GenV Special Care Nursery Registry Scoping Report

Authors

Jing Wang,[1, 2] Lauren Davenport,[1] Hayley Warren,[1] Lana Collins,[2] Jeanie Cheong,[1,3,4] Melissa Wake[1, 2]

Affiliation

1 Murdoch Children's Research Institute, Royal Children's Hospital, Parkville, Victoria, Australia
2 Department of Paediatrics, The University of Melbourne, Parkville, Victoria, Australia
3 Department of Obstetrics & Gynaecology, The University of Melbourne, Parkville, Victoria, Australia
4 Neonatal Services, Royal Women's Hospital, Parkville, Victoria, Australia.

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Abstract

Newborn babies who require specialist care account for substantial immediate and lasting burden of disease. The Australian and New Zealand Neonatal Network (ANZNN) has made major contributions towards improving the quality and consistency of neonatal intensive care data collection, but no comparable data set exists for the babies admitted to a special care nursery (SCN). Working with newborn experts across the state, this report aims to inform interim and final decisions as to whether to implement an ANZNN-harmonised extraction of data for all such babies born across Victoria, Australia, and entering GenV over two full years from mid-2021. This report considers requirements, likely data set, feasibility, stakeholder acceptability and consultation requirements, and funding and resourcing needs. We conclude that an SCN data extraction appears feasible, would generate translatable evidence, and could lay the groundwork for a stand-alone ongoing registry post-GenV.

Keywords

Special care nursery; Registry; Sick newborns; GenV

Citation

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Aboriginal acknowledgement

We acknowledge the Traditional Custodians of the land upon which we are situated. We pay our respect to their Elders—past, present and emerging.

Contents

1. Executive summary

Objective

To inform interim and final decisions as to whether GenV will implement a 'within-GenV registry' for babies admitted to special care nurseries (SCN). This registry would contain additional standardised clinical data for all babies enrolled in GenV over two full years from mid-2021 who are admitted to an SCN or neonatal intensive care unit (NICU) but do not meet registration criteria for the Australian and New Zealand Neonatal Network (ANZNN) data set. The proposed SCN data set would potentially contain (a) a subset of the items in the ANZNN Data Dictionary and (b) additional items relevant to SCN admissions.

Nature of proposal

- To outline the value and rationale of routine extraction of an additional data set for all GenV babies admitted to NICU and/or special care nurseries across Victoria.
- To consider the feasibility and resourcing to achieve this goal.
- To develop the methods to implement the data extraction, including a ready-to-go data extraction tool complementing the ANZNN data set, in consultation with newborn experts across Victoria.
- To provide essential information for funding proposals.

Findings

Standardised SCN data extraction appears feasible within GenV. We present an extraction tool developed in consultation with newborn experts across Victoria that complements and harmonises with existing ANZNN data for the sicker babies entering NICUs. Its implementation would generate a 'depth' cohort (a substudy within GenV) that equates to a 2-year statewide registry within GenV. We also lay out the steps needed to engage all SCNs and to implement and tailor this data extraction.

Conclusion and impact

We conclude that SCN data extraction appears feasible within GenV, and could provide much-needed evidence to develop better models of care, and statewide and nationwide guidelines for sick newborns. It could also provide mechanisms to monitor and benchmark care and provide a translational platform to conduct trials during the GenV birth window. Depending on the feasibility demonstrated, perceived value and stakeholder appetite, it could also provide a 2-year window to plan a subsequent transition to a stand-alone ongoing SCN registry post-GenV.

2. Introduction

Newborn babies who require specialist care account for substantial immediate and lasting burden of disease. Around 18%[1] of newborn babies are cared for in neonatal intensive care units (NICU) or special care nurseries (SCN), including post-NICU step-down care. These problems place them at risk of adverse outcomes—physical, mental, and developmental.[2,3]

Much of this morbidity relates to preterm birth. Worldwide, an estimated 15 million babies are born preterm (<37 weeks) each year—more than 1 in 10 babies around the world—and this number is rising.[4] Preterm birth complications (for example, jaundice, low birth weight, breathing problems) are the leading cause of death and disability in children up to 5 years of age, accounting for nearly 1 million deaths in 2015 globally.[5] In the newborn period, babies suffer higher rates of temperature instability, respiratory distress, apnoea, hypoglycaemia, seizures, jaundice, kernicterus, feeding difficulties, periventricular leukomalacia, and rehospitalisations.[6] In 2005, the annual societal cost of preterm birth in the US was US$26 billion. This value included medical care costs up to age 5 years for children born preterm, maternal delivery costs, and the cost of early intervention.[7]

High-risk babies experience gaps in knowledge and care. Around 14,000 sick newborns are admitted to Victorian NICUs and SCNs every year.[1] Most research has focused on understanding best care practices and long-term outcomes for very preterm babies (<32 weeks, approx 2,500 babies/year in Australia) and highly selected groups such as those requiring surgery. However, collectively these babies comprise less than 10% of NICU and SCN admissions.[1,6,8] Less is known about outcomes and their causal pathways in those born moderate-late preterm (32-36 weeks), who make up the vast majority of preterm children (approx 23,000 babies/year in Australia),[9,10] or for babies born full-term (≥37 weeks), who make up 60% of NICU and SCN admissions. These latter groups of babies may account for a large burden of adverse health and development in the long term, given their greater numbers. Knowing risk factors for poorer outcomes will improve identification of those babies most in need of early intervention.[11]

Registry-based research can improve outcomes for high-risk groups. Clinical quality registries are effective in monitoring and benchmarking outcomes through systematic and ongoing standardised data collection.[12] These registries enable identification of clinical practice variation and its effect on patient outcomes.[12,13] Well-constructed registries drive continuous improvements in patient outcomes (especially rare diseases) and reduce variation through better adherence to guideline-recommended care.[13,14] They provide a platform to implement new treatments and pragmatic trials.[12] In their absence, opportunities to improve mothers' and babies' care may be missed.

The Australian and New Zealand Neonatal Network (ANZNN) is a collaborative network that, since its establishment in 1994, has routinely collated a substantive minimum data set on the characteristics and care of all babies who receive intensive care.[15] However, routinely collected ANZNN data do not apply to babies admitted to SCNs. This hampers translatable evidence (prediction, prevention, treatments, services) to improve the care and future wellbeing and health of this much larger group of babies.

GenV provides a prospective opportunity for data collection for all babies born over a 2-year period from mid-2021 who are admitted to a neonatal unit in Victoria but who do not meet criteria for the ANZNN data collection. It is anticipated that such data collection would complement and partially harmonise with the full ANZNN data set. This would be a depth cohort of GenV; GenV's statewide nature effectively creates an SCN registry within GenV. GenV's 2-year recruitment period also provides a window within which to consider whether this initiative could transition to a stand-alone ongoing registry in subsequent years.

3. Aims

This scoping report aims to inform interim and final decisions as to whether to implement a 2-year extraction of statewide data for all babies admitted to NICU and/or special care nurseries across Victoria during the period of GenV. The report considers the requirements, likely data set, feasibility, stakeholder acceptability and consultation requirements, and funding and resourcing needs, and recommends whether to proceed. It provides information for grant applications to fund such an endeavour.

4. Key considerations and assumptions

4.1 An SCN registry will augment existing data frameworks to improve newborn care and outcomes

The Victorian Perinatal Data Collection (VPDC) maintains a core collection of data for all mothers and babies during pregnancy and the birth admission. However, as this is a universal data set, the VPDC cannot include all information that is specific to and important for babies receiving additional care. Separately from this, the highest risk babies cared for in the state's five NICUs share largely harmonised care pathways and data collection through the well-established ANZNN registry. Care for babies admitted to SCNs, however, is devolved across an additional 30+ sites, with potential for wide variation in data collection and care pathways. Further, long-term outcomes data regarding physical and mental health, development and wellbeing are not available for babies who entered SCNs.

