



Paediatric Research in
Emergency Departments
International Collaborative

PREDICT PROJECT REPORTS

**PREDICT Members Meeting
20th October 2021**

This report includes PREDICT projects and publications from the network commencement in 2004 to current project in 2021

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Executive Summary

The Paediatric Research in Emergency Departments International Collaborative (PREDICT) network, established in 2004, includes healthcare providers, research institutions, and researchers involved in paediatric emergency care across Australia and New Zealand. We are supported by a second NHMRC Centre of Research Excellence (CRE) grant 2020-2025. In addition, our ongoing research is supported by NHMRC and MRFF grants worth over \$17 million plus numerous additional funding of over \$1.3 million from philanthropic, Health services and charitable Foundation grants.

Our **Vision** is to establish an evidence base and improve emergency care for children and adolescents through rigorous research.

Our **Mission** is to improve the power and capacity of paediatric research by coordinating research activities among the participating institutions and providing a sustainable research infrastructure.

Behind all our research lies our commitment to achieve improvement in care for paediatric patients presenting to all emergency departments by adhering to our CRE aims:

- To improve the power of paediatric research activities by combining the efforts of individual institutions.
- To facilitate and coordinate research activities among the participating institutions.
- To create a research infrastructure for paediatric emergency medicine research on a national and international level in the participating countries.
- To mentor new investigators to improve research skills and develop research projects. This includes, but is not limited to, the support of research higher degree students of which there are 9 currently, and 9 who have completed their degree.

These aims place excellence, sustainability, generalisability and knowledge translation at the core of all our activities.

The **PREDICT Project Report (2021)** incorporates all research projects and publications produced by PREDICT since its inception until now, to show the breadth, depth and development of our various research streams. The research streams have evolved over time commencing with our initial studies evaluating the epidemiology and management of the commonest patient presentations across paediatric EDs, followed by the enhancement of our research agenda through a 3-step Delphi study with input from clinicians from tertiary and mixed EDs as well as consumer input. This has allowed us to understand the areas which require high-level multicentre research to address dilemmas in diagnosis and management.

Our **Trauma** stream undertook a 10-site prospective observational evaluation of head injuries, evaluating previously published international clinical decision rules concentrating on investigation. Following on from this study, we produced the evidence-informed **Australian and New Zealand Mild to Moderate Head Injury Guidelines** in 2020, along with the publication of over 20 sentinel papers on head injury evaluation.

The trauma stream's next multi-site large prospective observational study has commenced in evaluating paediatric acute neck injury in 2021, following preliminary work done in Queensland on cervical spine injury decision rules. This large study will again become a sentinel study on evaluation and management of a rare but potentially significant lifelong injury, which is anticipated to influence practice within our countries and across the world.

Studies on the recognition and novel therapies in major trauma and haemorrhage are being undertaken and or are in planning.

Our [Respiratory](#) stream commenced our involvement in the assessment and management of bronchiolitis through a NHMRC supported multi-centre RCT into fluid management for bronchiolitis, followed by the publication of the first evidence informed **Australasian Bronchiolitis Guideline** in 2017. We followed this with a program to develop expertise in knowledge translation and implementation science across PREDICT, as we recognized the need to not just produce the science but to effectively promote and translate the evidence into everyday practice, in order to embed improvement in care sustainably.

Within the respiratory stream, we continue to actively research into the diagnosis and management of asthma, pneumonia, COVID, croup, respiratory support techniques in acute respiratory failure, and ED airway management interventions and surveillance. Many of these studies are being undertaken in collaboration with international research networks (USA, Canada, UK, Europe and South America).

Excitingly, one of these studies is an, international multicentre RCT lead by the Canadian network (PERC), on drug therapy for bronchiolitis. This study has suffered significant challenges due to COVID restrictions and yet, we are coming to the end of our first ANZ recruiting year with 4 of 6 sites recruiting while the 6 Canadian sites are heading into their winter season.

Wide ranging studies are being undertaken by the [Infections and Sepsis](#) stream including international collaboration with the Pediatric Emergency Research Network (PERN) in the Influenza H1N1 pandemic, severe pneumonia management world-wide and more recently COVID presentations in the current pandemic. We have and continue to collaborate with our oncology and infectious diseases colleagues to explore ways to identify and manage low-risk neutropaenia in oncology patients.

Our relationship with the general paediatric research network (CIRCAN) is resulting in a new collaborative RCT exploring the differences on length of intravenous antibiotic therapy in children with complicated urinary tract infections. It is hoped this will lead to decreased hospital length of stay in a safe manner, by identifying the factors allowing reduced IV antibiotic duration.

In 2021 we have launched a large RCT on fluid therapy for children with severe sepsis in conjunction with the PECARN (USA) and PERC (Canada) networks. This pragmatic study is incorporating 11 Australian and NZ sites, including several mixed EDs, and is powered to demonstrate a difference in composite outcomes including death and renal function.

All our emergency departments are experiencing spikes in presentation of young people with mental health and behavioural disorders. The [Mental Health](#) stream is undertaking a suite of studies supported by the MRFF fund. These 5 studies include:

- Retrospective review of 100 randomly selected patients in 2019 at each site, exploring the frequency of repeated presentations and the factors influencing these presentations across the study sites.
- Delphi process with key stakeholders including ED, mental health staff, Police, Education, Ambulance services and most importantly patients and their families to define the priorities for research in the mental health area
- 2 RCTs exploring medications used for acute severe behavioural disorders presenting to ED are commencing towards the end of 2021 – Oral and IV medication arms.

- Prospective observational study of mental health presentations with active recruitment and follow up of young people, exploring methods to support the young people on discharge.

All these studies have been planned with consumers and broad consultation across EDs and acute mental health clinicians.

A major focus of PREDICT stems from the [Neurology](#) stream following the successful undertaking of a RCT of 2nd line intravenous therapy for management of status epilepticus in children, which resulted in amendment to national management algorithms for this condition. We also undertook a prospective registry over a 12-month period of children presenting with status epilepticus, to determine rates of recurrence and impacts on the child and their families. Through this work we engaged our consumers and explored aspects of consent in resuscitation scenarios.

The management of acute facial nerve palsy (Bell's palsy) has recently been explored through a blinded randomised controlled trial of prednisolone versus placebo, exploring outcomes for this common and potentially disfiguring condition, with publication pending. Another collaboration with neurology and radiology services is being undertaken supported through the MRFF, to identify and offer early neurology input and potentially re-perfusion procedures for children with acute strokes.

Broadly, a number of other studies have been or are being undertaken or are planned in the areas of abdominal pain/appendicitis assessment, linkage of databases on ED presentations to pre-hospital services, pathology service, pain and sedation management, education, knowledge translation and implementation.

Conclusion

The PREDICT Executive are pleased to present this report demonstrating the wide-ranging extent of research and knowledge translation taking place across the PREDICT network. The emphasis, at all times, is not just on producing world class research, but by keeping our patients and their families at the heart of everything we do, to ensure that we translate our vital research findings to improvement in acute care across all acute care settings in both our countries and beyond.

