International Journal of Population Data Science

Journal Website: www.ijpds.org

Study protocol: Generation Victoria (GenV) special care nursery registry

Jing Wang[1,2], Yanhong Jessika Hu[1,2], Lana Collins[5], Anna Fedyukova[1,2], Varnika Aggarwal[1,3], Fiona Mensah[1,2], Jeanie L.Y. Cheong[1,3,4], Melissa Wake[1,2,*], and on behalf of the GenV Newborns Working Group

Submission History

Submitted:	23/01/2023
Accepted:	02/05/2023
Published:	15/06/2023

[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 and Gynaecology, The University of Melbourne, Parkville, Victoria, Australia
[4]Newborn Research Royal Women's Hospital, Parkville, Victoria, Australia
[5]Faculty of Medicine, Dentistry and Health Sciences, The University of Melbourne, Victoria, Australia

Abstract

Introduction
Newborn babies who require admission for specialist care can experience immediate and sometimes lasting impacts. For babies admitted to special care nurseries (SCN), there is no dataset comparable to that of the Australian and New Zealand Neonatal Network (ANZNN), which has helped improve the quality and consistency of neonatal intensive care through standardised data collection.

Objectives
We aim to establish a proof-of-concept, Victoria-wide registry of babies admitted to SCN, embedded within the whole-of-Victoria Generation Victoria (GenV) cohort.

Methods
This prototype registry is a depth sub-cohort nested within GenV, targeting all babies born in Victoria from Oct-2021 to Oct-2023. Infants admitted to SCN are eligible. The minimum dataset will be harmonised with ANZNN for common constructs but also include SCN-only items, and will cover maternal, antenatal, newborn, respiratory/respiratory support, cardiac, infection, nutrition, feeding, cerebral and other items. As well as the dataset, this protocol outlines the anticipated cohort, timeline for this registry, and how this will serve as a resource for longitudinal research through its integration with the GenV longitudinal cohort and linked datasets.

Conclusion
The registry will provide the opportunity to better understand the health and future outcomes of the large and growing cohort of children that require specialist care after birth. The data would generate translatable evidence and could lay the groundwork for a stand-alone ongoing clinical quality registry post-GenV.

Keywords
special care nursery; sick newborns; clinical quality registry; protocol

*Corresponding Author:
Email Address: melissa.wake@mcri.edu.au (Melissa Wake)

https://doi.org/10.23889/ijpds.v8i1.2139

Introduction

In Australia, around 18% [1] of newborn babies are cared for in neonatal intensive care units (NICU) or in special care nurseries (SCN) that cater to lower-intensity conditions, including post-NICU care. The main, but not sole, reason for admission is preterm birth (<37 weeks), which affects one in 10 babies worldwide (15 million babies per year). The number of preterm births continues to rise [2], and is the leading cause of morbidity and mortality in children under five years of age worldwide [3].

Care for babies in SCNs is guided by a weaker evidence base than is the case for NICUs. Most research has focused on best care practices and outcomes for very preterm babies (<32 weeks, 2,500 babies/year in Australia) and specific groups such as those requiring surgery. However, collectively these babies comprise less than 10% of newborn admissions for specialist care [1, 4, 5]. The evidence base is much smaller regarding the care and outcomes of moderate-late preterm (32 to 36 weeks) or term (>37 weeks) babies that receive specialist care in SCNs, who comprise 80–90% of neonatal admissions in Australia [6, 7]. Problems experienced by these babies include respiratory distress, hypoglycaemia, jaundice, seizures, temperature instability and feeding issues [4]. Their ongoing care also incurs significant health (including rehospitalisation) and societal costs [8].

Registry-based research can improve outcomes for high-risk groups. Clinical quality registries can monitor and benchmark outcomes through systematic and ongoing standardised data collection [9]. They enable identification of clinical practice variation and its effect on patient outcomes [9, 10]. Well-constructed registries drive continuous improvements in patient outcomes and reduce variation through better adherence to guideline-recommended care [10, 11]. They provide a platform to implement new treatments and pragmatic trials [9]. Thus, the highest-risk babies cared for in the state's five NICUs share largely harmonised care pathways and, through the well-established Australia and New Zealand Neonatal Network (ANZNN) registry, data collection [12]. Additionally, due to their large size, registries provide a valuable resource for researchers to study rare events and small effect sizes that may incrementally improve care over time.

However, there is no coordinated data collection for the less-sick NICU babies who do not meet ANZNN criteria, or for any babies admitted to public and private SCNs across each state. This is not unique to Australia; to our knowledge, the UK national neonatal research database (NNRD) is the only such platform internationally. To date, NNRD contains information on approximately one million infants with approximately 25,000 new patients added each quarter [13]. Moreover, access to post-discharge health and developmental surveillance data (essential to understanding impacts of healthcare beyond the admission itself) is limited in Victoria and throughout Australia. This hampers translatable evidence (prediction, prevention, treatments, services) to improve the care and future wellbeing and health of this much larger group of babies. Therefore, a registry for SCN babies will provide much-needed evidence to develop better models of care and state-wide and nation-wide guidelines for sick newborns.