GenV aims to provide data that can help to rapidly improve care for all women and babies. GenV will collect data from parallel cohorts of mother and babies, targeting all 160,000 Victorian births for two full years from 2021,[16] to determine risks, care, costs and outcomes of *all* women with high-risk pregnancies and *all* sick newborns. To achieve this, GenV proposes to bring together linked clinical and administrative data, biosamples, and mother and child outcomes. GenV thus offers a unique infrastructure to support population-based data collection and data linkage across the state. However, its current funding does not extend to undertaking specific projects or enriching statewide data sets designed to address key questions on specific high-risk cohorts.

To create a more complete universal data framework that is augmented for more complex pregnancies and newborns, two new registries are proposed to coincide with GenV and to fill clinical quality gaps for secondary and tertiary care (see Figure 1).

- Monash Registries is developing a new stand-alone maternal fetal medicine (MFM) clinical quality registry, led by Assoc Prof Joanne Said. NONA (Newborn Obstetrics Network Australasia) will include pregnant women who have conditions associated with the greatest risk for maternal and perinatal morbidity and mortality and who have been referred to one of the five maternity services in Victoria co-located with a NICU. For mothers delivering in GenV's recruitment window, this registry will be complemented by GenV data for women with healthy pregnancies and with high-risk pregnancies receiving secondary care.
- In this report, we consider the establishment of a depth cohort within the GenV cohort that will, given GenV's whole-of-state remit, effectively function as an SCN registry. This will comprise babies admitted to all 40 SCNs across Victoria, and will complement the existing ANZNN Registry, which already collects harmonised data for babies admitted to NICUs.

GenV's biosamples and long-term outcomes data will enrich both NONA and GenV's SCN Registry, with likely overlap in participants enriching both activities.

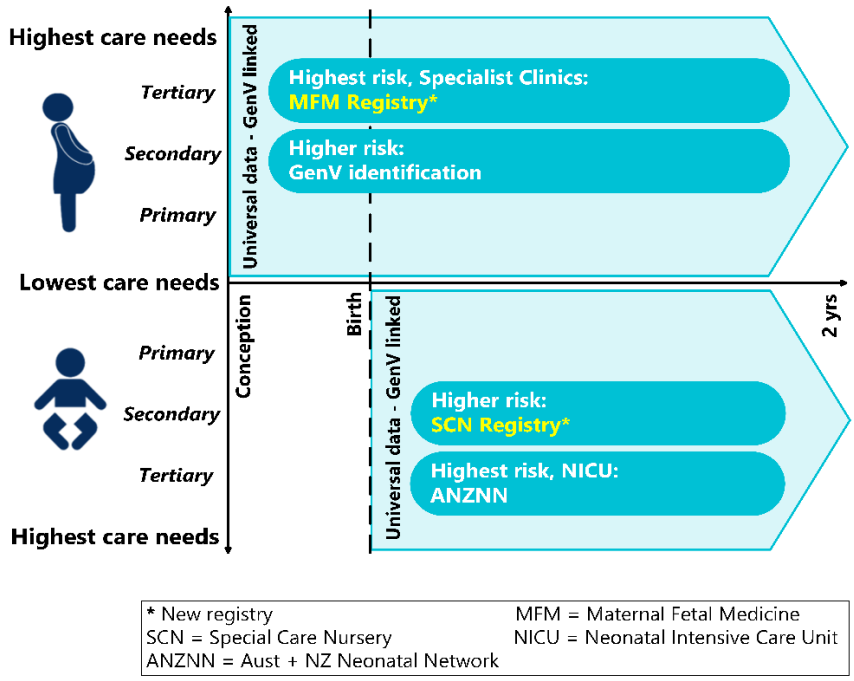

Figure 1 Cohorts of women and babies by levels of care needs, and how they integrate with the GenV cohort and timelines (blue arrows), existing (white) & new (yellow) registries.

Collectively, these new registries will generate:

- prospectively collected 'deep' data to augment GenV's universal data, including linked administrative and clinical data
- universal outcome assessments for mothers and children via digital technology
- maps of costs and care pathways by health services across the state
- a rapid translation-to-practice platform for conducting pragmatic randomised trials
- a lasting mechanism for surveillance of real-world effectiveness of new or more standardised interventions.

We anticipate that these data will lead to strategies to predict, prevent and manage pregnancy and neonatal conditions, thereby reducing inequity and variation in care.

4.2 Eligibility criteria should be established

Inclusion criteria: All babies admitted to Victoria's 5 NICUs and 40 SCNs (Appendix A), and born in the 2-year window of GenV recruitment, commencing mid-2021. We anticipate that approx 11,500 of the approx 14,000 admissions/yr will be to SCNs and NICUs.[1,17]

Exclusion criteria: This registry will not include data for the approx 2,500 NICU babies eligible for ANZNN Registry inclusion, since their data are already extracted by the ANZNN. Thus, we will not include babies who are less than 32 weeks' gestation, or less than 1500 g birthweight, or ventilated for more than 4 hrs, or receive therapeutic hypothermia, or receive major surgery.

4.3 GenV should only collect data items not reliably available elsewhere

All SCN babies are potentially contained within GenV's universal recruitment. GenV is seeking parent consent for GenV to access clinical and administrative data sets. The first step in defining a unique

SCN Registry data set was therefore to determine which items are already universally available from existing data sources, so would not need to be extracted specifically for GenV.

To our knowledge, these comprise:

- **The Victorian Perinatal Data Collection (VPDC).** VPDC was established in 1982, by an amendment to the *Health Act 1958* (Vic) under the functions of the Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM). It was established as a population-based surveillance system to collect and analyse information on, and in relation to, the health of mothers and babies in order to contribute to improvements in their health. Data collected includes information on obstetric conditions, procedures and outcomes, neonatal morbidity and birth defects relating to births in Victoria. The scope of the collection includes live births and still births (occurring before or during labour). Appendix B shows items relevant to this SCN Registry proposal. The full VPDC Data Dictionary for 2020 can be accessed on the health.vic website.
- **The Birthing Outcomes System (BOS).** BOS, launched in 2012, is an electronic database designed to assist maternity services. Data entered allows BOS to compile care summaries of clients' pregnancy and birth episodes and statutory reports to various health agencies, and to produce audits for quality and benchmarking of health care. The items required by VPDC comprise an already-harmonised core subset of BOS, which provides a mechanism to transfer them to VPDC. Many hospitals collect additional items in BOS that are beyond what is required by VPDC. These vary between hospitals. However, some BOS items relevant to this SCN Registry proposal may be largely congruent between the 40 Victorian SCNs. This requires further scoping.
- **Data that GenV will collect in its 15-20-minute postnatal recruitment visit**. This data includes essential baseline information to enable modelling to the population in face of future attrition. Appendix B also shows the GenV items relevant to this proposal.

4.4 The core of the SCN registry is a substantial subset of ANZNN items

As noted above, the SCN registry aims to fill a vital gap in data spanning the full continuum of newborn care across all sectors (primary, secondary, tertiary).

Many elements of the ANZNN data set are also relevant to SCN babies, because:

- Many babies move between NICU and SCN care, so will already have these data collected, avoiding duplication that may result in unnecessary workload and errors.

The SCN registry core will therefore comprise a substantial subset of ANZNN items.

