)	5.1
	3	52	(19.6)	360	(14.7)	14.4
ARIA	Remote/Very remote	166	(62.6)	1,254	(51.3)	19.9
	Mixed Outer Reg/Rem/VR*	84	(31.7)			
	Outer/Inner regional*			613*	(25.1)	13.7*
	Major cities	15	(5.7)	577	(23.6)	2.6
Indigenous or SEIFA Q1	Neither	5	(1.9)	592	(24.2)	0.8
	Either	80	(30.2)	1,030	(42.1)	7.8
	Both	180	(67.9)	822	(33.6)	21.9
SUDI prioritisation score number of factors	0 factors	27	(10.2)	576	(23.6)	4.7
	1 factors	79	(43.9)	1,008	(41.2)	7.8
	2 factors	110	(41.5)	644	(26.4)	17.1
	3 factors	42	(15.8)	195	(8.0)	21.5
	4 factors	7	(2.6)	21	(0.9)	33.3
SUDI prioritisation score 2 or more factors		159	(60)	860	(35.2)	22.7

* Different methodologies for mapping area (postcode / SA2) to ASGS Remoteness

Table 7. Characteristics of Subgroup 2
Pēpi-Pod® Program participants and whole postcode communities during years of participation

N (%)		Participants N=43 (%)		All births in those postcodes N=2,959 (%)		Participants as % of population 1.5% overall (%)
Infant male sex		14	(32.6)	1,283	(43.4)	1.1
Infant Indigenous		38	(88.4)	240	(8.1)	15.8
Infant gestation	<37 weeks	9	(20.9)	275	(9.3)	3.3
Infant birth weight	<2500g	10	(23.3)	228	(7.7)	4.4
Mother age group	<20 years	7	(16.3)	108	(3.6)	6.5
	20-24 years	15	(34.9)	477	(16.1)	3.1
Mother smoked during pregnancy		21	(48.8)	370	(12.5)	5.7
SEIFA Quintile	1	7	(16.3)	632	(21.4)	1.1
	2	19	(44.2)	1,042	(35.2)	1.8
	3	5	(11.6)	415	(14.0)	1.2
ARIA	Remote/Very remote	1	(2.3)	58	(2.0)	1.7
	Outer/Inner regional	11	(25.6)	575	(19.4)	1.9
	Major cities	31	(72.1)	2,326	(78.6)	1.3
Indigenous or SEIFA Q1	Neither	4	(9.3)	2,178	(73.6)	0.2
	Either	32	(74.4)	690	(23.3)	4.6
	Both	7	(16.3)	91	(3.1)	7.7
SUDI prioritisation score number of factors	0 factors	10	23.3	1,811	(61.2)	0.6
	1 factors	18	41.9	885	(29.9)	2.0
	2 factors	12	27.9	227	(7.7)	5.3
	3 factors	3	7.0	33	(1.1)	9.1
	4 factors	0	0.0	3	(0.1)	0.0
SUDI prioritisation score 2 or more factors		15	(34.9)	263	(8.9)	5.7

**Table 8. Characteristics of Subgroup 3
Pēpi-Pod® Program participants and whole postcode communities during years of participation**

N (%)		Participants N=91 (%)		All births in those postcodes N=19,166 (%)		Participants as % of population 0.5% overall (%)
Infant male sex		33	(36.3)	9,924	(51.8)	0.3
Infant Indigenous		88	(96.7)	1,958	(10.2)	4.5
Infant gestation	<37 weeks	8	(8.8)	1,724	(9.0)	0.5
Infant birth weight	<2500g	9	(9.9)	1,327	(6.9)	0.7
Mother age group	<20 years	11	(12.1)	953	(5.0)	1.2
	20-24 years	21	(23.1)	3,731	(19.5)	0.6
Mother smoked during pregnancy		46	(50.5)	2,828	(14.8)	1.6
SEIFA Quintile	1	34	(37.4)	5,637	(29.4)	0.6
	2	14	(15.4)	4,604	(24.0)	0.3
	3	27	(29.7)	1,521	(7.9)	1.8
ARIA	Remote/Very remote	12	(13.2)	73	(0.4)	24.7
	Mixed outer regional/Remote/Very remote*	6	(6.6)			
	Outer/Inner regional	22	(24.2)	7811	(40.8)	0.5
	Mixed major cities/Regional*	12	(13.2)			
	Major cities	39	(42.9)	11,282	(58.9)	0.5
Indigenous or SEIFA Q1	Neither	1	(1.1)	12,270	(64.0)	0.0
	Either	58	(63.7)	2,197	(11.5)	2.6
	Both	32	(35.2)	699	(3.6)	4.6
SUDI prioritisation score number of factors	0 factors	17	(18.7)	10,536	(55.0)	0.2
	1 factors	36	(39.6)	6,179	(32.2)	0.6
	2 factors	33	(36.3)	2,067	(10.8)	1.6
	3 factors	4	(4.4)	366	(1.9)	1.1
	4 factors	1	(1.1)	18	(0.1)	5.6
SUDI prioritisation score 2 or more factors		38	(41.8)	2,451	(12.8)	1.6

*Different methodologies for mapping area (postcode / SA2) to ASGS Remoteness

Table 9. Characteristics of Subgroup 4
Pēpi-Pod® Program participants and whole postcode communities during years of participation