Creating a new clinical quality registry involving 40 SCNs across Victoria without funding is challenging. Here, we have an opportunity to develop and test a registry with Generation Victoria (GenV) [14, 15], a population whole-of-state cohort targeting all Victorian babies born from October 2021 to October 2023 and their parents. GenV thus offers unique infrastructure to support population-based data collection for newborns requiring SCN admission. While a depth sub-cohort of GenV, GenV's state wide nature would effectively create an SCN registry within GenV. GenV's 2-year recruitment period provides a window within which to set up the methods and outcomes for a registry and consider whether it could transition to a stand-alone ongoing registry in subsequent years. This protocol outlines the anticipated cohort, dataset, and timeline and how this registry will also serve as a resource for longitudinal research through its integration with the GenV cohort and linked datasets.

Methods and analysis

Study design

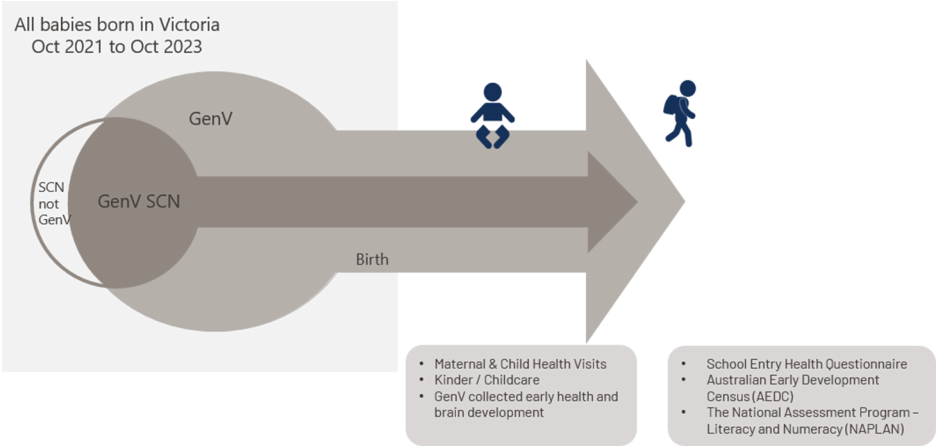
This study is nested within GenV, which aims to create parallel whole-of-state birth and parent cohorts for discovery and interventional research [15]. GenV is open to all newborns and their parents from all 58 birthing hospitals in the state of Victoria from October 2021 for a period of two full years; thus, the sampling frame is all ∼150,000 births amongst the full state population ∼6.5 million), of whom we would expect 12,500 to be admitted in each year to an SCN [1, 16]. The GenV cohort design comprises four elements: 1) Consent soon after birth to follow the child and parent/s indefinitely until study end or withdrawal, 2) Retrospective and prospective linkage to clinical and administrative datasets, 3) Universal and clinical biosamples, and 4) GenV-collected demographic, risk, geographic and outcomes data that are not available in linked datasets or existing biosamples.

One goal of GenV is to include more detailed clinical data for higher risk newborns within the cohort. Therefore, GenV is establishing a depth sub-cohort within GenV (GenV SCN registry) comprising babies admitted to all 40 SCNs across Victoria (Figure 1). This will complement the existing ANZNN registry, which already collects data for most babies admitted to NICUs.

Participant recruitment

The Victorian Infant Hearing Screen Program (VIHSP) creates a daily census of all births in Victoria. Drawing on this census, GenV recruiters visit the parent(s)/guardian and infant soon after birth (or once the child is >34 weeks gestational age and not ventilated) and invite them to participate in GenV. The parent(s) choose(s) whether or not to participate voluntarily and free from coercion. If willing, an electronic consent (eConsent) process takes place for their own and their child's overall participation in GenV, including both bundled and item-by-item components of the consent. Those who are missed or initially decline can join later via virtual or self-guided recruitment.

Figure 1: How SCN sub-cohort integrates with the GenV and the potential state-wide SCN registry



SCN = special care nursery; GenV = Generation Victoria.

Participant selection

Inclusion criteria

This registry aims to include all babies admitted to Victoria's 40 SCNs and recruited to GenV. *Exclusion criteria:* This registry will not include data for the 2,500 NICU babies per year eligible for ANZNN registry inclusion, i.e. babies who are <32 weeks' gestation, <1500 g birthweight, ventilated for >4 hrs or those that received therapeutic hypothermia or major surgery. *Estimated number:* This will depend on the uptake into GenV, which is not yet known; we estimate the sampling frame to be around 23,000 children ((14,000–2,500) × 2). As this is an opt-in process with informed consent (due to collection of biosamples and extended data linkage) uptake is likely to be lower than for the opt-out UK national neonatal research database (uptake rate around 96%). This in itself will provide important knowledge for future registries.