- This will create a pre-harmonised data set spanning all specialist care sectors.
- The ANZNN data set is tried and tested, with a polished data dictionary that is the product of years of development, testing and reporting, and consultation with families and those who care for sick babies.

However, the SCN registry will not include all ANZNN data items, because:

- Some are already collected by VPDC or GenV at recruitment.
- Many NICU items (for example, extracorporeal membrane oxygenation (ECMO), necrotising enterocolitis, ventilation) are not relevant to SCNs.
- The much larger numbers of SCNs and lack of resourcing for this initiative require parsimony; that is, collection of only the most important data items.

4.5 The SCN registry must include novel items not in ANZNN

Some important conditions with possible long-term morbidity need to be captured. However, as these babies are not usually admitted to NICUs (for example, neonatal abstinence syndrome, risk of hypoglycaemia), these items are not in the ANZNN data set.

4.6 Development of the minimum data set requires expert input

A working group was established to decide on the data that should be collected in the SCN Registry. The group comprised experts from multiple disciplines involved in newborn care, research and data collection; ANZNN leads at each of the ANZNN contributing centres; and the neonatal/paediatric leads at each of the hospitals with NICUs and SCNs. The composition of the final group is shown in Table 1.

Table 1 The working group composition according to craft group.

Craft group	N
Neonatal/Paediatric medical	Metropolitan (n=17) Regional (n=2)
Neonatal/Paediatric nursing	Metropolitan (n=4) Regional (n=0)
Epidemiology	n=2
GenV core support	n=3

4.7 An interim SCN Registry minimum data set is defined

The minimum data set was defined in the following steps:

- **Data mapping.** We mapped ANZNN data items against VPDC, GenV-collected data, and recent SCN scoping work from NSW led by Assoc Prof Adam Buckmaster. Duplicates were removed after mapping. Appendix B summarises all ANZNN data items not already collected by VPDC or GenV.
- **Items screening and classification.** We reviewed the data items with Prof Jeanie Cheong (Chair, GenV Newborns Working Group) and grouped the data items into three categories: 1) Suggested to collect; 2) Suggested not to collect; 3) Unsure.
- **Further consultation.** In Jan 2020, we circulated the summary table with suggested categories to the GenV Newborns Working Group. We asked all group members to indicate whether each data item should be collected for the SCN registry and why. They were also able to suggest

additional items (Appendix C).

- **Shortening the data list.** We summarised and integrated the feedback. We then removed all the 'Suggested not to collect' items from the summary table. This resulted in the proposed SCN Registry minimum data set shown in Table 2.

Table 2 Proposed SCN registry minimum data set

MATERNAL
Previous preterm birth
ANTENATAL
Maternal antibiotics during labour
Antenatal corticosteroids
BABY AND BIRTH
Date of birth
Admission time
Date of discharge to home
Intubated at resuscitation
Temperature at admission
Base excess after birth (first recorded, time recorded)
Cord lactate (mmol/L)
First lactate (mmol/L, date and time of first lactate)
Hypoxic-ischaemic encephalopathy
Seizures (yes/no)
RESPIRATORY
Main indication for respiratory support
Surfactant (yes/no) • Method of administration of first dose of surfactant • Date and time of surfactant first given • Numbers of doses of surfactant
Air leak requiring drainage (yes/no) • Date and time of first drainage of pulmonary air leak
RESPIRATORY SUPPORT
IPPV (yes/no/unknown) • Date and time intubated for ongoing ventilation • Date and time of final extubation from mechanical ventilation • Remain ventilated/ongoing ventilation (yes/no)
Nasal CPAP (yes/no/unknown) • Date and time of initiation of nasal CPAP • Date and time of final cessation of nasal CPAP
Nasal high flow (yes/no/unknown) • Date and time of initiation of nasal high flow • Date and time of final cessation of nasal high flow
CARDIAC
Pharmacological treatment for patent ductus arteriosus (PDA)
INFECTION AND NECROTISING ENTEROCOLITIS
Probiotics
Infection • Organism (type and date of specimen)
Antibiotics/antiviral
NUTRITION
Parenteral nutrition (yes/no/unknown) • Date and time of initiation of TPN

• Date and time of cessation of TPN
FEEDING AND BIRTHWEIGHT REGAIN
Breast milk feeding at onset of enteral feeds
Donor breast milk in any quantity (yes/no/unknown)
Breast milk (any) at discharge to home
IVH AND CRANIAL ULTRASOUND
Left and right IVH
Cerebellar haemorrhage
6-week head ultrasound
OTHER SUGGESTED ITEMS
Hypoglycaemia (yes/no) • If Y: record lowest blood glucose + date and time • If Y: record treatment (glucose gel, extra milk, IV glucose) • If Y: record signs (seizures yes/no)
Neonatal abstinence syndrome (NAS) (yes/no) • If Y: record which maternal medication/substance use • If Y: record what treatment baby received
Jaundice (yes/no) • If Y: record test date of highest level and highest level • If Y: record treatment
Vitamin K given

4.8 A data extraction form and REDCap survey are established

We established the SCN Registry Data Extraction Form (Appendix C) and an online REDCap (research electronic data capture) survey based on the SCN minimum data set (Table 2).

4.9 Governance and operating principles are established

Recruitment will be via GenV, which will include the additional depth cohort. GenV consent already includes permission to access clinical data.

This work from 2021 will be overseen by a committee led by the Chairs of GenV's Newborns Working Group (currently Prof Jeanie Cheong and Prof Melissa Wake), with additional members to be appointed. Members will include service providers, care quality and safety experts, and individuals with experience (both nationally and internationally) in large epidemiological and population cohorts and consortia. Meetings will be held at least every 3 months to discuss progress of the project, any challenges or barriers to timely completion, and delivery of key performance indicators.

GenV's Solutions Hub will be responsible for design and implementation, working with the Cohort 2020s and Data Innovation teams.

It is anticipated that data extraction will be undertaken in dedicated employment fractions either by a subset of GenV's field recruitment team or by hospital staff (similar to ANZNN data extraction). Where GenV staff undertake this role, it is likely that these individuals will need honorary appointments at their respective hospitals for this work.

All data will be stored and accessed via GenV's already-built data repository operating under FAIR[18] and Five Safes[19] principles. For GenV participants born within the two-year recruitment window, GenV will hold the additional SCN data as an accessible sub-registry. During this period, considered decisions can be taken and mechanisms put in place regarding permanent extension and/or expansion to other states, and whether long-term custodianship accordingly moves to ANZNN or

Monash Registries.

The SCN Registry will work towards achieving all Operating Principles for Clinical Quality Registries (CQR), as outlined in the *Framework for Australian Clinical Quality Registries* developed by the Australian Commission on Safety and Quality in Healthcare.[20]

4.10 The GenV interim SCN Registry considers long-term sustainability

Among the anticipated benefits from the interim SCN registry is gaining information to guide future decisions about a permanent registry that may come under the ANZNN in the long-term. Initial discussions commenced in May 2019 with the ANZNN Executive Committee Chair, Prof Kei Lui, followed by an invited presentation and discussion at the annual ANZNN Clinical Practice Improvement (CPI) conference in September 2019.

In order to transition to a permanent registry, the interim SCN registry would need to fully embed the CQR operating principles by the end of its 2-year implementation.

Once quality registries establish their completeness and quality improvement (QI) value, transfer to government support becomes possible. We will report on data quality (for example, missing data per variable) and usability. GenV's 2-year period is a window to tune and automate processes, to consult (researcher/stakeholder surveys, focus groups) on data set improvements, and to make the case for 'business as usual' sustainability. We will work with stakeholders for permanent funding to improve the state's lasting data framework and to expand elements nationally.