Meredith L Borland (Chair, PREDICT)

TRAUMA

HEAD INJURY

CURRENT PROJECTS

Project Title:	Australian Paediatric Head Injury Rules Study: Assessing the gap prior to implementation (APHIRST Gap)
Co-ordinating PI:	Franz Babl, Emma Tavender
Study coordinator:	Cate Wilson
Project aim/s:	The aims of this research were to i) determine the baseline CTB rate for a broad range of hospitals; ii) understand why there may be variations in CTB rates and iii) determine what resources are currently available and used by the ED community to inform their management of head injuries.
Study design:	Mixed methods: <ul style="list-style-type: none">- A multicentre retrospective medical record audit- Qualitative semi-structured telephone interviews with doctors and nurses.
Primary outcome:	Conduct a multi-centre medical records audit to: <ul style="list-style-type: none">a) Assess ED-level variation in the use of CT scanning of the brain (CTB) in the diagnosis of children with head injury in tertiary, urban, and rural/regional hospitals in Australia and NZ.b) Identify potential hospital and/or patient level factors associated with CTB use. Conduct qualitative research to: <ul style="list-style-type: none">a) Identify and explore the clinician and organisational related factors influencing the use of CTB at participating EDs in children with mild head injuries.b) Determine the resources available and used by clinicians in the ED to inform their management of mild head injuries; through qualitative research.
Current study status:	Study completed, data cleaned and analysed, publications underway.
Publications:	<p>Wilson CL, Tavender EJ, Phillips NT, Hearps SJ, Foster K, O'Brien SL, Borland ML, Watkins GO, McLeod L, Putland M, Priestley S, Brabyn C, Ballard DW, Craig S, Dalziel SR, Oakley E, Babl FE; PREDICT. Variation in CT use for paediatric head injuries across different types of emergency departments in Australia and New Zealand. Emerg Med J. 2020 Nov;37(11):686-689. doi: 10.1136/emmermed-2020-209719. Epub 2020 Aug 17. PMID: 32816840. [link]</p> <p>Wilson CL, Hearps SJ, Tavender EJ, Phillips NT, Lawton B, Kinnear F, Beattie A, Mitenko H, Young R, Cole J, Kochar A, George S, Teo SS, Georgeson T, Michael A, Mukherjee A, King A, Gamage L, Archer P, Cassidy C, Rao A, Thosar D, Borland ML, Babl FE. Factors predictive for computed tomography use and abnormality in paediatric head injuries in Australia and New Zealand. Emerg Med Australas. 2021 Feb;33(1):157-160. doi: 10.1111/1742-6723.13694. Epub 2020 Dec 22. PMID: 33354919. [link]</p>
Submitted to EMJ and pending acceptance:	Tavender EJ, Wilson CL, Dalziel S, Oakley E, Borland M, Ballard D, Cotterell E, Phillips N, Babl F. A qualitative study of emergency clinicians to inform a national guideline on the management of children with mild to moderate head injuries.

TRAUMA

HEAD INJURY

CURRENT PROJECTS

Project Title:	PREDICT Australian and New Zealand Guideline for Mild to Moderate Head Injuries in Children
Co-ordinating PI:	Franz Babl, Stuart Dalziel
Study coordinator:	Emma Tavender
Project aim/s:	Develop an evidence-based, locally applicable, practical clinical guideline for clinicians in Australia and New Zealand caring for children with mild to moderate head injury presenting to acute care settings.
Study design:	Adapted guideline development process
Primary outcome:	Objectives: <ul style="list-style-type: none">• improve outcomes for children who present with mild to moderate head injury including those with underlying complicating conditions;• identify all paediatric patients who have a clinically important intracranial injury in need of intervention, such as neurosurgery and/or intensive care; promote consistency of management;• reduce unnecessary interventions including inappropriate use of head CT scans in children at very low risk of intracranial injury; and• develop guidance for discharge and follow-up of children with mild to moderate head injuries
Current study status:	Guideline launched on the PREDICT website in February 2021: https://www.predict.org.au/head-injury-guideline/
Endorsement by:	ACEM, RACP, RACGP, RACS, APLS, ACRRM, Australian Haemophilia Centre Directors' Organisation (AHCDO), CENNZ, NZEMN, New Zealand Institute of Medical Radiation Technology (NZIMRT), Sports Medicine Australia (SMA), The Council of Ambulance Authorities Inc (CAA), The Australasian College of Paramedicine (ACP), The Paediatric Society of New Zealand (PSNZ). Two papers published in EMA (see below), 2x ACEM (2021) conference abstracts and DFTB training materials: https://dontforgetthebubbles.com/predicting-paediatric-traumatic-brain-injuries Currently developing an introductory video for the algorithm.
Publications:	Babl FE, Tavender E, Ballard DW, Borland ML, Oakley E, Cotterell E, Halkidis L, Goergen S, Davis GA, Perry D, Anderson V, Barlow KM, Barnett P, Bennetts S, Bhamjee R, Cole J, Craven J, Haskell L, Lawton B, Lithgow A, Mullen G, O'Brien S, Paproth M, Wilson CL, Ring J, Wilson A, Leo GS, Dalziel SR; (PREDICT). Australian and New Zealand Guideline for Mild to Moderate Head Injuries in Children. <i>Emerg Med Australas.</i> 2021 Feb 2. doi: 10.1111/1742-6723.13722. Epub ahead of print. PMID: 33528896. [link] Tavender E, Ballard DW, Wilson A, Borland ML, Oakley E, Cotterell E, Wilson CL, Ring J, Dalziel SR, Babl FE; (PREDICT). Review article: Developing the Australian and New Zealand Guideline for Mild to Moderate Head Injuries in Children: An adoption/adaption approach. <i>Emerg Med Australas.</i> 2021 Feb 2. doi: 10.1111/1742-6723.13716. Epub ahead of print. PMID: 33528917. [link]

TRAUMA

HEAD INJURY

CURRENT PROJECTS

Project Title:	Co-designing discharge communication strategies for paediatric minor head injuries.
Co-ordinating PI:	Emma Tavender/Franz Babl
Study coordinator:	Emma Tavender/Cate Wilson
Project aim/s:	To improve discharge communication currently provided to children presenting to the ED with mild to moderate head injuries (concussion). Specifically, adolescents who have an increased risk of post-concussion symptoms (PCS).
Study design:	Mixed Methods: stepped co-design method to engage consumers (parents and youths) and clinicians in the development of head injury discharge communication strategies.
Primary outcome:	Co-designed discharge communication strategies for adolescents with mild to moderate head injuries (concussion) with parents, youths and clinicians. Training materials that can be used for future co-design efforts. Advancement in the science of implementation and contribution to future discharge communication strategy development for other common paediatric ED presentations.
Current study status:	<ul style="list-style-type: none">• Ethics received from RCH and Western Health.• Recruitment in progress for co-design group (4 of 4 ED clinicians, 2 of 3 Youths and 2 of 3 parents of Adolescents recruited).• Training materials in development.• First meeting of four to be held by end of the year.

TRAUMA

NECK INJURY

CURRENT PROJECTS

Project Title:	SONIC – Study of Neck Injuries in Children
Co-ordinating PI:	Natalie Phillips, Franz Babl
Study coordinator:	Sharon O’Brien
Project aim/s:	Primary aim: To externally validate in children existing clinical decision rules (CDRs) by assessing the (i) accuracy of detecting cervical spine injury (CSI); (ii) the ability to accurately identify children who do not need cervical spine imaging; and (iii) the cost effectiveness of different CDRs.
Study design:	Multi-centre prospective observational study.
Primary outcome:	Performance accuracy (sensitivity, specificity, NPV, and PPV) in identifying the study defined CSI of (a) the Paediatric Emergency Care Applied Research Network (PECARN) risk criteria (b) the two adult-derived CDRs (National Emergency X-Radiography Utilization Study Low Risk Criteria (NEXUS) and Canadian C spine Rule(CCR)) and (c) current CSI management practice.
Current study status:	<ul style="list-style-type: none">• Ethics approval for all Australian sites obtained. NZ pending.• Recruitment commenced at Queensland Children’s Hospital on 7/9/2021.• Roll-out to 12 other participating sites planned in coming months – aiming for most sites to commence by end of 2021. Hospitals involved: RCH, QCH, PCH, Westmead, W&CH Adelaide, Starship Children’s, SCH, Monash Medical Centre, Kidz First, Gold Coast University, Logan, Royal Darwin/Palmerston, Sunshine Coast University.

TRAUMA

MAJOR HAEMORRHAGE

CURRENT PROJECTS

Project Title:	Composition and Quality of Major Haemorrhage Protocols (MHP) and critical bleeding clinical practice guidelines in hospitals across the PREDICT network.
Co-ordinating PI:	Shane George / Elliot Long
Study coordinator:	Elizabeth Wake
Project aim/s:	To compare paediatric Major Haemorrhage Protocols (MHP) and critical bleeding clinical practice guidelines in hospitals across the PREDICT network for content and quality.
Study design:	Comparative review of Major Haemorrhage and Critical Bleeding guidelines and algorithms of participating centres.
Primary outcome:	Outcomes will describe differences in the MHP across sites, we will also analyse for patterns of difference between different hospital types. Quality of the guidelines will be reported using the AGREE II framework. Clinical Practice Guidelines will be compared for: <ul style="list-style-type: none">• Activation criteria• Deactivation criteria• Blood product delivery schedule, with specific focus on the timing of fibrinogen replacement in the schedule.• Blood products and factors available at the site• Operational factors (e.g. how to activate, who co-ordinates products, how are products delivered)• Non transfusion specific targets (temperature, pH, Calcium, etc)• Monitoring of coagulation status (frequency, testing method, etc)• Treatment thresholds based on coagulation results• Indications for anti-fibrinolytic medications• Current study status: Data collection in process, guidelines received from 21 hospitals date.