Minimum dataset and data extraction form

A GenV Newborns Working Group was established in 2019 to advise on opportunities and directions relating to newborn research in the GenV cohort, which has to date included this protocol and minimum dataset. The group comprises experts from multiple disciplines involved in newborn care, policy, research, and data collection and the neonatal/paediatric leads at hospitals with NICUs and SCNs. As GenV moves from recruitment to data management and release, composition of this group will evolve to potentially include all the principal investigators of studies that include participants from both GenV and the study itself (where a data sharing agreement is in place), representatives from the Australia and New Zealand Neonatal Network, and health care service providers. The composition of the working group will be reviewed annually, and with input from consumers and other end-users. The group meets 4 times/year to discuss progress of the project, any challenges or barriers to timely completion, and delivery of key performance indicators.

The minimum dataset was defined in the following steps:

1) In order to harmonise with the ANZNN dataset, our starting point was ANZNN data items that are relevant to babies in SCNs and not already collected by GenV directly or through data linkage with Victorian Perinatal Data Collection (VPDC).
2) The items unique to the ANZNN dataset were reviewed for relevance with neonatologist Professor Jeanie Cheong (Chair, GenV Newborns Working Group) and additional items relevant to SCN care added.
3) The items were circulated to the GenV Newborns Working Group for feedback and additional suggestions.
4) The expert feedback led to the final proposed SCN registry minimum dataset in Table 1, from which we developed the SCN Registry Data Extraction Form (Appendix 1).

Proposed data collection process and tools

The proposed data collection process comprises the following steps:

1) GenV-hospital authorisation and agreement with each site (see Ethics and Governance, below).
2) GenV data scientist creates a modified Australian Statistical Linkage Key (SLK-581) in GenV dataset and shares the keys with a hospital using GenV Owncloud account.
3) Designated hospital staff (in departments such as Health Information Services, Performance Units, Medical Records on a hospital-by-hospital basis) creates SLK-581 in hospital's dataset, undertakes matching and returns to GenV the linkage outcome (linked or not linked). Our pilot study drew on a one-year (births from 5 December 2020–31 December 2021) cohort for a single Australian birthing hospital selected as GenV's Vanguard on the basis of its large size and ethnically and socioeconomically diverse patient base. For 1819 consented mother-baby pairs and 58 additional babies (whose mothers were not themselves participating), approximately 93% of participants were linked using SLK-581 [17].

Table 1: Proposed SCN registry minimum data set

Maternal
Previous preterm birth
Antenatal
Maternal antibiotics in labour
Antenatal corticosteroids
Baby and birth
Date and time of birth
1st SCN admission (date, time and admitted from)
Intubated at resuscitation
Temperature at admission
Base excess after birth
Cord lactate and first lactate
Hypoxic-ischaemic encephalopathy
Seizures
Respiratory
Main indication for respiratory support
Surfactant
Method of administration of first dose of surfactant
Date and time of surfactant first given
Numbers of doses of surfactant
Air leak requiring drainage
Date and time of first drainage of pulmonary air leak
Respiratory support
IPPV (intermittent positive pressure ventilation)
Date and time intubated for ongoing ventilation
Date and time of final extubation from mechanical ventilation
Remain ventilated/ongoing ventilation at final discharge
Nasal CPAP (continuous positive airway pressure)
Date and time of initiation of nasal CPAP
Date and time of final cessation of nasal CPAP
Remain nasal CPAP at final discharge
Nasal high flow
Date and time of initiation of nasal high flow
Date and time of final cessation of nasal high flow
Remain nasal high flow at final discharge
Cardiac
Patent ductus arteriosus
Pharmacological treatment for patent ductus arteriosus
Infection
Probiotics
Infection (type and date of specimen)
Antibiotics/antiviral (name, date and time)
Nutrition
Parenteral nutrition
Date and time of initiation
Date and time of cessation
Remain parenteral nutrition at final discharge
Feeding
Breast milk feeding at onset of enteral feeds
Donor breast milk in any quantity
Breast milk (any) at discharge to home

Continued

Table 1: Continued

IVH and cranial ultrasound
Left and right IVH
Cerebellar haemorrhage
6-week head ultrasound
Other suggested items
Hypoglycaemia
Lowest blood glucose + date and time
Treatment
Signs
Neonatal abstinence syndrome
Maternal medication/substance use
Treatment
Jaundice
Highest total bilirubin (level + test date and time)
Treatment
Vitamin K given
Final destination from this hospital
Transferred to another hospital
Death
Discharge to home
How many admissions altogether to this special care nursery (SCN)?
Date of 2nd SCN admission and discharge
Date of 3rd SCN admission and discharge

4) GenV data scientist prepares and transfers minimum personally identifiable information (PII) of unlinked GenV participants in step (3) to the clinical sites to enable another attempt of matching. The participants' UR numbers will be used to assist with matching where this is available to GenV.