5. Cost

Appendix A shows the numbers of babies recorded as being admitted to Victoria's SCNs and NICUs. However, at point or writing, we are uncertain as to how many babies appear in both SCN and NICU within hospitals, or appear in figures for more than one hospital. Thus, for the SCN, there are three possible scenarios (Figure 2) for costing data extraction, depending on the proportion of SCN babies also eligible for ANZNN:

1. *Largest numbers (scenario 1):* NICU babies are completely different babies from those admitted to SCNs. This is the most costly scenario. In the worst case, we fund 20 minutes per baby for 11,500 babies pa, which adds up to around 3833 hours or 110 working 34-hour weeks, or around three FT salaries for two years.
2. *Intermediate numbers (scenario 2):* NICU babies overlap with SCN babies (that is, some but not all babies are admitted to both the NICU and the SCN in those hospitals and are counted in both sets of numbers—plus some NICU babies in those five hospitals come from other SCNs; that is, numbers in smaller SCNs are also overstated a little for our purposes), in which case the staff hours would be somewhere in the middle.
3. *Smallest numbers (scenario 3):* NICU babies are a complete subset of SCN babies; that is, all NICU babies are also included in SCN figures and we simply subtract them. We know this not to be the case.

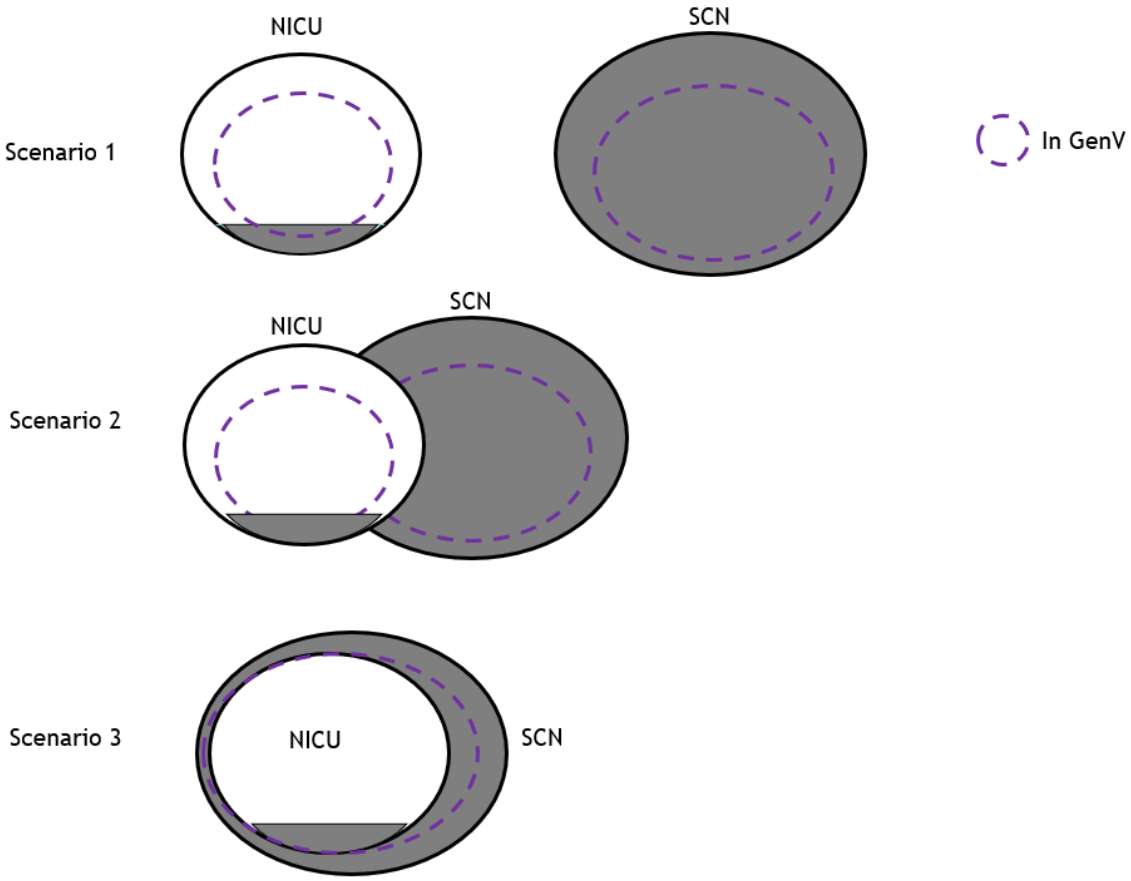

Figure 2 Three possible scenarios for SCN data extraction costing. Grey shading represents babies who have data requiring extraction

Assumptions for the costings below are given in Table 3.

Table 3 Assumptions for the costings

Assumption	Likely final costs scenario
1. There is no overlap between NICU and SCN babies (scenario #1)	**Lower**, as the two populations overlap
2. Data extraction requires 20 minutes per baby, as per ANZNN extraction for NICU babies	**Lower**, as SCN babies require less complex care so there is less to record
3. No baby is transferred between units, ie none is counted twice in different rows of Appendix A	**Lower**, as Victoria's five NICUs transfer babies back to their 'home' SCN as soon as possible
4. Salaries are paid at NHMRC level	**Higher**, as NHMRC levels are lower than actual salaries
5. A full 6-month mop-up is required after GenV recruitment ends in Dec 2022	**Lower**, as long SCN stays are largely accounted for by NICU babies who are already in ANZNN
6. None of the five NICUs already extracts ANZNN data items for SCN babies	**Lower**, as we know some units already routinely extract data for all NICU and SCN babies
7. Numbers of admissions to Victorian SCN/NICU are similar to 2019	**Lower**, as (a) overall births are projected to fall following COVID, and (b) the marked reduction in % of preterm births during COVID may not fully reverse

8. All babies entering Victorian SCNs over the GenV recruitment period also enter GenV	**Lower**, with GenV uptake not yet known. It may be that SCNs can help promote uptake of their patients to maximise the benefits of the SCN data set to them.

As none of these assumptions is likely to hold, final costs will differ (and should be less, since all but assumption 4 is likely to result in reduction of scope). Final costings depend on accurately determining this.

To understand what numbers we are actually dealing with, we need information from the five NICUs to determine:

- Are our annual figures for admissions to SCN and NICU correct?
- Under our likely scenario, how many/what proportion of babies are admitted annually to –
  - SCN only
  - NICU only
  - SCN and NICU (Table 4).

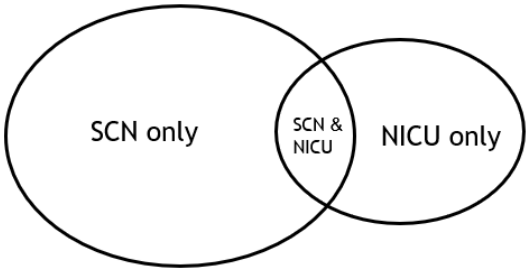

Table 4 Data table for admission figures

	RWH	Mercy	Monash	RCH	Joan Kirner
NICU only annually *(regardless of meeting ANZNN criteria)*					
SCN only annually					
NICU and SCN annually *(regardless of meeting ANZNN criteria)*					
Total					

- Of the babies admitted to NICU, how many/what proportion are in ANZNN already?
- Does their hospital already extract these data for NICU babies not eligible for ANZNN (Table 5)?

Table 5 Data table for hospital data extraction

	RWH	Mercy	Monash	RCH	Joan Kirner
Does the hospital already extract the data? (yes/no)					

- How many babies annually does each hospital transfer back to SCNs in other hospitals?