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

Project Title:	Nasal High Flow Therapy for Children with Acute Hypoxemic Respiratory Failure - a Randomised Controlled Trial – PARIS II Trial.
Co-ordinating PI:	Andreas Schibler/Franz Babl
Study coordinator:	Donna Franklin
Project aim/s:	To investigate in a randomised controlled trial performed in children aged 1-4 years presenting with acute hypoxemic respiratory failure if the early use of NHF therapy reduces the hospital length of stay when compared to standard oxygen therapy.
Study design:	A phase III randomised controlled trial.
Primary outcome:	The primary outcome is defined as hospital length of stay.
Current study status:	PARIS II has completed data cleaning and unlocked the dataset late August 2021. 1517 patients recruited (Sample size was 1512). Currently analysing data for write up of main outcome results. Draft manuscript ready for results to be dropped in. Appendices 70% written. Soon ready for circulation amongst PIs. SAP paper uploaded onto ANZ registry – prior to unlocking dataset. Plan: <ol style="list-style-type: none">1. Publish main results in peer reviewed journal – aim for high-ranked journal again.2. Commence secondary outcomes papers immediately thereafter – following discussion with PI's on priority level.
Publications:	<p>Franklin D, Shellshear D, Babl FE, Schlapbach LJ, Oakley E, Borland ML, Hoepfner T, George S, Craig S, Neutze J, Williams A, Acworth J, McCay H, Wallace A, Mattes J, Gangathimn V, Wildman M, Fraser JF, Moloney S, Gavranich J, Waugh J, Hobbins S, Fahy R, Grew S, Gannon B, Gibbons K, Dalziel S, Schibler A; PARIS and PREDICT. Multicentre, randomised trial to investigate early nasal high-flow therapy in paediatric acute hypoxaemic respiratory failure: a protocol for a randomised controlled trial-a Paediatric Acute respiratory Intervention Study (PARIS 2). BMJ Open. 2019 Dec 18;9(12):e030516. doi: 10.1136/bmjopen-2019-030516. PMID: 31857300; PMCID: PMC6937038. [link]</p> <p>Franklin D, Shellshear D, Babl FE, Hendrickson R, Williams A, Gibbons K, McEnery K, Kennedy M, Pham TM, Acworth J, Levitt D, Oakley E, Schibler A; PARIS and PREDICT. High flow in children with respiratory failure: A randomised controlled pilot trial – A paediatric acute respiratory intervention study. J Paediatr Child Health. 2020 Dec 30. doi: 10.1111/jpc.15259. Epub ahead of print. PMID: 33377568. [link]</p>

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

Project Title:	Knowledge Translation Bronchiolitis Study
Co-ordinating PI:	Stuart Dalziel and Ed Oakley
Study coordinator:	Libby Haskell
Project aim/s:	To determine the effectiveness of targeted, theory-informed implementation interventions versus passive dissemination of an evidence-based bronchiolitis guideline, in reducing inappropriate therapies in infants with bronchiolitis.
Study design:	Multi-centre, cluster randomised controlled trial. Twenty-six hospitals (Australian=20; New Zealand=6) randomised (intervention group=13; control group=13), including 7 Australian tertiary paediatric hospitals.
Primary outcome:	Compliance during the first 24 hours of hospitalisation with no use of CXR, salbutamol, glucocorticoids, antibiotics, and adrenaline occurred in 1,631 (85.1%, 95%CI 82.6-89.7%) infants in the intervention group and 1,321 (73.0%, 95%CI 65.3-78.8%) infants in the control group (adjusted risk difference [RD] for baseline stratification factors (14.1%, 95%CI 6.5%-21.7%, p<0.001).
Current study status:	Study is completed and analysed.
Publications:	
	Haskell L, Tavender EJ, Wilson C, O'Brien S, Babl FE, Borland ML, Cotterell L, Schuster T, Orsini F, Sheridan N, Johnson D, Oakley E, Dalziel SR; PREDICT. Implementing evidence-based practices in the care of infants with bronchiolitis in Australasian acute care settings: study protocol for a cluster randomised controlled study. BMC Pediatr. 2018 Jul 6;18(1):218. doi: 10.1186/s12887-018-1187-7. PMID: 29980177; PMCID: PMC6035428. [Link]
	O'Brien S, Borland ML, Cotterell E, Armstrong D, Babl F, Bauert P, Brabyn C, Garside L, Haskell L, Levitt D, McKay N, Neutze J, Schibler A, Sinn K, Spencer J, Stevens H, Thomas D, Zhang M, Oakley E, Dalziel SR; PREDICT Network, Australasia. Australasian bronchiolitis guideline. J Paediatr Child Health. 2019 Jan;55(1):42-53. doi: 10.1111/jpc.14104. Epub 2018 Jul 15. PMID: 30009459. [Link]
	O'Brien S, Borland ML, Oakley E, Dalziel S, Babl FE. Letters to the Editor: National guidelines for bronchiolitis. J. Paediatr. Child Health. 2019 June 2. 55(2019) 728–729, PMID: 31155791. DOI: 10.1111/jpc.14463. [link]
	Haskell L, Tavender EJ, Wilson C, Babl FE, Oakley E, Sheridan N, Dalziel SR; PREDICT network, Australia. Understanding factors that contribute to variations in bronchiolitis management in acute care settings: a qualitative study in Australia and New Zealand using the Theoretical Domains Framework. BMC Pediatr. 2020 May 1;20(1):189. doi: 10.1186/s12887-020-02092-y. PMID: 32357866. [Link]
	Haskell L, Tavender EJ, Wilson CL, O'Brien S, Babl FE, Borland ML, Cotterell E, Schembri R, Orsini F, Sheridan N, Johnson DW, Oakley E, Dalziel SR; PREDICT Network. Effectiveness of Targeted Interventions on Treatment of Infants With Bronchiolitis: A Randomized Clinical Trial. JAMA Pediatr. 2021 Aug 1;175(8):797-806. doi: 10.1001/jamapediatrics.2021.0295. PMID: 33843971; PMCID: PMC8042564. [Link]

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

Knowledge Translation Bronchiolitis Study (contd.)

Publications:

Haskell L, Tavender EJ, Wilson CL, O'Brien S, Babl FE, Borland ML, Cotterell E, Sheridan N, Oakley E, Dalziel SR; PREDICT network, Australasia. **Development of targeted, theory-informed interventions to improve bronchiolitis management.** BMC Health Serv Res. 2021 Aug 3;21(1):769. doi: 10.1186/s12913-021-06724-6. PMID: 34344383.