5) Hospital data staff undertakes the matching of unlinked participants and then returns to GenV the original PII of unlinked GenV participants and linkage outcome (linked or not linked). According to our pilot study at one hospital, approximately 3–4% of participants could be further linked [18].

6) GenV data scientist returns a final list of linked participants to the hospital.

7) Automated extraction of SCN variables into an Excel spreadsheet by designated authorised hospital staff from a combination of (a) hospital administrative datasets prepared for the Victorian Admitted Episodes Dataset (VAED) and Victorian Emergency Minimum Dataset (VEMD), (b) the Birthing Outcomes System (BOS), in which all Victorian birthing hospitals record standardised maternity and newborn data, and (c) the site's Electronic Medical Record (EMR) if used.

8) For any remaining data not retrieved via these automated routes, GenV staff with an honorary site appointment to undertake manual EMR and/or paper extraction into REDCap.

9) The hospital to transfer the retrieved SCN data to GenV via a secured architecture solution provided by GenV.

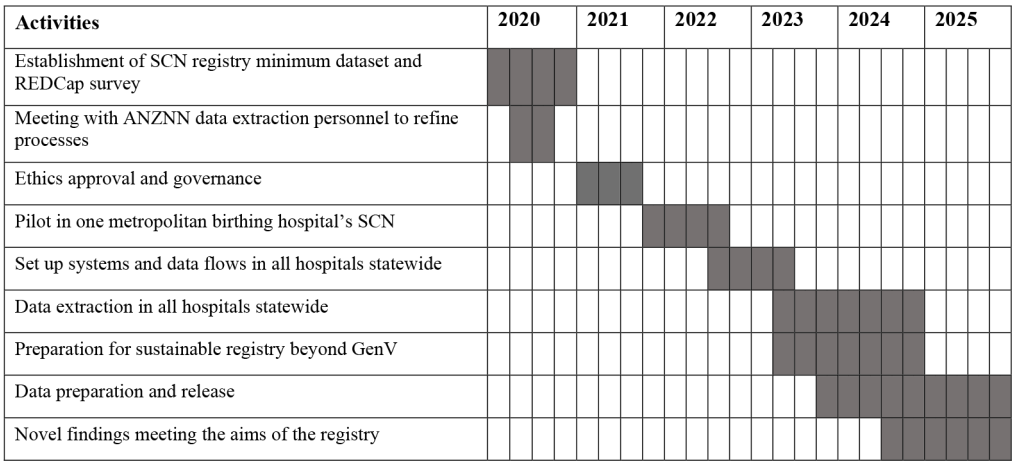
Engagement with SCNs

This work is advised by the GenV Newborns Working Group. Clinical site engagement is essential to success, including authorisation from Heads/Directors of the clinical sites for data extraction from neonatal unit records. Therefore, we will send an introductory letter to the Heads/Directors of SCNs to introduce the concept of GenV SCN registry and request general support of the intended data collection. Each site will complete a site assessment survey regarding number and flow of admissions, feasibility of extracting the proposed dataset and the form (paper/electronic) of its medical records. Their feedback will enable potential issues to be raised and processes to be fine-tuned. The following will be vital to mitigate the potential risk of non-support from key stakeholders at SCNs: early engagement, a strong value proposition, identifying a key contact person at each site, and regular communication between the project team and service teams. Between-site process variations in data extraction could reduce data consistency and thus value; to mitigate this risk, we will develop a clear overarching data architecture and flows that are consistent yet flexible across all sites.

Timeline

Figure 2 provides an overview of the protocol timeline. The first stage of this protocol, including the generation of the SCN minimum dataset, preliminary clinical site engagement and a pilot study of participant matching and data extraction, has already taken place as of October 2022. Formal engagement and agreements with clinical sites to refine the dataset and enable future data collection are projected to occur in late 2022/early 2023. The later activities of the protocol

Figure 2: Timelines for SCN registry within GenV



SCN = special care nursery; GenV = Generation Victoria.

(from early 2023 through 2024) include participant matching, data extraction and storage and subsequent utilisation of the generated registry data for quality initiatives, primary publications, future research and guidelines. We will be applying for funding in parallel with these activities which will be material to the outcomes of this work.

Data management

The GenV data management team will be responsible for the quality checks of the SCN data before loading the data for end users. These will span completeness, usability (ensuring formatting of variables is suitable for researchers), validity (confirming no impossible values) and accessibility (excluding or changing variables that are not suitable for researchers).