These questions are covered in the SCN site assessment survey (see section 7 below) that we propose to collect for each SCN/NICU site in the first half of 2021.

6. Data collection methods and process are developed

Proposed data collection methods include:

- direct retrospective medical data entry from hospital medical records into the REDCap database (generating the SCN registry) via the SCN data extraction REDCap survey; this will be done by trained local or study personnel at the participating clinical site. This process is outlined in Figure 3.

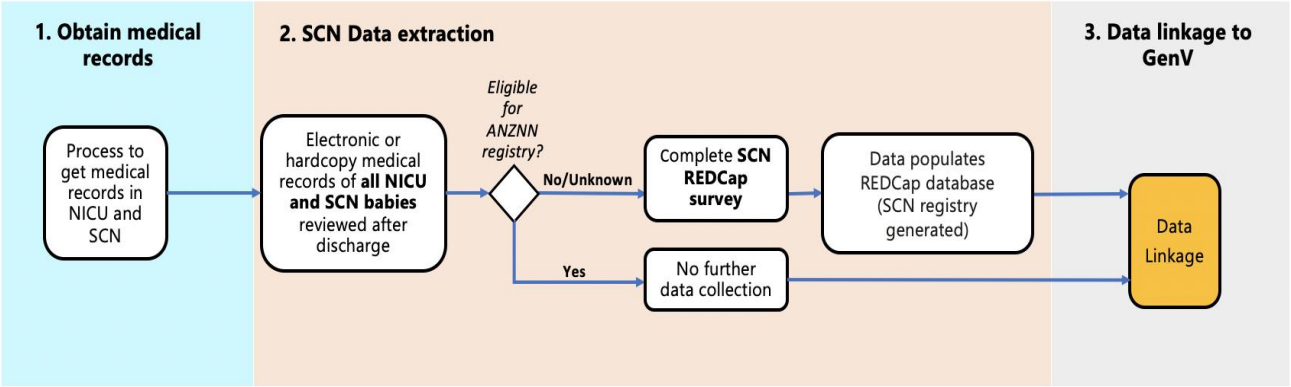

Figure 3 SCN registry data collection pathway

- possible periodic retrospective data extraction from existing SCN databases or electronic medical records (EMRs) where data items and responses can be exactly mapped to the SCN data set.
- possible data extraction by natural language processing of hand-written records (still the norm in most smaller Victorian hospitals); however, given the dispersed nature of the data to be extracted throughout a record, this seems unlikely.
- data linkage to GenV for the purposes of quality auditing and/or follow-up data collection to ascertain longer term complications/outcomes.

These methods are still under development and will be refined with input from relevant parties including the SCN providers after engagement.

7. SCN/NICU site engagement

Clinical site engagement is essential for the generation of the SCN registry. The development of the SCN registry requires Heads/Directors of the clinical sites to authorise data extraction to be conducted within neonatal nurseries. Clinical staff should know about the registry and be broadly supportive of the intended data collection. Ideally, they would see the SCN as a highly valuable activity, and thus additionally promote participation in GenV to all families coming through their SCN. To achieve such outcomes, we are planning a 5-phase SCN engagement strategy.

- **Building the foundation**

We will undertake scoping research and liaise with individuals who have prior interactions with SCNs/NICUs. Introductory materials (Appendix D) will introduce the concept of GenV and the SCN registry and request future collaboration, cooperation and participation.

- **Creating an authorising environment in SCNs/NICUs**

We will build relationships with nursing and medical Heads/Directors of SCNs/NICUs to facilitate data extraction in all SCNs and NICUs in Victoria. A site-assessment survey will be provided to each site to

request information on the number and flow of admissions, feasibility of extracting the proposed data set and the form (paper, electronic, combined) in which medical records are kept. The site-assessment survey will also inform projections for time and budget allocations that will be required for future data extraction. We will also seek the endorsement and support of peak bodies such as the Perinatal Society of Australia and New Zealand (PSANZ), the ANZNN, the Royal Australasian College of Physicians (RACP) and the Australian College of Midwives (ACM).

- **Preparation and refinement**

The data extraction process (Figure 3) will be revised with the feedback from the sites, allowing for potential issues to be raised and explored and for the process to be tailored to each site. Formal and informal endorsement of the SCN registry from the SCNs/NICUs should occur.

- **Agreements in place**

A memorandum of understanding (MOU) will be generated with each clinical site.

- **Implementation**

The data extraction process will be executed for the SCN Registry: dedicated research coordinators at every SCN will extract data items from hospital medical records into the SCN data extraction form (Appendix C) using the REDCap survey. An implementation plan and standard operating procedures (SOPs) will be written.

Phase 2 of the engagement strategy involving preliminary engagement with SCN/NICU executive teams is currently under way. Once a MOU is in place, we will begin engaging with clinical staff to refine our methods.

8. Timeline

The primary stages of the protocol, including generating the SCN minimum data set and preliminary engagement with clinical sites, have already taken place. Formal engagement and agreements with clinical sites to refine the data set and enable future data collection are projected to occur during 2021.

This preparatory work occurs before and during the early stages of the GenV cohort 2020s recruitment period, which is currently scheduled to commence in mid-2021 and continue for two full years. This will establish the cohort from which the registry is derived.

The later activities of the protocol (from late 2021 onwards) include data extraction and storage and subsequent use of the generated registry data within quality initiatives, primary publications, future research, and guidelines. An overview of the protocol timeline is provided in Table 6.

Table 6 Timelines for SCN Registry within GenV

Activity	2020				2021		2022		2023		2024				2025			
							Likely GenV recruitment											
Gain ethics approval and establishing governance																		
Establish SCN Registry minimum data set and REDCap survey																		
Generate SCN key contact table																		
Meet with ANZNN data extraction personnel to refine processes																		
Provide introductory materials and site assessment survey to each SCN/NICU																		
Refine SCN data set and survey																		
Sign agreements with SCN/NICU sites																		
Recruit and train data staff																		
Recruit GenV cohort 2020s																		
Develop and test GenV ePhenome																		
Extract and clean SCN Registry data																		
Obtain ePhenome outcomes and diagnoses																		
Plan for permanent SCN Registry																		
Use data for research and policy																		
Disseminate results (eg publications)																		
Translate arising knowledge into guidelines and recommendations																		

9. Risk assessment

Table 6 shows the risks associated with this project according to their likelihood and impact. Overall risk is graded from A (high) to D (low), or N (no risk), as shown in the key.

Table 4 summarises risk for likelihood and impact, providing an overall risk grade (A-D, N).