Process evaluation - accepted BMC Health Services Research, 2021. [\[Link\]](#)

Haskell L, Tavender EJ, O'Brien S, Wilson CL, Borland ML, Cotterell E, Babl FE, Zannino D, Sheridan N, Oakley E, Dalziel SR. **Can targeted interventions change the factors influencing variation in management of infants with bronchiolitis? A survey of Australian and New Zealand clinicians: A paediatric research in emergency departments international collaborative (PREDICT) study.** J Paediatr Child Health. 2021 Sep 9. doi: 10.1111/jpc.15710. Epub ahead of print. PMID: 34498782. [\[Link\]](#)

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

Project Title:	Reducing the overuse of proven ineffective interventions in infants with bronchiolitis. Developing an evidence-based implementation intervention package for national roll-out.
Co-ordinating PI:	Meredith Borland
Study coordinator:	Sharon O'Brien
Project aims:	To operationalise the findings of the Knowledge Translation in Bronchiolitis cluster RCT which demonstrated implementation tools to improve bronchiolitis care. In this study we aim to demonstrate adaptations required to effectively implement support materials prior to national roll out of the tools.
Study design:	A multi-centred mixed method study of management of children with bronchiolitis following the implementation of interventions shown to reduce the use of low value interventions.
Outcome:	<ul style="list-style-type: none">• Operationalise the core components of the PREDICT bronchiolitis implementation strategies for use in four West Australian hospital emergency departments. Implementation of these strategies will be done using a structured/documented local adaptation process.• Evaluate the impact of the implementation strategies on the uptake of the Australasian Bronchiolitis Guideline at each site.• Understand the uptake and adaptation of the implementation strategies by conducting process evaluation of the implementation strategy and tracking the local adaptation process at each site.• Refine the National Bronchiolitis Implementation Support Package for national roll out.
Current study status:	<ul style="list-style-type: none">• This project is underway at four West Australian sites (PCH, Rockingham General Hospital, Armadale Hospital and Bunbury Regional Hospital EDs).• All sites have appointed and trained local opinion leaders (clinical leads) who are delivering tailored educational sessions, providing promotional material/reminders to staff and undertaking monthly audit and feedback.• Tracking of all education is recorded by each site. Regular contact and support is provided by the lead site to maintain engagement and site participation and minimise any potential issues.• Sites are auditing 2019 patient data which will be utilised to evaluate the impact of the strategies at each site. This data will be compared to similar data collected from the audit on patients who presented in 2021.• Each site will also undertake qualitative interviews to define the adaptations and strategies undertaken. Collection of this data will commence at the end of 2021 with manuscript preparation into 2022.

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

Project Title:	A randomized controlled trial comparing epinephrine and dexamethasone to placebo in the treatment of infants with bronchiolitis (BIPED)
Co-ordinating PI:	Meredith Borland, Stuart Dalziel and Amy Plint
Study coordinator:	Sharon O’Brien (Aust) and Megan Bonisch (NZ)
Project aim/s:	A multicentre clinical trial that will compare nebulized epinephrine and two doses of oral dexamethasone (over two days) to nebulized saline and oral placebo.
Study design:	We will conduct a phase III multicenter, randomized, double-blind trial comparing treatment with nebulized epinephrine and 2-day course of oral dexamethasone to placebo for infants with bronchiolitis.
Primary outcome:	Primary Objective: To determine if treatment of infants presenting with bronchiolitis to the emergency department (ED) with nebulized epinephrine and a 2-day course of oral dexamethasone is effective in reducing the need for admission to hospital (due to bronchiolitis) by day 7 post enrolment compared to placebo. Secondary Objectives: (1) To determine if treatment of infants presenting with bronchiolitis to the ED with nebulized epinephrine and a 2-day course of oral dexamethasone is effective in reducing admissions to hospital (for bronchiolitis) at enrolment ED visit compared to placebo. (2) To determine if there is a difference between groups in all cause admission within 21 days post enrolment, all cause health care provider visits over 21 days post enrolment, and health care-related costs. Safety Objectives: To examine the safety of epinephrine and dexamethasone when used to treat bronchiolitis among infants.
Current study status:	The current SARS-CoV-2 pandemic has brought to the fore concerns that nebulized medication delivery may potentially increase the risk of respiratory virus transmission to health care staff through virus aerosolisation. To address this concern, participating study sites will have the option to use Primatene MIST “puffer” (MDI) in place of nebulized epinephrine to deliver inhaled epinephrine. An ethics amendment was submitted and approved for the use of Epinephrine MDIs to be used for the study. <ul style="list-style-type: none">• Perth Children’s Hospital commenced recruitment in December 2020 for the unseasonal Bronchiolitis presentations and have continued to recruit throughout 2021 (total of >60).• Women’s and Children’s Hospital Adelaide commenced recruitment in July 2021 and have recruited a total of 6, with a brief period of COVID-19 related shut down.• Monash Children’s Hospital have commenced recruitment in Aug 2021 and have a total of 2 however due to COVID have had to put recruitment on hold. They are planning to recommence when the MDIs become available.

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

(cont):

A randomized controlled trial comparing epinephrine and dexamethasone to placebo in the treatment of infants with bronchiolitis (BIPED) (contd.)

Current study status:

- New Zealand sites have deferred commencement of recruitment while awaiting for the arrival of the MDI's as well as a heavy clinical season that forced research staff to work clinically, and currently lockdown related to COVID.
- Waikato Hospital has commenced recruitment on the 29 Sept and have recruited 2 patients. The 2 Auckland sites are still pending commencement.
- Overall, total number of recruited patients for the study is 230 of a total required 1616.

Project Title:

High Flow Nasal Cannula Therapy – Factors influencing care in the paediatric setting

Co-ordinating PI:

Meredith Borland

Study coordinator:

Sharon O'Brien

Project Aims:

The aim is to explore factors influencing clinicians' decisions related to the use of HFNC therapy for infants with bronchiolitis within ED and general paediatric wards in Australia and New Zealand.

Study design:

A qualitative study using semi-structured interviews is being undertaken to investigate factors influencing health clinicians' decision to use HFNC therapy.

Primary outcomes:

To explore and identify potential barriers and enablers to the appropriate use of HFNC therapy.

Sites involved:

Perth Children's Hospital – representing tertiary Australian site
Starship Children's Hospital – representing tertiary New Zealand site
Logan Hospital, Queensland – representing suburban peripheral hospital
Ballarat Health Service, Victoria – representing regional peripheral hospital
Rotorua Hospital New Zealand – potentially representing secondary New Zealand site

Current study status:

Ethics and governance was approved for the 4 sites.
Interviews with a range of nurses and doctors have been completed from the 4 sites, totalling 19. These transcripts have all been transcribed and are currently being analysed using the Theoretical Domains Framework.

Expected finish:

Dec 2021

RESPIRATORY

BRONCHIOLITIS

CURRENT PROJECTS

Project Title:	Sustaining improvements in the management of infants with bronchiolitis – a PREDICT study
Co-ordinating PI:	Emma Tavender/Sandy Middleton/Stuart Dalziel
Study coordinator:	Emma Tavender/PhD Student: Victoria Ramsden
Project aim/s:	The aim of this study is to: i) determine if the use of targeted interventions from the PREDICT Bronchiolitis KT Study have been effective at sustaining improvements in evidence-based practices in Australasian paediatric acute care settings one and two years after completion of the trial at intervention group hospitals (n=13); ii) determine if there are any improvements in control group hospitals (n=13); iii) understand the factors which influenced the sustainability of improvements in intervention group hospitals and; iv)) explore factors which may have contributed to improvements at control group hospitals.
Study design:	A mixed-methods study design: retrospective medical record audit (approximately 150 infants per site for the years 2018 and 2019) and qualitative semi-structured individual or group interviews (3-5 individuals per site).
Primary outcome:	Outcomes: medical record audit The proportion of infants presenting with bronchiolitis to intervention and control group hospitals, who received care that adhered with five inappropriate therapies (chest X-ray, salbutamol, glucocorticoids, antibiotics, and adrenaline) one year (2018) and two years (2019) following delivery of an intervention designed to promote evidence-based practice adherence (composite of all five practices). Outcomes: medical record audit: Factors that contributed to sustainability of improvements of evidence-based practice adherence at intervention group hospitals four years post-implementation; Factors that contributed to improvements/deterioration of evidence-based practice adherence at control group hospitals four years post-implementation; Fidelity and adaptation to the PREDICT Bronchiolitis KT Study implementation strategy at intervention and control group hospitals four years following intervention delivery (2018, 2019, 2020, 2021).
Current study status:	Ethics and governance received from RCH. Currently completing ethics approval process for New Zealand sites. Recruitment emails to be send to Australian sites in the next month.