Data analysis plan

This dataset will support multiple questions for a range of risks and conditions including circumstances of rare events and small effect sizes. The primary description will include the incidence estimation of key high-risk conditions and their co-occurrence for the full cohort, by level of care, by sector, and according to recorded perinatal risk factors. Once integrated with the ongoing GenV datasets and supported by high-quality data and strong research design, this registry will enable exploration of potential causal relationships of neonatal conditions and risk/protective factors with children's long-term outcomes. It will also support examination of variations in care, explore relationships between different care pathways (from the first point of antenatal contact up to 2 years) and child outcomes. Last, as GenV's recruitment period overlapped with the COVID-19 pandemic, it could support research into the effects of the SARS-CoV-2 virus and of the pandemic more broadly on these vulnerable babies.

The proposed dataset has several novel axes. It is Australia's first SCN registry that includes all birthing hospitals. As it spans every service in all areas, it can summarise whole-of-state neonatal care and its variations on multiple parameters such as metro/regional/rural, public/private and disadvantage. Its comprehensive clinical data (see Table 1) are not well captured in any current collated administrative or clinical database. Lastly, partnering with GenV to access its linked administrative and clinical data, biosamples and long-term child outcomes expands the scope and time horizon of research questions that can be addressed.

Ethics and governance

Ethical approval is in place for the GenV cohort (Royal Children's Hospital Human Research Ethics Committee (HREC)-2019/11), including consent to access clinical data. During recruitment, one primary parent/guardian is asked to provide consent for themselves and their child (index participant), and any additional parents/guardians are asked to consent for themselves only. At consent, parents provide broad consent for GenV to access (1) current and future clinical and service records, from primary sources (such as general practitioners (e.g., Medical Director) and hospitals (e.g., electronic medical records) and from secondary collated sources (e.g., My Health Record, National Disability Insurance Scheme (NDIS), Maternal and Child Health); and (2) administrative data (e.g., health (Medicare), education (National Assessment Program – Literacy and Numeracy (NAPLAN)) and social (Centrelink). This includes all electronic health record and service data available, including demographics, visits, assessments, diagnoses, procedures, vital signs, medications, laboratory and notes. Before clinical data extraction commences at each location, GenV will work with the hospital to obtain governance authorisation, including site-specific assessment (SSA) to augment GenV's overarching ethical approval and material transfer agreement (MTA).

Dissemination of the findings

We anticipate that members of the GenV Newborns Working Group will be instrumental in a range of formal and informal dissemination activities to their peers throughout the state.

In order to foster the conditions for a successful long-term Clinical Quality Registry (CQR) beyond the GenV birth window, the SCN Registry will work towards achieving all Operating Principles for CQRs (Appendix 2), as outlined in the *Framework for Australian Clinical Quality Registries* developed by the Australian Commission on Safety and Quality

in Healthcare [19]. All data will be stored and accessed via GenV's already-built data repository operating under FAIR [20] and Five Safes [21] principles.

GenV is committed to an Open Science philosophy to the greatest extent possible within ethical and legal requirements, with completed waves of GenV datasets (once cleaned and prepared) made available to end-user researchers and analysts. We do not anticipate any periods of exclusive individual use for the GenV SCN registry data. Ultimately, released completed waves of GenV datasets and biosamples will be available to end-user researchers and analysts.

GenV will maintain on its website a summary of publications and outputs to the best of its knowledge. It will disseminate this via media releases, printed brochures and online summaries, social media, blogs, working papers, forums for diverse audiences (public, policy, clinical, academic etc) and featured posts on the GenV website. Reports may also be posted on Figshare, a publicly accessible online repository where researchers share their research outputs. GenV will provide participants with periodic overviews of findings, and direct them to the other forms of dissemination above.

Conclusion

Many of the significant health problems Australians increasingly face have their roots in early life. By embedding the features of a Clinical Quality Registry, the GenV SCN registry will be able to systematically address multiple questions relating to causal and care pathways for high-risk babies, enhancing translation into standardised healthcare that is accessible to everyone. Should it demonstrate a high level of acceptability and value, there may be the opportunity to transition this GenV-dependent registry into a formal ongoing clinical registry after GenV recruitment ends, supporting quality improvement activities for years to come.

Funding statement

No specific funding was secured for the development of this protocol. JW is supported by a Melbourne Children's LifeCourse postdoctoral fellowship, funded by Royal Children's Hospital Foundation grant [2018-984] and the Jack Brockhoff Foundation Early Career Medical Research Grant. MW is supported by the Australian National Health and Medical Research Council Principal Research Fellowship 1160906. Generation Victoria (GenV) is supported by grants from the Victorian government, the Paul Ramsay Foundation, and the Royal Children's Hospital Foundation. Research at the Murdoch Children's Research Institute is supported by the Victorian Government's Operational Infrastructure Program. JC is supported by the Medical Research Future Fund Career Development Fellowship 1141354.