Table 6 Risk assessment plan

Key		Impact (I)			
		Low (L)	Medium (M)	High (H)	Extreme (E)
Likelihood (LH)	Low (L)	N	D	C	A
	Medium (M)	D	C	B	A
	High (H)	C	B	A	A

Risk theme	Risk	Characteristics			How risk is mitigated or managed
		LH	I	Grade	
People	GenV target participant recruitment not met	M	M	C	Preventative: Carefully engage all stakeholders (Maternity services, NICU, SCNs) prior to recruitment Appoint staff experienced in participant recruitment Quarterly appraisal of recruitment targets Contingency: Direct more resources into recruitment if falling short
	Difficulty appointing staff with the right skillset	L	M	D	Preventative: Use rigorous recruitment procedures Train properly and run 6-monthly workshops to troubleshoot Contingency: Appraise performance and manage appropriately
	Key stakeholders from recruitment centres do not support study	L	M	D	Preventative: Engage stakeholders early Provide a genuine and strong value proposition including how this registry fills a data gap Support proactively with regular contact from project team Contingency: Senior team members address stakeholder concerns
Information	Data extraction from SCN hampered due to process variation between centres	L	M	D	Preventative: Clarify with each SCN processes to access data at each site Identify contact person at each site who is able to assist Contingency: Seek help from the contact persons
	Inadvertent data disclosure	L	L	N	Preventative: Ensure databases are secure and password protected Store all data in re-identified format, with participant identifying information (PII) in separate secure files Contingency: Inform HREC, and if necessary, the individual(s) affected
Governance	Accountability and reporting of the project	L	L	N	Preventative: Form an Executive committee with overall responsibility for the project Hold monthly Executive meetings in the first 3 months,

					then every 3 months, to ensure integrity, progress and adherence to budget Report annually to the Human Research Ethics Committee and GenV Advisory Group
Delivery	Budget shortfall	L	L	N	Preventative: Ensure budget proposal is careful and accurate Contingency: Identify potential savings (eg reduce the number of lesser value items) Seek additional funding sources
Regulatory	Ethics process delays impact project timelines	M	L	D	Preventative: Prioritise ethics submission in timeline Submit as amendment through existing GenV approval
	Inability to implement outcomes to policy	M	M	C	Preventative: Identify main barriers and possible solutions to policy implementation early, with guidance of experts Engage end users and stakeholders in translation plan

10. Conclusion: A lasting legacy for Australians

The significant health problems Australians increasingly face have their roots in early life. For far too long, research efforts to understand causal pathways for poorer health have been piecemeal, impeding translation into the best standardised healthcare that is accessible to everyone. Creating this one-off lifelong cohort of over 160,000 mothers and babies—across all sectors of care, demographics and environments from inner urban to remote—will have real-life impact.

In the **short-term**, this new SCN registry will:

- address multiple key gaps in knowledge and healthcare for high-risk babies.

Long-term benefits of leveraging this whole-state cohort of high-risk babies include:

- large scale research around the world via streamlined access to high quality data
- growing value, as noncommunicable diseases (NCD) and other outcomes accrue
- a registry that drives healthcare improvements and provides a platform for trials and translation
- experience that can be adopted across Australia and around the world
- an international resource that answer key questions in maternal and child health.

11. Acknowledgements

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At time of writing, the Working Group comprised:
Dr Arun Sasi, Consultant Neonatologist, Mercy Hospital
Dr Dave Tickell, Consultant Paediatrician, St John of God Ballarat Hospital
Dr David Tran, Consultant Paediatrician, Northern Health
Dr Dan Garrick, Consultant Paediatrician, Goulburn Valley Health
Assoc Prof Wei Qi Fan, Consultant Paediatrician and Neonatologist, Northern Health
Prof Rod Hunt, Chair in Neonatal Paediatrics, Monash Health
Prof Peter Davis, Consultant Neonatologist, Royal Women's Hospital
Prof Lex Doyle, Associate Director of Research, Royal Women's Hospital

Assoc Prof Brett Manley, Consultant Neonatologist, Royal Women's Hospital
Dr Trisha Prentice, Consultant Neonatologist, Royal Women's Hospital
Dr Clare Collins, Head of Neonatology, Western Health
Prof Peter Anderson, Professor of Paediatric Neuropsychology, Monash University
Prof Alicia Spittle, Paediatric Physiotherapy, Royal Women's Hospital
Dr Rose Boland, Postdoctoral Neonatal Nurse Researcher, Paediatric Infant Perinatal Emergency Retrieval (PIPER)
Dr Anna Tottman, Consultant Neonatologist, Royal Women's Hospital

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13. Appendices

Appendix A: Summary of SCN and NICU admissions per year

No	Region	Public/ private	Site	Newborn capability level	SCN	NICU	Number of admissions in SCN	Number of admissions to NICU	Births: 2018
1	Metro	Public	Mercy Hospital for Women	6	√	√	849	1300	5693
2	Metro	Public	Monash Medical Centre	6	√	√	1186	1500	4060
3	Metro	Public	Royal Women's Hospital	6	√	√	1162	1600	7600
4	Metro	Public	Royal Children's Hospital	6	√	√	544	851	
5	Regional	Public	Geelong Hospital (Barwon Health)	5	√		506	NA	2586
6	Metro	Public	Northern Hospital	5	√		564	NA	3687
7	Metro	Public	Western Health (Joan Kirner)	5	√	√	947	NA	5524
8	Regional	Public	Ballarat Health Services	4	√		266	NA	1413
9	Regional	Public	Bendigo Hospital	4	√		267	NA	1503
10	Metro	Public	Box Hill Hospital	4	√		377	NA	2635
11	Metro	Public	Casey Hospital	4	√		519	NA	2326
12	Regional	Public	Goulburn Valley Health [Shepparton]	4	√		197	NA	1052
13	Regional	Public	Latrobe Regional Hospital [Traralgon]	4	√		171	NA	829
14	Metro	Public	Mercy Werribee Public Hospital	4	√		485	NA	3859
15	Regional	Public	Mildura Base Hospital	4	√		72	NA	839
16	Regional	Public	Wodonga Regional Health Service	4	√		269	NA	1629
17	Regional	Public	Peninsula Health	4	√		TBC	NA	302
18	Metro	Public	Angliss Hospital	3	√		247	NA	2227

No	Region	Public/ private	Site	Newborn capability level	SCN	NICU	Number of admissions in SCN	Number of admissions to NICU	Births: 2018
19	Regional	Public	Central Gippsland Health Service [Sale]	3	√		71	NA	417
20	Metro	Public	Dandenong	3	√		300	NA	2673
21	Regional	Public	Northeast Health Wangaratta	3	√		131	NA	665
22	Regional	Public	South West Healthcare [Warrnambool]	3	√		108	NA	730
23	Regional	Public	West Gippsland Healthcare Group [Warragul]	3	√		144	NA	883
24	Regional	Public	Wimmera Base Hospital [Horsham]	3	√		7	NA	322
25	Metro	Public	Women's at Sandringham	3	√		141	NA	1614
26	Metro	Private	Cabrini Malvern	TBC	√		178	NA	1836
27	Metro	Private	Epworth Freemasons	TBC	√		70	NA	395
28	Regional	Private	Geelong – Epworth	TBC	√		67	NA	395
29	Metro	Private	Frances Perry	TBC	√		540	NA	3031
30	Metro	Private	Jessie McPherson	TBC	√		169	NA	952
31	Metro	Private	Mitcham Private	TBC	√		181	NA	1019
32	Metro	Private	Northpark	TBC	√		138	NA	776
33	Regional	Private	Peninsula Private	TBC	√		54	NA	302
34	Regional	Private	St John of God Ballarat	TBC	√		79	NA	445
35	Regional	Private	St John of God Bendigo	TBC	√		51	NA	287
36	Metro	Private	St John of God Berwick	TBC	√		143	NA	804
37	Regional	Private	St John of God Geelong	TBC	√		88	NA	493
38	Metro	Private	St Vincent's Private Hospital	TBC	√		265	NA	2598
39	Regional	Private	The Bays Mornington	TBC	√		81	NA	457
40	Metro	Private	Waverley Private	TBC	√		145	NA	813

TBC: To be confirmed via the SCN site assessment survey

Appendix B: Summary of constructs in Victorian Perinatal Data Collection (VPDC)/ Birthing Outcomes System (BOS), recommended for GenV, or both—as of Nov 2020