RESPIRATORY

ASTHMA

CURRENT PROJECTS

Project Title:	Severe asthma observational study
Co-ordinating PI:	Charmaine Gray
Study coordinator:	TBA
Project aim/s:	<p>To determine the test characteristics of various clinical asthma scores for the prediction of:</p> <ul style="list-style-type: none">• Later use of escalated asthma treatment (IV bronchodilators, non-invasive or invasive ventilation, high-flow nasal cannulae)• Hospital admission• Intensive care unit admission• ED length of stay <4 hrs
Study design:	Prospective observational study of children with asthma. Data collection at commencement of treatment, 1 hour after initiation of treatment, at time of escalating treatment to IV therapy (if this occurs), and at discharge.
Primary outcome:	To determine the performance accuracy of (sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV)) of each clinical asthma score at predicting patients who need admission when applied 1 hour after initial asthma (“burst”) treatment.
Current study status:	Finalising protocol. Planning to commence in early 2022.

RESPIRATORY

ASTHMA

CURRENT PROJECTS

Project Title:	Treatment decisions for children with acute severe exacerbations of asthma: interviews with clinicians: A Pediatric Emergency Research Networks (PERN) study
Co-ordinating PI:	Charmaine Gray
Study coordinator:	Charmaine Gray
Project Aims:	<ol style="list-style-type: none">1. To determine how clinicians define both asthma and an acute severe exacerbation of asthma in children.2. To determine which aspects of clinical care and which outcomes are most important to clinicians in this setting.3. To understand the drivers for treatment decisions and perceived priorities of research.
Study design:	Qualitative interview study. Thematic analysis will be performed by the principal Investigator (CG). This will be done in accordance with the theoretical domains framework and reported with reference to a published taxonomy for outcomes in medical research.
Primary outcomes:	The results of these interviews will be collated and described as major themes.
Sites involved:	Collaboration with PERN network. Investigators represented across all major paediatric research networks and interviews conducted across most major geographical regions.
Current study status:	Completed 26 interviews. Final analysis with coding of themes underway. Planned paper submission end of 2021. Ongoing challenge of combining research.
Publication:	Craig S, Babl FE, Dalziel SR, Gray C, Powell C, Al Ansari K, Lyttle MD, Roland D, Benito J, Velasco R, Hoeffe J, Moldovan D, Thompson G, Schuh S, Zorc JJ, Kwok M, Mahajan P, Johnson MD, Sapien R, Khanna K, Rino P, Prego J, Yock A, Fernandes RM, Santhanam I, Cheema B, Ong G, Chong SL, Graudins A; Pediatric Emergency Research Networks (PERN). Acute severe paediatric asthma: study protocol for the development of a core outcome set, a Pediatric Emergency Research Networks (PERN) study. <i>Trials</i> . 2020 Jan 13;21(1):72. doi: 10.1186/s13063-019-3785-6. [link] .

RESPIRATORY

ASTHMA

CURRENT PROJECTS

Project Title:	Cochrane asthma overview
Co-ordinating PI:	Simon Craig
Study coordinator:	N/A
Project aim/s:	<ul style="list-style-type: none">• To summarise Cochrane Reviews with or without meta-analyses of randomised controlled trials on the efficacy and safety of second-line treatment for children with acute exacerbations of asthma (i.e. after first-line treatments, titrated oxygen delivery, and administration of intermittent inhaled short-acting beta2-agonists and oral corticosteroids have been tried and have failed).• To identify gaps in the current evidence base that will inform recommendations for future research and subsequent Cochrane Reviews.• To categorise information on reported outcome measures used in trials of escalation of treatment for acute exacerbations of asthma in children, and to make recommendations for development and reporting of standard outcomes in future trials and reviews.• To identify relevant randomised controlled trials that have been published since the date of publication of each included review
Study design:	Overview of Cochrane systematic reviews
Primary outcomes:	<ul style="list-style-type: none">• Length of stay• ED disposition• Number of adverse events in each treatment group
Current study status:	Complete
Publications:	Craig SS, Dalziel SR, Powell CV, Gaudins A, Babl FE, Lunny C. Interventions for escalation of therapy for acute exacerbations of asthma in children: an overview of Cochrane Reviews. Cochrane Database Syst Rev. 2020 Aug 5;8:CD012977. doi: 10.1002/14651858.CD012977.pub2. PMID: 32767571 Review. [link] . https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012977.pub2/full

RESPIRATORY

AIRWAY MANAGEMENT

CURRENT PROJECTS

Project Title:	Australian and New Zealand Emergency Department Airway Registry (ANZEDAR)
Co-ordinating PI:	Elliot Long
Study coordinator:	Amanda Williams
Project aim/s:	Monitor safety outcomes from paediatric ED intubations
Study design:	Multi-centre prospective observational
Primary outcome:	First pass success without hypoxia or hypotension
Current study status:	Sites enrolling: Gold Coast University Hospital, PCH, MMC, RCH Melbourne. Sites interested: Midland Hospital, Ipswich Hospital, Royal Hobart Hospital, Prince Charles, Hospital, John Hunter Hospital, University Hospital Geelong, Logan Hospital, The Children's Hospital at Westmead, Townsville Hospital, Sunshine Hospital, Ballarat Health Service, Redcliffe Hospital, Flinders Medical Centre, Kids First Hospital.

Project Title:	Kids THRIVE – Apnoeic oxygenation in Paediatric Intubation
Co-ordinating PI:	Shane George
Study coordinator:	Tara Williams
Project aim/s:	The aim of this study is to assess the effect of apnoeic oxygenation using the nasal high flow oxygen during the emergency intubation of children to reduce the proportion adverse events (specifically, oxygen desaturation) and increase the proportion of first attempt success for endotracheal intubation.
Study design:	Randomised Controlled Trial
Primary outcome:	<ul style="list-style-type: none">• Hypoxaemia (SpO₂ <90%)• First attempt intubation success
Current study status:	<ul style="list-style-type: none">• Recruitment ongoing at all Australian Sites. Soon to commence in Vancouver and Zurich. COVID related pauses to recruitment in some centres, but overall recruitment continues at reasonable rate.• Data monitoring and cleaning underway, with plans for essentially clean data set at the conclusion of recruitment.• Statistical Analysis Plan and STATA code in final draft for publication in open access environment prior to study completion.• Currently 730 of 960 participants enrolled. Planned completion in 2022.
Publications:	<p>George, S., Humphreys S., Williams, T., Gelbart, B., Chavan, A. Rasmussen, K., Ganeshalingham, A., Erickson, S., Ganu, S.S., Singhal, N., Foster, K., Gannon, B., Gibbons, K., Schlapbach, L.J., Festa, M., Dalziel, S., Schibler, A. (2019) Transnasal humidified rapid insufflation ventilatory exchange in children requiring emergent intubation (Kids THRIVE): a protocol for a randomised controlled trial. BMJ Open. DOI: 10.1136/bmjopen-2018-025997. [link].</p> <p>George S, Long E, Gelbart B, Dalziel SR, Babl FE, Schibler A, Paediatric Critical Care Research Group (PCCRG), Australian and New Zealand Intensive Care Society Paediatric Study Group (ANZICS PSG) and Paediatric Research in Emergency Departments International Collaborative (PREDICT) research networks. Intubation practices for children in emergency departments and intensive care units across Australia and New Zealand: A survey of medical staff. Emerg Med Australas. 2020 Sep 23. doi: 10.1111/1742-6723.13620. PMID: 32969150. [Online ahead of print].[link]</p>

INFECTIONS

PNEUMONIA

CURRENT PROJECTS

Project Title:	Predicting Severe Pneumonia in the Emergency Department: A Global Study of the Pediatric Emergency Research Networks (PERN)
Co-ordinating PI:	Franz Babl / Stuart Dalziel
Study coordinator:	Hannah Elborough
Project aim/s:	The purpose of the study is to develop accurate, objective models of prognosis in pediatric Community Acquired Pneumonia (CAP) using a global cohort of pediatric emergency departments. It will also assess the predictive accuracy of this rule for clinically important outcomes, including empyema, respiratory failure, sepsis, and death
Study design:	Prospective Observational Cohort Study.
Primary outcome:	The primary outcome will be a 3-tiered composite outcome of pneumonia severity, with outcomes occurring within 7 days of the index ED visit. Mild CAP will be defined as CAP treated in the outpatient setting. Moderate CAP will be defined as children requiring hospitalization, but not having an outcome that is part of the definition of severe CAP. Severe CAP will be defined as CAP with the development of empyema or effusion requiring drainage procedures, intensive care unit admission > 48 hours in duration, respiratory failure requiring positive pressure ventilation (invasive or non-invasive), septic shock, receipt of vasoactive infusions, receipt of extracorporeal membrane oxygenation (ECMO), or death.
Current study status:	Recruitment and data collection completed. 11 PREDICT sites took part. A total of 69 sites from PERC, PECARN, REPEM and PREDICT in total. Data analysis is underway and publications are being drafted.