Conflicts of interest

The authors have no potential conflicts of interest to disclose.

Ethics statement

The Royal Children's Hospital Human Research Ethics Committee approved the GenV cohort ((HREC)-2019/11), including consent to access clinical data.

References

1. Australian Institute of Health and Welfare 2020. Australia's mothers and babies 2018: in brief. Perinatal statistics series no. 36. Cat. no. PER 108. Canberra: AIHW.

2. Sammallahti S, Heinonen K, Andersson S, Lahti M, Pirkola S, Lahti J, Pesonen AK, Lano A, Wolke D, Eriksson JG, Kajantie E, Raikkonen K. Growth after late-preterm birth and adult cognitive, academic, and mental health outcomes. Pediatr Res. 2017 May;81(5):767–74. https://doi.org/10.1038/pr.2016.276

3. WHO. World Health Organization. Care of the preterm and low-birth-weight newborn. Accessed on 20/01/2023. https://apps.who.int/iris/bitstream/handle/10665/363697/9789240058262-eng.pdf 2022.

4. Saigal S, Doyle LW. An overview of mortality and sequelae of preterm birth from infancy to adulthood. Lancet (London, England). 2008 Jan 19;371(9608):261–9. https://doi.org/10.1016/S0140-6736(08)60136-1

5. Hunt RW, Hickey LM, Burnett AC, Anderson PJ, Cheong JLY, Doyle LW. Early surgery and neurodevelopmental outcomes of children born extremely preterm. Archives of disease in childhood Fetal and neonatal edition. 2018 May;103(3):F227–f32. http://doi.org/10.1136/archdischild-2017-313161

6. Cheong JL, Doyle LW, Burnett AC, Lee KJ, Walsh JM, Potter CR, Treyvaud K, Thompson DK, Olsen JE, Anderson PJ, Spittle AJ. Association Between Moderate and Late Preterm Birth and Neurodevelopment and Social-Emotional Development at Age 2 Years. JAMA pediatrics. 2017 Apr 3;171(4):e164805. http://doi.org/doi:10.1001/jamapediatrics.2016.4805

7. Cheong JL, Doyle LW. Long Term Outcomes in Moderate and Late Preterm Infants. Emerging Topics and Controversies in Neonatology: Springer; 2020. p. 403–13.

8. Petrou S, Eddama O, Mangham L. A structured review of the recent literature on the economic consequences of preterm birth. Archives of disease in childhood Fetal and neonatal edition. 2011 May;96(3):F225–32. http://doi.org/10.1136/adc.2009.161117

9. Wilcox N, McNeil JJ. Clinical quality registries have the potential to drive improvements in the appropriateness of care. The Medical journal of Australia. 2016 Nov 21;205(10):S27–S9. https://doi.org/10.5694/mja15.00921

10. Fonarow GC. Improving quality of care and outcomes for heart failure. -Role of registries. Circulation journal : official journal of the Japanese Circulation Society. 2011;75(8):1783–90. https://doi.org/10.1253/circj.CJ-11-0582

11. Kodra Y, Weinbach J, Posada-de-la-Paz M, Coi A, Lemonnier SL, van Enckevort D, Roos M, Jacobsen A, Cornet R, Ahmed SF, Bros-Facer V, Popa V, Van Meel M, Renault D, von Gizycki R, Santoro M, Landais P, Torreri P, Carta C, Mascalzoni D, Gainotti S, Lopez E, Ambrosini A, Muller H, Reis R, Bianchi F, Rubinstein YR, Lochmuller H, Taruscio D. Recommendations for Improving the Quality of Rare Disease Registries. International journal of environmental research and public health. 2018 Aug 3;15(8). https://doi.org/10.3390/ijerph15081644

12. Chow SSW, Creighton, P., Chambers, G.M., Lui, K. Report of the Australian and New Zealand Neonatal Network 2018. Sydney: ANZNN; 2020.

13. Modi N. Information technology infrastructure, quality improvement and research: the UK National Neonatal Research Database. Translational Pediatrics. 2019;8(3):193.

