PACS Study Governance

1. Introduction

1.1 Project summary

Each year up to 600 Australian children suffer a stroke; 1 in 20 die and more than half of survivors experience long-term impairments. Time-critical reperfusion therapies to salvage brain are key to improving outcomes but there is a huge gap between adults and children in accessing these treatments.

The Australian Paediatric Acute Code Stroke (PACS) study (the Project) is a partnership project between the Murdoch Children's Research Institute and Stroke Foundation along with researchers, health professionals and patients with the aim of transforming the care of children with stroke by decreasing time to diagnosis and increasing the number of children receiving reperfusion therapies. This will be achieved through the development and implementation of a world first national PACS protocol, using innovative decision support tools and advanced imaging technologies.

> **Vision:** To improve health outcomes of Australian children affected by stroke by narrowing the gap between adults and children in accessing life-changing treatments.
>
> **Objective:** Bring childhood stroke diagnosis into the 4.5-hour time-window for reperfusion therapies

1.2 Project description and key activities

Objective

The objective of this study is to improve survival outcomes after paediatric stroke, bridging the inequity gap between adults and children in accessing reperfusion therapies through implementation of the PACS protocol.

Study design and setting

A staged, two-tiered pre- and post-intervention study design will be utilised to evaluate PACS. Seven paediatric hospitals will partner with adult comprehensive stroke centres to develop tailored PACS protocols. The tiers will consist of 6 sites that have not yet developed PACS protocols (Group 1), and 3 sites with established PACS protocols (Group 2).

The study will be led by an Advisory Group with members from the Stroke Foundation, Murdoch Children's Research Institute, and 8 paediatric hospitals in Australia and 1 in New Zealand. It will be undertaken in partnership with paramedics, paediatric ED physicians, paediatric neurologists, adult stroke neurologists, imaging experts, telemedicine providers, implementation scientists, health economics experts, biostatisticians, advocacy groups and consumers. Working in partnership will maximise the likelihood of effecting change across the care continuum from symptom onset to treatment on a national scale.

Project aims and outcomes

The PACS study is an exciting, essential and much needed step towards transformative improvements in treating children with stroke. A world first, innovative study, it has the potential to change the way stroke is treated in children nationally and internationally.

The primary aim of the study is to increase the proportion of children aged 1 month -18 years with stroke diagnosed within 4.5 hours.

The secondary aims are to:

- Increase the proportion of children receiving reperfusion therapies.
- Investigate the feasibility and utility of automated perfusion software (RAPID) to guide clinical decision making about reperfusion therapies.
- Improve the accuracy of paramedic and emergency department (ED) physician diagnosis by refining the Brain Attack and Stroke In Children Screen (BASICS) decision support tools.
- Demonstrate improvements in paramedic/ED physician practice and timelines of care pre- and post-PACS implementation.
- Measure the economic impact of shorter time to diagnosis and increased rates of reperfusion therapy.

Metrics to demonstrate effectiveness and efficiency of the PACS pathway will include:

1) time to diagnosis and treatment, length of stay (benchmarking across sites and with adult centres)

2) accuracy of clinical diagnosis

3) selection of the most sensitive first imaging modality

4) access to time-limited reperfusion therapies,

5) recruitment of subjects to national registries.

Given the roles of paediatric and adult stroke neurologists, and emergency physicians, as leaders in their fields of care, and in development of national best practice and advanced paediatric life support (APLS) guidelines, the PACS study will rapidly translate into improvements in clinical practice, and result in better outcomes for children impacted by stroke. This study will mean more Australian children can survive and live well after stroke.

In addition to improved neurological outcomes for children with stroke, the evidence gathered will inform stroke clinical practice guidelines, ambulance services and ED protocols, as well as educational programs such as APLS. The economic impact will include savings as a result of fewer unnecessary diagnostic investigations, and improved outcomes leading to a reduced burden of stroke on hospitals, families and the community.

Once PACS protocols are implemented and have been shown to be effective in tertiary paediatric centres, there is potential for adaptation of these protocols for use in rural and regional centres. There is also potential for the development of targeted public education to increase awareness of childhood stroke and maximise timely access to emergency treatment.