Constructs	VPDC	Both	GenV
Full name – Child/mother*/2nd parent			● (recruiter)
Sex – Child	●	●	● (recruiter)
Sex – Mother/2nd parent			● (recruiter)
DOB – Child/mother	●	●	● (recruiter)
DOB – 2nd parent			● (recruiter)
Place of birth – Mother	●	●	● (recruiter)
Place of birth – 2nd parent			● (recruiter)
Parent email			● (recruiter)
Parent mobile no.			● (recruiter)
Respondent relationship to child			● (recruiter)
Preferred language/translator used and language			● (recruiter)
Mother's current residential address	●	●	● (recruiter) refuser: postcode
Mother's previous residential addresses during pregnancy			● (recruiter)
Date/timestamp of completion			● (recruiter)
Hospital child was born in/home birth			● (recruiter)
Baby born is a singleton/twin/triplet			● (recruiter)
Birth plurality	●	●	● (recruiter)
Birth order	●	●	● (recruiter)
How did you hear about GenV? (Vanguard only)			● +refuser
What put you off? (Vanguard refusers)			● refuser only
Main & other languages spoken (by mother)			●+ refuser
Main & other languages spoken (by 2nd parent)			● +refuser
Year of arrival in Australia – Mother	●	●	●
Year of arrival in Australia – 2nd parent			●
Ethnicity/culture/identity	●	●	● +refuser
ATSI status	●	●	● +refuser
Family structure			●?refuser if permitted
Education – Mother			●
Education – 2nd parent			●
Mother height (point & click)	●	●	●
Mother weight at start of pregnancy/booking (point & click)	●	●	●
Mother weight at end of pregnancy (point & click)			●
Global health – pregnancy & before			● +refuser
Mental health – pregnancy & before			●
Global health – 2nd parent			●
Mental health – 2nd parent			●
Sleep position – pregnancy & before			●

Constructs	VPDC	Both	GenV
Nausea or vomiting during pregancy			●
Alcohol – during pregnancy	●		
Smoking – during pregnancy	●		
Vaccine safety beliefs			●
Breastfeed attempted	●		
Intention to breastfeed?			●
Optimism/pessimism for child's future			● +refuser
Gestational age at birth	●	●	●From green book +refuser
Baby length, weight and head circ at birth	●	●	●From green book +refuser
Apgars	●	●	●From green book
Congenital anomalies (ICD)	●		
Parity	●		
Gravidity	●		
Antenatal care	●		
Vaccinations (flu/pertussis) – pregnancy & before	●		
Anaesthesia for operative delivery	●		
Artificial reproductive technology	●		
Admission to high dependency unit (HDU)/intensive care unit (ICU) – mother	●		
Admission to special care nursery (SCN)/neonatal intensive care unit (NICU) – baby	●		
Admitted patient election status	●		
Analgesia for labour	●		
Birth presentation	●		
Birth status	●		
Blood product transfusion – mother	●		
Date of completion of last pregnancy	●		
Date of onset of labour	●		
Date of onset of second stage of labour	●		
Date of rupture of membranes	●		
Episiotomy – indicator	●		
Estimated blood loss (ml)	●		
Estimated date of confinement	●		
Events of labour and birth (International Classification of Disease (ICD)/free text)	●		
Fetal monitoring in labour	●		
Fetal monitoring prior to birth – not in labour	●		
Formula given in hospital	●		
Hepatitis B vaccine received – baby	●		
Indication for induction (ICD/free text)	●		
Indications for operative delivery (ICD/free text)	●		
Labour induction/augmentation agent	●		
Labour type	●		
Last birth – caesarean section	●		
Last feed before discharge taken exclusively from the breast	●		
Manual removal of placenta	●		
Marital status	●		
Maternal medical conditions (ICD/free text)	●		
Method of birth	●		

Constructs	VPDC	Both	GenV
Neonatal morbidity (ICD/free text)	●		
Obstetric complications (ICD/free text)	●		
Outcome of last pregnancy	●		
Perineal/genital laceration – degree/type	●		
Perineal laceration – indicator/repair	●		
Plan for vaginal birth after caesarean	●		
Postpartum complications (ICD/free text)	●		
Procedure – (Australian Classification of Health Interventions (ACHI) code/free text)	●		
Prophylactic oxytocin in third stage	●		
Reason for transfer out – baby/mother	●		
Resuscitation method – drugs	●		
Resuscitation method – mechanical	●		
Separation date – baby/mother	●		
Separation status – baby/mother	●		
Setting of birth – intended/actual/change of intent	●		
Spoken English proficiency – mother	●		
Time of birth	●		
Time of onset of labour	●		
Time of onset of second stage of labour	●		
Time of rupture of membranes	●		
Time to established respiration	●		
Total number of previous abortions – induced/spontaneous	●		
Total number of previous caesareans	●		
Total number of previous ectopic pregnancies	●		
Total number of previous live births	●		
Total number of previous neonatal deaths	●		
Total number of previous stillbirths (fetal deaths)	●		
Total number of previous unknown outcomes of pregnancy	●		
Antenatal corticosteroid exposure	●		
Chorionicity of multiples	●		
Blood loss assessment – indicator	●		
Cord complications	●		
Diabetes mellitus during pregnancy – type	●		
Diabetes mellitus – gestational – diagnosis timing	●		
Diabetes mellitus – pre-existing – diagnosis timing	●		
Diabetes mellitus therapy during pregnancy	●		
Main reason for excessive blood loss following childbirth	●		
Note: *Mother/other primary caregiving parent.			

Appendix C: Proposed SCN registry data items—for extraction, this will be configured into REDCap

SCN DATA EXTRACTION FORM

ELIGIBILITY

Inclusion criteria: All babies admitted to Victoria's 5 NICUs and 28 SCNs, and born Jan 1 2021-Dec 31 2022.

Exclusion criteria: This collection does not include babies who were **admitted to NICU**, with any of the following: **<32 weeks' gestation; <1500 g birthweight; ventilated >4 hrs; therapeutic hypothermia; and/or major surgery.**

Is this baby eligible for ANZNN NICU data collection? ☐**Yes→stop now** ☐No→continue ☐Unknown→continue

MATERNAL

Previous preterm birth: ☐No ☐Yes ☐Unknown (*not include stillbirth*)

ANTENATAL

Maternal antibiotics in labour (within 48 hours of birth): ☐No ☐Yes ☐Unknown

If Yes:

Antibiotic 1:
Name:
Date started: / / Time: :
Date ceased: / / Time: :

Antibiotic 2:
Name:
Date started: / / Time: :
Date ceased: / / Time: :

Antibiotic 3:
Name:
Date started: / / Time: :
Date ceased: / / Time: :

Antenatal corticosteroids:

☐ None ☐Given <24 hours before birth (incomplete)
☐ Complete ☐ Given >7 days before birth
☐ Unknown

BABY AND BIRTH

Date of birth: / / Time: :

Date of SCN admission: / / Time: :

Date of discharge to home: / /

Intubated at resuscitation: ☐No ☐Yes ☐Unknown

Temperature at admission (to 1 decimal place): . °C

Base excess taken: ☐No ☐Yes ☐Unknown

If Yes:

Worst base excess (to 1 decimal place): . mmol/L
Time: :

(*within 12 hours of birth*)

Cord lactate: ☐No ☐Yes ☐Unknown

If Yes: Cord lactate (to 1 decimal place): . mmol/L

First lactate (baby):
☐No ☐Yes ☐Unknown

If Yes:

First lactate (baby) (to 1 decimal place): . mmol/L
Date of first lactate (baby): / / Time: :

(*within 12 hours of birth*)