Project Title:	PERN-Pneumonia COVID-19 arm
Co-ordinating PI:	Stuart Dalziel
Study coordinator:	Hannah Elborough
Project aim/s:	This study is an optional arm of the PERN-Pneumonia prospective cohort study that aims to collect data to provide understanding of the clinical characteristics of the all children (<18 years old) with suspected SARS-CoV-2 infection presenting to a participating Emergency Departments (ED). All sites will be a part of the PERN-Pneumonia study and most of these sites are part of the Pediatric Emergency Research Networks (PERN). Together, the research networks participating in PERN have access to data from over 3 million pediatric ED presentations annually, and to more than 100 hospitals, in five of the six WHO regions.
Study design:	Prospective observational study.
Primary outcome:	The primary outcome will be the severity of the child's illness, defined by intensive care unit admission for ventilator or inotropic support, death, and other outcomes as appropriate.
Current study status:	Recruitment is complete. Two sites from PREDICT participated. Data analysis has been done. Publications have been drafted.

INFECTIONS

FEBRILE NEUTROPAENIA

CURRENT PROJECTS

- Project Title:** **No place like home**
Part 1. Predicting Infectious Complications of Children with Cancer (PICNICC)
Part 2. National Scale Up of the Low Risk Febrile Neutropenia Program
- Co-ordinating PI:** Gabrielle Haeusler
PREDICT co-I: Franz Babl, Meredith Borland
Study coordinator: Marijana Vanevski
Project aim/s:
- Validate and recalibrate clinical decision rules for the prediction of infection in children with cancer and FN; evaluation of the economic and quality of life impact of current FN management strategies and evaluate the implementation of a home-based FN pathway across 8 tertiary hospitals in Australia.
- Study design:** Prospective cohort study.
- children aged ≤ 18 years with a diagnosis of cancer or leukaemia, on active treatment and diagnosed with febrile neutropenia.
- Primary outcomes:**
- The primary outcome measure will be microbiologically documented infection, defined as an infection that is clinically detectable and microbiologically proven.
 - Acceptance and update of home-based FN treatment.
- Current study status:**
- Part 1 – completed.
 - Part 2 – recruiting across 7 or 8 study sites.

Publications:

Haeusler GM, Thursky KA, Slavin MA, Babl FE, De Abreu Lourenco R, Allaway Z, Mechinaud F, Phillips R; Australian PICNICC study group and the PREDICT network. **Risk stratification in children with cancer and febrile neutropenia: A national, prospective, multicentre validation of nine clinical decision rules.** *EClinicalMedicine*. 2020 Jan 7;18:100220. doi: 10.1016/j.eclinm.2019.11.013. eCollection 2020 Jan. [[link](#)]

Haeusler G, Phillips R, Slavin M, Babl FE, De Abreu Lourenco R, Mechinaud F, Thursky K on behalf of the Australian PICNICC study group and the PREDICT network. **Re-evaluating and recalibrating predictors of bacterial infection in children with cancer and febrile neutropenia.** *EClinicalMedicine*. June 2020, 15;23. doi: 10.1016/j.eclinm.2020.100394. eCollection 2020 Jun. PMID: 32637894. [[link](#)].

Haeusler GM, Gaynor L, Teh B, Babl FE, Orme LM, Segal A, Mechinaud F, Bryant PA, Phillips B, Lourenco RA, Slavin MA, Thursky KA. **Home-based care of low-risk febrile neutropenia in children-an implementation study in a tertiary paediatric hospital.** *Support Care Cancer*. 2020 Aug 1. doi: 10.1007/s00520-020-05654-z. Online ahead of print. PMID: 32740894. [[link](#)].

McMullan BJ, Haeusler GM, Hall L, Cooley L, Stewardson AJ, Blyth CC, Jones CA, Konecny P, Babl FE, Mechinaud F, Thursky K; Australian PICNICC study group and the PREDICT network. **Aminoglycoside use in paediatric febrile neutropenia - Outcomes from a nationwide prospective cohort study.** *PLoS One*. 2020 Sep 16;15(9):e0238787. doi: 10.1371/journal.pone.0238787. PMID: 32936822; PMCID: PMC7494114. [[Link](#)]

Haeusler GM, De Abreu Lourenco R, Bakos C, O'Brien T, Slavin MA, Clark JE, McMullan B, Borland ML, Babl FE, Krishnasamy M, Vanevski M, Thursky KA, Hall L. **Managing low-risk febrile neutropenia in children in the time of COVID-19: What matters to parents and clinicians.** *J Paediatr Child Health*. 2021 Jun;57(6):826-834. doi: 10.1111/jpc.15330. Epub 2021 Feb 3. PMID: 33533525; PMCID: PMC8013774. [[Link](#)]

Doerflinger M, Haeusler GM, Li-Wai-Suen CSN, Clark JE, Slavin M, Babl FE, Allaway Z, Mechinaud F, Smyth GK, De Abreu Lourenco R, Phillips B, Pellegrini M, Thursky KA. **Procalcitonin and Interleukin-10 May Assist in Early Prediction of Bacteraemia in Children With Cancer and Febrile Neutropenia.** *Front Immunol*. 2021 May 20;12:641879. doi: 10.3389/fimmu.2021.641879. PMID: 34093531; PMCID: PMC8173204. [[Link](#)]

INFECTIONS

SEPSIS

CURRENT PROJECTS

Project Title:	PROMPT Bolus
Co-ordinating PI:	Elliot Long
Study coordinator:	Amanda Williams
Project aim/s:	Does fluid resuscitation and initial maintenance with balanced fluids reduce renal injury (MAKE 30) in children with sepsis when compared to 0.9% saline
Study design:	International pragmatic RCT
Primary outcome:	Major adverse kidney events within 30 days of enrolment (MAKE 30; composite outcome of death, new RRT, or persistent kidney injury)
Current study status:	ANZ arm: <ul style="list-style-type: none">- Enrolling at: RCH Melbourne, PCH, MMC, Gold Coast University Hospital. Other sites pending commencement : Royal Darwin Hospital, Women’s and Children’s Hospital, SCH Randwick, CHW , QCH, Starship Hospital, Kidz First Hospital to begin enrolment by end of 2021.- As of Sept 2021, 17 patients enrolled in ANZ.- Data transferred successfully to CHOP, harmonised with US data.- Initial study reports compiled. US arm: <ul style="list-style-type: none">- Enrolling CHOP since Oct 2021, 10 other sites have started since then, aim to have 23 sites enrolling. Canadian arm: <ul style="list-style-type: none">- Funded, going through ethics / database build stages

Project Title:	SENTINEL – Sepsis Epidemiology in Australian and New Zealand Children
Co-ordinating PI:	Elliot Long
Study coordinator:	Amanda Williams
Project aim/s:	Describe prevalence, therapy, and outcomes for community acquired sepsis in Australian and New Zealand children.
Study design:	Multicentre prospective observational
Primary outcome:	Develop high-reliability diagnostic criteria
Current study status:	Sites enrolling: RCH Melbourne, PCH, MMC, Gold Coast University Hospital. Sites to begin by end 2021: Royal Darwin Hospital, Women’s and Children’s Hospital, Starship Hospital, Kidz First Hospital. Funding sought for additional sites (Townsville/Alice Springs). Three-month follow-up for enrolled patients has begun. REDCap database developed/piloted/initial data analysis performed.