This research proposal is aligned with the goals of best practice national paediatric stroke guidelines, which include:

- reducing variations in care across Australian paediatric centres
- reducing time to diagnosis and treatment in the acute setting
- facilitating collaborative research to improve outcomes.

Project duration

The Project duration is 5 years. With a start date of 1 July 2020 and an end date of 30 June 2025.

Funding
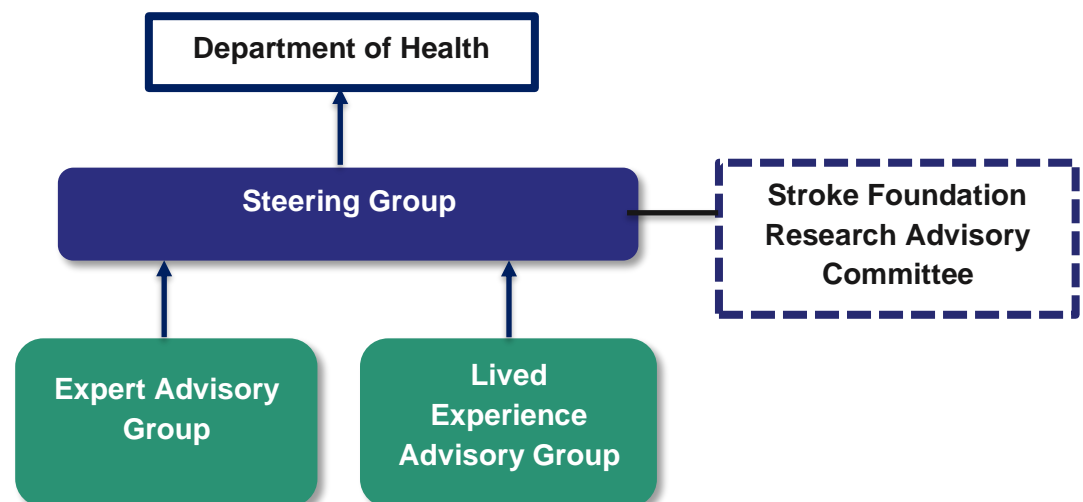
The Project is funded by an MRFF grant.

2. Governance

2.2. Governance structure

The governance structure of the PACS project is shown in Figure 1 below.

Figure 1: PACS governance structure

Role of Groups

Below is a summary of the role of the Steering Group, Expert Advisory Group and Lived Experience Advisory Group. Details about the working group operations and communications will be outlined in each of the respective Terms of Reference.

Steering Group

The role of the Steering Group will include oversight of governance, responsibility for milestone achievement, stewardship of financial performance against budget, and oversight of required reporting to the Department of Health.

The Steering Group will consist of Stroke Foundation CEO, ED Stroke Services, Stroke Foundation Clinical Council representative, PACS lead Chief Investigator, PACS Stroke Nurse Consultant, 2 x Stroke Nurse Consultants, Chief Investigators from the 9 paediatric hospitals, Chair of the Lived Experience Advisory Group.

PACS Expert Advisory Group

The role of the Expert Advisory Group is to oversee expert input into the project. The Expert Advisory Group will be Chaired by the PACS lead Chief Investigator. Members of the Expert Advisory Group will include PACS Stroke Nurse Coordinator and subject matter experts. The group will be responsible for identifying, engaging with and overseeing input from additional subject matter experts required to deliver the project. The Expert Advisory Group will report to the Steering Group.

Lived Experience Advisory Group

The role of the Lived Experience Advisory Group is to provide the Project with lived experience input and perspectives. The Chair of the Lived Experience Advisory Group will be a member of and report to the Steering Group.

Subject matter expertise

Table 1 outlines areas of expertise or content area representation which will be required to deliver the project. These content areas or stakeholder groups may be represented within the Steering Committee, Expert Advisory Groups or may be engaged separately by the Steering Group and/or the Expert Advisory Group.

Table 1: Subject matter expertise
Paediatric neurology
Paediatric emergency medicine
Adult stroke neurology
Medical imaging
Anaesthetics
Haematology
Neuro-interventional radiology
Paediatric intensive care
Cardiac services
Telemedicine providers
Ambulance services
Biostatisticians
AuSCR
Health economists
Cochrane Living Evidence