14. Wang J, Hu YJ, Clifford S, Goldfeld S, Wake M. Selecting life course frameworks to guide and communicate large new cohort studies: Generation Victoria (GenV) case study. Journal of developmental origins of health and disease. 2021 Dec;12(6):829-48. https://doi.org/10.1017/S2040174420001245

15. Wake M, Hu YJ, Warren H, Danchin M, Fahey M, Orsini F, Pacilli M, Perrett KP, Saffery R, Davidson A. Integrating trials into a whole-population cohort of children and parents: statement of intent (trials) for the Generation Victoria (GenV) cohort. BMC Med Res Methodol. 2020 Sep 24;20(1):238. https://doi.org/10.1186/s12874-020-01111-x

16. CCOPMM. Victoria's Mothers, Babies and Children 2018. Safer Care Vic, Melbourne 2019.

17. Hu YJ, Fedyukova A, Wang J, Said JM, Thomas N, Noble E, Cheong JLY, Karanatsios B, Goldfeld S, Wake M. Improving cohort-hospital matching accuracy through standardization and validation of participant identifiable information. Children (Basel, Switzerland). 2022 Dec 7;9(12). https://doi.org/10.3390/children9121916

18. Hu YJ, Fedyukova A, Wang J, Said J, Thomas N, Noble E, Karanatsios B, Goldfeld S, Wake M. Improving cohort-hospital matching accuracy through stand-ardization and validation of participant identifiable infor-mation. Submitted to Children. 2022. https://doi.org/10.3390/children9121916

19. Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries. Sydney. ACSQHC, March 2014.

20. Wilkinson MD, Dumontier M, Aalbersberg IJ, Appleton G, Axton M, Baak A, Blomberg N, Boiten JW, da Silva Santos LB, Bourne PE, Bouwman J, Brookes AJ, Clark T, Crosas M, Dillo I, Dumon O, Edmunds S, Evelo CT, Finkers R, Gonzalez-Beltran A, Gray AJ, Groth P, Goble C, Grethe JS, Heringa J, t Hoen PA, Hooft R, Kuhn T, Kok R, Kok J, Lusher SJ, Martone ME, Mons A, Packer AL, Persson B, Rocca-Serra P, Roos M, van Schaik R, Sansone SA, Schultes E, Sengstag T, Slater T, Strawn G, Swertz MA, Thompson M, van der Lei J, van Mulligen E, Velterop J, Waagmeester A, Wittenburg P, Wolstencroft K, Zhao J, Mons B. The FAIR Guiding Principles for scientific data management and stewardship. Scientific data. 2016 Mar 15;3:160018. https://doi.org/10.1038/sdata.2016.18

21. Desai T, Ritchie F, Welpton R. Five Safes: designing data access for research. 2016. https://doi.org/10.13140/RG.2.1.3661.1604

Abbreviations

ANZNN:	Australia and New Zealand Neonatal Network
BOS:	Birthing Outcomes System
CQR:	Clinical Quality Registry
EMR:	Electronic Medical Record
GenV:	Generation Victoria
HREC:	Human Research Ethics Committee
MTA:	Material Transfer Agreement
NAPLAN:	National Assessment Program – Literacy and Numeracy
NDIS:	National Disability Insurance Scheme
NICU:	Neonatal Intensive Care Unit
PII:	Personal Identifiable Information
REDCap:	Research Electronic Data Capture
SCN:	Special Care Nursery
SLK-581:	Statistical Linkage Key
SSA:	Site-specific assessment
VAED:	Victorian Admitted Episodes Dataset
VEMD:	Victorian Emergency Minimum Dataset
VIHSP:	Victorian Infant Hearing Screen Program
VPDC:	Victorian Perinatal Data Collection

Appendix 1: SCN data extraction FORM

ELIGIBILITY

Inclusion criteria: All babies admitted to Victoria's 5 NICUs and 40 SCNs, and born 5th Dec 2021-Dec 31st 2023.
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 1st SCN admission: / / Time: :

Admitted from:
☐This hospital (Delivery suite or Postnatal ward)
☐Other hospital, specify hospital:
☐Home (incl. by emergency department)

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 (e.g. MIST)
☐Other (e.g. 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 at time of final discharge: ☐Yes ☐No

Nasal CPAP: ☐No ☐Yes ☐Unknown

If Yes:

Date nasal CPAP commenced: / / Time: :

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

Remain nasal CPAP at time of final discharge: ☐Yes ☐No

Nasal high flow: ☐No ☐Yes ☐Unknown

If Yes:

Date nasal high flow commenced: / / Time: :

Date nasal high flow ceased: / / Time: :

Remain nasal high flow at time of final discharge: ☐Yes ☐No

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: :

Remain parenteral nutrition at time of final discharge: ☐Yes ☐No

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

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

☐ Grade 4 extensive ☐ Note examined
☐ Note examined

Cerebellar haemorrhage:

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

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

Final destination from this hospital

☐Transferred to another hospital

Specify hospital:

Date of transfer: / /

or

☐ Death (Date: / /)

or

☐ Discharge to home (Date: / /)

How many admissions altogether to this SCN?