Hypoxic-ischaemic encephalopathy:
☐None
☐Grade 1 (mild HIE)
☐Grade 2 (moderate HIE)
☐Grade 3 (severe HIE)
☐HIE diagnosed but grade unknown
☐Unknown

Seizures: ☐Yes ☐No

RESPIRATORY

Main indication for respiratory support
☐No support ☐Non-specific ☐HMD
☐Pneumonia ☐Meconium aspiration ☐PPHN
☐Apnoea ☐Congenital anomaly ☐Other
☐Peri-surgical ☐Newborn encephalopathy
☐Transient tachypnoea of newborn (TTN) ☐Unknown

Surfactant: ☐No ☐Yes ☐Unknown
If Yes:

Method of administration of first dose of surfactant
☐Unknown ☐Endotracheal tube
☐Catheter (eg MIST)
☐Other (eg laryngeal mask, aerosolisation)

Date of first dose of surfactant : / / Time: :

Numbers of doses of surfactant:

Air leak requiring drainage: ☐No ☐Yes ☐Unknown

If Yes:

Date of first air leak: / / Time: :

RESPIRATORY SUPPORT

IPPV: ☐No ☐Yes ☐Unknown

If Yes:

Date intubated for ongoing ventilation: / / Time: :

Date final extubation from mechanical ventilation: / / Time: :

Remain ventilated/ongoing ventilation: ☐Yes ☐No

Nasal CPAP: ☐No ☐Yes ☐Unknown

If Yes:

Date nasal CPAP commenced: / / Time: :

Date of final cessation of nasal CPAP: / / Time: :

Nasal high flow: ☐No ☐Yes ☐Unknown

If Yes:

Date nasal high flow commenced: / / Time: :

Date nasal high flow ceased: / / Time: :

CARDIAC

Patent ductus arteriosus (PDA):
☐No ☐Yes ☐Not tested

If Yes:

Treatments for PDA (*tick all that apply*):
☐Ibuprofen ☐Indomethacin
☐Other (eg Paracetamol) ☐Clinical trial
☐Unknown ☐None

INFECTION

Probiotics: ☐No ☐Yes ☐Unknown

Infection (proven or suspected):
☐No ☐Yes ☐Unknown
If Yes:
☐ Specimen not taken
Or
☐ Negative culture
Or
Organism (type and date of specimen)

Organism	Site of specimen*	Date of specimen
		/ /
		/ /
		/ /

* Blood, CSF, urine, stool, swab (specify)

Antibiotics/antiviral: ☐No ☐Yes ☐Unknown

If Yes:

Antibiotic/antiviral 1
Name
Date started: / / Time: :
Date ceased: / / Time: :
Antibiotic/antiviral 2:
Name
Date started: / / Time: :
Date ceased: / / Time: :
Antibiotic/antiviral 3:
Name
Date started: / / Time: :
Date ceased: / / Time: :

NUTRITION

Parenteral nutrition: ☐No ☐Yes ☐Unknown
If Yes:

Date parenteral nutrition commenced: / / Time: :

Date parenteral nutrition ceased: / / Time: :

FEEDING

Breast milk feeding at onset of enteral feeds: ☐No ☐Yes ☐Unknown

Donor breast milk in any quantity: ☐No ☐Yes ☐Unknown

Breast milk (any) at discharge to home:

☐Breast milk only ☐Formula (powdered milk) only
☐Both ☐Not recorded

IVH AND CRANIAL ULTRASOUND

Left IVH
(worst grade in first 14 days)
☐ None
☐ Grade 1
☐ Grade 2
☐ Grade 3
☐ Grade 4 localised
☐ Grade 4 extensive
☐ Note examined

Right IVH
worst grade in first 14 days)
☐ None
☐ Grade 1
☐ Grade 2
☐ Grade 3
☐ Grade 4 localised
☐ Grade 4 extensive
☐ Note examined

Cerebellar haemorrhage:
☐ None
☐ Right hemisphere only
☐ Bilateral hemisphere
☐ Not examined
☐ Left hemisphere only
☐ Vermis only
☐ Either or both hemisphere AND vermis

6-week head ultrasound (4 to 8 weeks) ☐No ☐Yes ☐Unknown

If Yes:

Date: / /

Left cysts:
☐ None
☐ Porencephalic cyst(s)
☐ PVL primarily confined to one of: anterior frontal, posterior frontal, parietal, temporal or occipital region
☐ Extensive leukomalacia involving two or more of the above regions
☐ Unknown

Right cysts:
☐ None
☐ Porencephalic cyst(s)
☐ PVL primarily confined to one of: anterior frontal, posterior frontal, parietal, temporal or occipital region
☐ Extensive leukomalacia involving two or more of the above regions
☐ Unknown

OTHER SUGGESTED ITEMS:

Hypoglycaemia: ☐No ☐Yes ☐Unknown

If Yes:

Lowest blood glucose (to 1 decimal place): . mmol/L

Date lowest blood glucose: / / Time: :

Treatment (tick all that apply):
☐Glucose gel
☐Extra milk (either breast and/or formula)
☐IV glucose

Signs:
☐Seizures
☐Other/s, please specify:
☐ None

Neonatal abstinence syndrome (NAS):
☐No ☐Yes ☐Unknown

If Yes:

Due to which maternal medications/substance use?
Specify:
Or
☐ Unknown medications/substance

Any treatments given for NAS:
☐No ☐Yes ☐Unknown

If Yes to treatment, please specify:

Jaundice: ☐No ☐Yes ☐Unknown

If Yes:

Test date of highest level : / / Time: :
Highest total bilirubin: mmol/L

Treatment:
☐ Phototherapy only
☐ Exchange transfusion +/- phototherapy
☐ None

Vitamin K given: ☐No ☐Yes ☐Unknown

Appendix D: Proposed NICU and SCN site introduction letter

Dear [Head/Director of Newborns at Clinical Site],

I write to introduce the Generation Victoria (GenV) initiative and the GenV-led Special Care Nursery (SCN) Registry. We hope that you can nominate and introduce us to a senior clinical lead of your SCN, with whom GenV's Newborns Team member ([name] [email]) can liaise regarding [clinical site]'s participation in the SCN Registry.

GenV is a statewide initiative that will be open to all babies born in Victoria from mid-2021 for two years. [Clinical site] is already engaged, working with [name][position] as our liaison for GenV's overall implementation. As one of the world's largest studies, it aims to improve the health and wellbeing of children and adults now and in the future by generating translatable evidence accessible to all researchers, services and policymakers. The Victorian Government recognises the benefits that GenV will bring to Victorians, committing $14 million in funding towards the initiative in the 2019-2020 budget. GenV has gained broad support across Victoria and Australia, including the nursing and medical maternity peak bodies, the Victorian Hearing Infant Screening Program, the State Pathology Executive, and all Victorian maternal and fetal medicine specialist services

Within GenV, we are establishing a detailed registry of clinical information on all newborns admitted to Victoria's 40 SCNs. Our registry will cover important events during pregnancy and the postnatal admission that are not recorded in administrative data sets. This means that future babies like them can benefit from data that are currently only available for the much smaller numbers admitted to the state's five NICUs (via the ANZNN). This statewide evidence base should help to improve physical, mental and developmental outcomes for these very vulnerable babies, no matter where they live.

The focus now is to explore how to implement SCN data collection at every Victorian SCN from early 2021. We hope it can include sick babies at [clinical site].

To that end, I look forward to your nomination of a liaison contact to get some basic information about your SCN and advice around the plans for the GenV SCN registry.

Kind regards,

[GenV personnel sending letter]

[Position and contact details]

Cc GenV liaison at [Clinical site]