N (%)		Participants N=272 2015-2018 (%)		Characteristics Indigenous Queensland Births 2007-11* (%)	Characteristics all Queensland Births 2015^ (%)
Infant male sex		n/a			51.6
Infant Indigenous		204	(75.0)		6.5 (mother)
Infant gestation	<37 weeks	49	(18.0)	(10.9) <37 wk*	9.1 < 37 wk
OR Infant birth weight	<2500g			(11.2) < 2,500g ~	6.6 <2,500g
Mother age group	<20 years	54	(19.9)	(18.6)	3.9
	20-24 years	84	(30.9)	(32.5) ~	16
Mother smoked during pregnancy		128	(47.1)	(45.9) *	12.4
SEIFA Quintile	1	122	(44.9)	(50.6) *	
	2	34	(12.5)	(27.4) *	
	3	65	(23.9)	(11.3) *	
ARIA	Remote/Very remote	61	(22.4)	(24.3) *	3.3
	Mixed outer regional/Remote/Very remote**	23	(8.5)		
	Outer/Inner regional	43	(15.8)	(33.8) Outer regional**	33.7
	Mixed major cities/Regional**	26	(9.6)	(24.3) Mixed Metro/Inner regional**	
	Major cities	119	(43.8)		62.9
Indigenous or SEIFA Q1	Neither	40	(14.7)	n/a	n/a
	Either	138	(50.7)		
	Both	94	(34.6)		
SUDI prioritisation score number of factors	0 factors	41	(15.1)	n/a	n/a
	1 factors	99	(36.4)		
	2 factors	92	(33.8)		
	3 factors	37	(13.6)		
	4 factors	3	(1.1)		
SUDI prioritisation score 2 or more factors		132	(48.5)	n/a	n/a

** Different methodologies for mapping area (postcode / SA2) to ASGS Remoteness

*Source: "A multivariate approach to the disparity in perinatal outcomes between Indigenous and non-Indigenous women, Queensland 2007/7-2011/12. Health Statistics Branch, Queensland Health. 2014." www.health.qld.gov.au/hsu/peri/indigenous-peridisparity.pdf

~ Source: AIHW Australia's mothers & babies 2011 <https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-babies-2011/formats>

^ Source: AIHW Australia's Mothers & Babies 2015 <https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-and-babies-2015-in-brief/data>

Results: Study IMR "ill-defined" deaths

Table 10. Study IMR comparisons between subgroups for "ill-defined" deaths age 28-183 days, per 1,000 live birth

	Population Pre-intervention	Population Post-intervention	Rate Ratio Pre vs Post (95% CI)
Subgroup 1: N deaths / births	8 / 6,522	1 / 3,528	
Study MR (95% CI) p value	1.23 (0.58, 2.47)	0.28 (0.00, 0.18)	0.23 (0.03-1.85) p=0.24
Subgroup 2: N deaths / births	4 / 9,630	3 / 6,491	
Study MR (95% CI) p value	0.42 (0.12, 1.11)	0.46 (0.09, 1.43)	1.11 (0.25-4.97) p=0.99
Subgroup 3: N deaths / births	28 / 54,825	19 / 44,061	
Study MR (95% CI) p value	0.51 (0.35, 0.74)	0.43 (0.27, 0.68)	0.84 (0.47 - 1.51) p=0.57
Subgroup 1 vs Subgroup 2 Rate Ratio (95% CI) p value	2.95 (0.89, 9.80) p=0.12	0.61 (0.06, 5.89) p=0.99	
Subgroup 1 vs Subgroup Rate Ratio (95% CI) p value	2.40 (1.10-5.27) p=0.02	0.66 (0.09-4.91) p=0.99	

Results: Estimation of Queensland priority population for a statewide Pepi-Pod Program

Table 11. Characteristics of the 2017 Queensland mother-infant population, examined to calculate size of possible participant population

N (%)	Participants N=272 2015-2018 (%)	Characteristics Indigenous Queensland Births 2007-11* (%)	Characteristics all Queensland Births 2015^ (%)
Live births	N=5,083 #1	N=5,4196 #1	N=59,279 #1
Mother age			
<20 years	N=846 #2	N=1,404 #3	
20-24 years	N= 2,086 #2	N= 7,395 #3	
<25 years	N=2,932	N=8,799	
Mother smoke			24.9% #4 of mothers age <20 smoke after 20 weeks
anytime in pregnancy	42.7% #5 N=1,765	9.6% #5 N=7,054	
Young mothers who smoke showing calculations	N=42.7% smoke* 2,932 <25 years =1,251 *	N=24.9% smoke* 8,799 <25 years =2,146 **	N=3,397 **
Preterm	N=661 preterm	N=3984 preterm	
SGA	12.5% #2	8.2% #2	16% #4 of mothers who smoked had SGA infants vs 7.5% for non smokers 11.9% of mothers age <20 had SGA infants
Birth weight <2500	N= 551	N=8.2% #5 * 49,264 N=4,039	
Young mothers with SGA term infant		N=12.2% * 9,129 N=1,114	12.2% #4 of mothers age <20 had SGA infants

NR not reported

Data sources

#1 QH SSB data for this study

#2 Australian Bureau of Statistics Note ABS gives total live births as 61,158 for Queensland in 2017, different from 59,279 as provided by QH SSB

http://stat.data.abs.gov.au/Index.aspx?DatasetCode=FERTILITY_AGE_STATE

http://stat.data.abs.gov.au/Index.aspx?DatasetCode=ATSL_FERTILITY

#3 calculated from total minus Indigenous

#4 QMPQC combined 2016-2017

#5 <https://www.health.qld.gov.au/hsu/peri/peri2017/queensland-perinatal-statistics-2017>

** Number of mother-infant pairs where mother is young and smokes during pregnancy, used as one estimate of the cost of a statewide priority population Pēpi-Pod® Program

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