□ Only one admission

□ Two or more admissions

If two or more, record admission and discharge dates for the 2nd and subsequent admissions (maximum 3 admissions)

Date of 2nd SCN admission: / /

Date of 2nd SCN discharge: / /

Date of 3rd SCN admission: / /

Date of 3rd SCN discharge: / /

Appendix 2: Operating Principles for Clinical Quality Registries (CQR) development (from Principles, guidelines and standards for CQR development section), endorsed by Australia's Health Ministers in November 2010

Attributes of clinical quality registries

1. CQRs must be developed with clear and precisely defined purposes aimed at improving the safety and/or quality of health care.
2. For CQRs to provide the maximum value to the health system they must focus their core data collection on the essential elements required to serve their main purposes.
3. Data collected by CQRs must be confined to items that are epidemiologically sound, i.e. simple, objective, and reproducible, valid (including for risk adjustment) and related to a specific case definition.
4. Methods used to collect data in CQRs must be systematic, with identical approaches used at the different institutions contributing information.
5. Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.
6. In determining the time to outcome assessment, CQRs must consider the burden and cost of data collection together with the likelihood of loss to follow-up.
7. CQRs should seek to ensure that complete CQR data are collected from the entire eligible population.

Data collection

8. The collection of data for a CQR should maintain an appropriate balance between the time and cost of data collection and the impact on patient care, particularly where clinicians are directly involved in data collection. The collection of data must not be an unreasonable burden on consumers, nor incur any cost to consumers.
9. Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors.
10. Data should be uniformly and easily accessible from the primary data source.
11. Standard definitions, terminology and specifications must be used in CQRs to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other CQRs and other databases (if approved by relevant ethics committees, etc.).
12. CQRs must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. CQRs must publish their eligibility criteria, metadata, data dictionaries, etc.
13. To avoid duplicating data capture, CQRs should use data from existing data sources, including administrative data, where they are of a satisfactory quality.
14. CQRs should have the capacity to enhance their value through linkage to other disease and procedure CQRs or other databases.

Data elements

15. CQRs must collect sufficient patient identifying information to support the CQR's stated purpose. Most clinical quality registries would require individually identifiable data, for which use of national Individual Healthcare Identifiers is recommended.
16. Where patterns or processes of care have an established link to outcomes and process measures that are simple, reliable and reproducible, they should be considered for collection by CQRs.
17. Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools.

Risk adjustment

18. CQRs must collect objective, reliable co-variates for risk adjustment to enable factors outside the control of clinicians to be taken into account by the use of appropriate statistical adjustments.

Data security

19. To protect CQR data, CQRs must use secure access controls and secure electronic transfer and electronic messaging systems.
20. The collection, storage and transmission of clinical CQR data must be in accordance with relevant legislation, regulation, principles, standards and guidelines.

Ensuring data quality

21. CQRs must report as a quality measure the percentage of eligible patients recruited to the CQR.
22. CQRs must have a robust quality assurance plan which allows ongoing monitoring of the completeness and accuracy of the data collected.
23. CQR data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data must be identified by the data centre and remedied as soon as possible.

24. CQRs should incorporate in-built data management processes such as data range and validity checks.

Organisation and governance

25. CQRs must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the CQR.

26. CQRs must establish policies to manage a range of contingencies arising from the analysis of data from the CQR, which includes a formal plan ratified by the CQR Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately.

Data custodianship

27. Custodianship of CQR data must be made explicit in contracts and/or funding agreements. CQRs should make clear, publicly available statements of data custodianship.

28. Data access and reporting policies for CQRs must be made available to persons wishing to use CQR data. CQRs should make data access and reporting policies publicly available.

29. Third parties wishing to access data and publish findings must seek approval from the CQR Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data is sought.

Ethics and privacy

With the exception of instances where data collection has been mandated through legislation or enabled through regulation or legislation:

30. Appropriate ethics approval must be obtained to establish and maintain the CQR.

31. CQR personnel must be familiar with and abide by the requirements set out in relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

32. Participants or their next of kin must be made aware of the collection of CQR data. They must be provided with information about the CQR, the purpose to which their data will be put and provided with the option to not participate. This must be at no cost to the CQR participant.

33. Where projects are undertaken using CQR data, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity.

Information output

34. Data from CQRs must be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.

35. CQRs must report without delay on risk-adjusted outcome analyses to all CQR stakeholders in accordance with agreed reporting requirements of the CQR.

36. CQRs should verify data collected using a formalised peer review process prior to publishing findings.

37. Clinicians and/or staff at contributing units should have the capacity to undertake ad-hoc analyses of the data they contribute to the CQR to enable monitoring of clinical care.

38. CQRs must produce a publicly accessible, annual report detailing aggregated clinical and corporate findings.

39. CQR reports must be produced according to a strict timeline and should demonstrate funding to enable this to occur.

40. CQRs must have documented procedures, including methods employed, for reporting on quality of care, including addressing outliers or unexplained variance.

Resources and funds

41. CQRs should demonstrate sufficient funding is allocated to allow data collection, reporting and the institution of strong quality assurance procedures.