INFECTIONS

COVID-19

CURRENT PROJECTS

Project Title:	Audit of COVID-19 Infections: Clinical Characteristics and Outcomes at PREDICT Sites
Co-ordinating PI:	Franz Babl, Laila Ibrahim
Study coordinator:	Cate Wilson
Project aim/s:	To describe clinical features and outcomes of patients < 18 years with COVID-19 and the proportion of those testing positive out of all tested < 18 years.
Study design:	Retrospective data collection of medical record information from all possible and confirmed paediatric COVID-19 cases at participating PREDICT sites. Patients will be identified via a search of electronic hospital search systems, electronic medical records or laboratory systems for COVID-19 testing ordered.
Primary outcome:	To identify clinical features of COVID-19 that may facilitate diagnosis such as: 1) Demographic Data 2) Signs, sign and onset/duration 3) Results of virology/serology and Laboratory test 4) Results of Imaging study
Current study status:	14 PREDICT sites recruited and completed data audit from Feb to Sept 2020. This data cleaned, analysed and published. Currently expanding study to include another 10+ sites and repeating audit up until Dec 2021. Potential overall audit period to be extended to Dec 2023 so that further audits can be included if there are further outbreaks.
Publications:	Ibrahim LF, Tham D, Chong V, Corden M, Craig S, Buntine P, Jani S, Zhang M, George S, Kochar A, O'Brien S, Robins-Browne K, Tosif S, Daley A, McNab S, Crawford NW, Wilson C, Babl FE. The characteristics of SARS-CoV-2-positive children who presented to Australian hospitals during 2020: a PREDICT network study. Med J Aust. 2021 Sep 6;215(5):217-221. doi: 10.5694/mja2.51207. Epub 2021 Aug 13. PMID: 34389995. [Link]

INFECTIONS

URINARY TRACT INFECTION

CURRENT PROJECTS

Project Title:	CHOICE UTI Trial (Clinical efficacy of early IV to oral antibiotic switch (single dose IV) compared to 3 days IV antibiotics for children with complicated urinary tract infections: a multicentre randomised trial)
Co-ordinating PI:	Laila Ibrahim
Study coordinator:	Laila Ibrahim
Project aim/s:	To compare whether Early switch - single dose of IV plus 2 days oral antibiotics is as clinically effective (non-inferior) in resolving UTI symptoms at 72 hours after the first IV dose, as 3 days IV for complicated urinary tract infections presenting to the ED.
Study design:	An open label, multi-centre, pragmatic, non-inferiority RCT.
Primary outcome:	Clinical failure defined as persistence of baseline symptoms (fever or vomiting or rigors) or development of new symptoms (fever or vomiting or rigors) attributable to UTI: at 72 hours from the first dose of IV antibiotics.
Current study status:	<ul style="list-style-type: none">• Ethics and governance approved April 2021 at lead site RCH.• Concerns raised about the 3 day arm - whether general paediatricians managing patients admitted to ward can adhere to the protocol.• Data from each site extracted to estimate the length of stay (LOS). Median LOS for UTI was 44-48 hours ie despite paediatricians reporting that they do not admit patients with UTI beyond 48 hours.• Royal Children's Hospital, Perth Children's Hospital, Monash, Starship Children's Hospital, Women's and Children's Hospital sites to participate. Currently making final protocol amendments before commencing recruitment.

FEBRILE CONVULSION

CURRENT PROJECTS

Project Title:	Febrile Convulsion study
Co-ordinating PI:	Simon Craig
Study coordinator:	Marietta John-White
Project aim/s:	To determine if a treatment strategy of recommending regular antipyretic medication (intervention) compared to usual Emergency Department (ED) care (control) for children who are discharged home from the ED following a febrile convulsion is superior for: (a) Reducing the recurrence of febrile seizures within the same febrile illness; (b) Reducing hospital re-attendance with febrile convulsion; (c) Improving parent and child health-related quality of life; (d) Reducing health care costs.
Study design:	Stepped Wedge –Randomised Clinical Trial across 25 hospitals within Australia and New Zealand.
Primary outcome:	Recurrence of febrile seizures within the same febrile illness.
Current study status:	Grant submitted to NHMRC (Clinical Trials and Cohort Studies) – outcome likely to be released early 2022.

MENTAL HEALTH

CURRENT PROJECTS

Project Title:	PEACHY-O
Co-ordinating PI:	Franz Babl (CPI), Elyssia Bourke (PhD candidate)
Study coordinator:	Kate Klein
Project aim/s:	To determine whether oral olanzapine is more effective than oral diazepam to manage paediatric ASBD in the ED.
Study design:	Randomised controlled open label effectiveness trial directly comparing two active arms (oral olanzapine versus oral diazepam).
Primary outcome:	Successful sedation without the requirement for additional sedation 1 hour post randomisation. Successful sedation will be defined as reaching a SAT of ≤ 0 .
Current study status:	<ul style="list-style-type: none">• Approval obtained from the RCH HREC.• RCH governance obtained.• ANZCTR registration obtained.• Education being undertaken at RCH with aim to commence the study in early October pending COVID restrictions.• Other sites currently working through governance for the study with aim to launch study at these sites as soon as feasible post governance being obtained.• Trial website, twitter account @PeachyRct and investigator whatsapp in progress.• First DSMB meeting has been held.

Project Title:	PEACHY-M
Co-ordinating PI:	Franz Babl (CPI), Elyssia Bourke (PhD candidate)
Study coordinator:	Kate Klein
Project aim/s:	To determine whether intramuscular (IM) olanzapine is more effective than IM droperidol to manage paediatric ASBD in the ED.
Study design:	Randomised controlled open label effectiveness trial directly comparing two active arms (IM olanzapine versus IM droperidol).
Primary outcome:	Successful sedation without the requirement for additional sedation 1 hour post randomization. Successful sedation will be defined as reaching a SAT of ≤ 0 .
Current study status:	<ul style="list-style-type: none">• HREC approval expected from RCH HREC by late September- early October.• RCH governance also submitted.• ANZCTR registration obtained.• Education being undertaken at RCH with aim to commence the study in late October (after PEACHY-O) pending COVID restrictions.• Once central HREC approval obtained Kate will distribute governance documents to sites.• Trial website, twitter account @PeachyRct and investigator whatsapp in progress.• First DSMB meeting has been held.
Publications:	
Bourke EM, Say DF, Carison A, Hill A, Craig S, Hiscock H, Babl FE, O'Donnell SM. Emergency mental health presentations in children with autism spectrum disorder and attention deficit hyperactivity disorder. J Paediatr Child Health. 2021 May 8. doi: 10.1111/jpc.15535. Epub ahead of print. PMID: 33963626. [link] .	

MENTAL HEALTH

CURRENT PROJECTS

Project Title:	Management of paediatric acute severe behavioural disturbance: a qualitative exploration of health care professionals experiences
Co-ordinating PI:	Elyssia Bourke PhD student (Supervised by Franz Babl, Simon Craig, Jonathon Knott)
Study coordinator:	N/A
Project aim/s:	To understand HCPs experiences managing children with ASBD.
Study design:	Qualitative methodology is being used. Elyssia is undertaking semi-structured one-to-one interviews with HCPs involved in the management of children with ASBD in Aust and NZ which will be transcribed and analysed using thematic analysis.
Primary outcome:	As this is qualitative research, the outcome is to better understand HCPs experiences when caring for these young people.
Current study status:	<ul style="list-style-type: none">• HREC approval obtained.• Medical interviews completed, transcribed and analysis underway.• Mental health clinician interviews completed and being transcribed.• Elyssia will attempt to interview nursing staff, security staff, police and staff from Ambulance Victoria (governance approval obtained from police and

Project Title:	Mental Health Delphi study
Co-ordinating PI:	Simon Craig
Study coordinator:	Marietta John-White
Project aim/s:	To determine a prioritised list of research questions, and a set of core clinical, mental health and social outcomes that should be researched for children and young people attending the ED with mental health concerns.
Study design:	Modified Delphi study. 3 survey rounds followed by online consensus meeting.
Primary outcome:	Prioritised list of research questions Consensus on relevant research outcomes
Current study status:	Unable to be commenced in 2021 due to long delays with governance and approvals across multiple jurisdictions (hospitals, ambulance, police, education, schools) and impact of COVID delta variant in NSW and Victoria. Hoping to commence February 2022.

Project Title:	Safety Planning Study
Co-ordinating PI:	Simon Craig / Glenn Melvin
Study coordinator:	Marietta John-White
Project aim/s:	To determine whether a developmentally appropriate Safety Planning Plus (SP+) intervention is more effective than usual treatment at reducing ED mental health re-presentation within 3 months in adolescents (12-18 years) presenting to the ED with suicidal thoughts and behaviour.
Study design:	Stepped wedge cluster randomised clinical trial.
Primary outcome:	ED representation within 3 months of initial visit.
Current study status:	Significant changes to mental health care within the ED have occurred due to the COVID-19 pandemic, including a significant investment in mental health care services and rollout of various safety planning and follow-up interventions. As a result, the safety planning study will not be able to go ahead as originally planned. An alternative approach is being developed to test various aspects of the use of smartphone apps to improve safety planning in the ED. This is likely to occur at 1-2 hospitals only.

MENTAL HEALTH

CURRENT PROJECTS

Project Title:	Mental Health prospective observational study
Co-ordinating PI:	Simon Craig
Study coordinator:	Marietta John-White
Project aim/s:	<ul style="list-style-type: none">• To describe the epidemiology of mental health-related ED presentations by young people, including risk factors for these presentations;• To describe and compare the mental health issues in mental health-related ED presentations of key subgroups of young people, including those with neurodevelopmental disorders; drug and/or alcohol misuse issues; self-harm and/or suicidal behaviour; living in, or with experience of, out-of-home care; with prior contact with the criminal justice system; identifying as Aboriginal and/or Torres Strait Islander; identifying as current or previous refugees at any time during their lives.• To document the 3-, 6-, and 12-month health and social outcomes of young people following a mental health-related ED presentation;• To document healthcare utilisation (including predictors of frequent utilisation) and the associated healthcare costs in young people following a mental health-related ED presentation.• To investigate the role of genetic factors in the mental health issues and in the health and social outcomes.
Study design:	Prospective observational cohort study, including data linkage and genetics.
Primary outcome:	An ED reattendance with a mental health concern within 12 months of enrolment.
Current study status:	Protocol being finalised. Planning to submit to ethics October / November, with a view to commence early 2022.

Project Title:	Mental Health retrospective study
Co-ordinating PI:	Simon Craig
Study coordinator:	Marietta John-White
Project aim/s:	<ul style="list-style-type: none">• To describe the overall epidemiology of children and adolescents presenting to the ED with mental health concerns;• To describe key subgroups (suicidality/self-harm; acute behavioural disturbance; drug and alcohol related presentations; eating disorders; and neurodevelopmental disorders such as autism spectrum disorder);• To determine the short-term health and social outcomes;• To compare ED treatment and outcomes between rural, regional, metropolitan, and tertiary paediatric settings; and between the key subgroups (listed above);• To compare the use of physical and chemical restraint between different regions, and between the subgroups identified above.
Study design:	Retrospective cohort study.
Primary outcome:	Describe epidemiology of key subgroups of children and adolescents presenting to the ED with mental health concerns.
Current study status:	Data collection complete at 6 sites, in progress at another 5 sites. Ethics and governance approvals underway at other hospitals.

NEUROLOGICAL

CONVULSIVE STATUS EPILEPTICUS (CSE)

CURRENT PROJECTS

Project Title:	SEARCH - Status Epilepticus Australasian Registry for Children
Co-ordinating PI:	Jeremy Furyk
Study coordinator:	Jeremy Furyk
Project aim/s:	Describe the management and outcomes of paediatric SE in Australia
Study design:	Prospective observational cohort study
Primary outcome:	Time to AED administration, route of administration and agents used.
Current study status:	Data collection and follow up has been completed at the four study sites (Townsville, Gold Coast, Brisbane Children's, Perth Children's). Data cleaning has been completed; preliminary analysis is completed. A first draft of manuscript has been circulated to selected investigators for feedback and direction. Additional analysis being sought (Investigator K Watt), and anticipated further draft of manuscript to be circulated in late September.

BELL'S PALSY

CURRENT PROJECTS

Project Title:	Bell's Palsy in Children (BellPIC)
Co-ordinating PI:	F Babl
Study coordinator:	A Williams
Project aim/s:	Determine if prednisolone improves recovery from Bell's palsy in children when compared with placebo.
Study design:	Double-blind multicentre RCT.
Primary outcome:	Recovery to full facial function at 1 month using the House Brackmann scale.
Current study status:	Study completed, data cleaned, analysis ongoing; in write up phase.
Publications:	<p>Babl FE, Mackay MT, Borland ML, Herd DW, Kochar A, Hort J, Rao A, Cheek JA, Furyk J, Barrow L, George S, Zhang M, Gardiner K, Lee KJ, Davidson A, Berkowitz R, Sullivan F, Porrello E, Dalziel KM, Anderson V, Oakley E, Hopper S, Williams F, Wilson C, Williams A, Dalziel SR; PREDICT. Bell's Palsy in Children (BellPIC): Protocol for a Multi-centre, Placebo-Controlled Randomized Trial. BMC Pediatrics 2017 Feb 13;17(1):53. doi: 10.1186/s12887-016-0702-y. [Link]</p> <p>Babl F, Gardiner KK, Kochar A, Wilson CL, George SA, Zhang M, Furyk J, Thosar D, Cheek JA, Krieser D, Rao AS, Borland ML, Cheng N, Phillips NT, Sinn KK, Neutze JM, Dalziel SR; PREDICT. Bell's Palsy in Children: Current Treatment Patterns in Australia and New Zealand. A PREDICT Study. J Paediatr Child Health. 2017 Apr;53(4):339-342. doi: 10.1111/jpc.13463. [Link]</p> <p>Babl FE, Kochar A, Osborn M, Borland ML, West A, Williams A, Dalziel SR; PREDICT network. Risk of Leukemia in Children With Peripheral Facial Palsy. Ann Emerg Med. 2021 Feb;77(2):174-177. doi: 10.1016/j.annemergmed.2020.06.029. Epub 2020 Aug 9. PMID: 32788067. [Link]</p>

NEUROLOGICAL

STROKE

CURRENT PROJECTS

Project Title:	The Australian Paediatric Acute Code Stroke (PACS) Study
Co-ordinating PI:	Mark Mackay
Study coordinator:	Belinda Stojanovski
Project aim/s:	To increase the proportion of children aged 1 month – 18 years with stroke diagnosed within 4.5 hours of symptom onset.
Study design:	A staged, two-tiered pre-and-post intervention study. The tiers will consist of six sites that have not yet developed paediatric acute code stroke protocols (Group 1) and three sites with established paediatric code stroke protocols (Group 2).
Primary outcome:	The primary outcome is the change in proportion of children with radiologically confirmed stroke diagnosed within 4.5 hours of symptom onset, pre-and –post implementation of paediatric acute code stroke protocols.
Current study status:	<ul style="list-style-type: none">• Ethics approval obtained on 5/8/2021.• 1 site (Monash Children’s) has Governance approval & is currently working towards recruitment of a site study coordinator.• Additional study site (John Hunter Hospital, Newcastle) is joining the study. Dr. Christina Miteff will be the site PI.• Other study sites currently working on Governance applications.• Study coordinators in place at QCH, PCH & Starship Children’s Hospital.• PACS Study REDCap database in final stages of development.• RAPID perfusion imaging software installed at RCH & Monash Children’s.• RCH currently piloting the BASICS decision support tools. QCH & Monash Children’s Hospitals will trial the tool next.• Steering Committee established, Chair is Sharon McGowan, CEO Stroke Foundation.

ABDOMINAL PAIN

APPENDICITIS

CURRENT PROJECT

Project Title:	Study of Paediatric Appendicitis Scores and Management Strategies
Co-ordinating PI:	Meredith Borland
Project aim/s:	To externally validate the PAS, AS and pARC clinical prediction scores (CPSs) for appendicitis in children aged 5 to <18 years presenting to EDs in Australia and New Zealand with acute abdominal pain and suspicion of appendicitis.
Study design:	Multi-centre prospective observational study of consecutive children presenting with possible appendicitis to 5 large paediatric EDs, which offer a full access to laboratory, imaging (US, CT, MRI) and on-site 24-hour paediatric surgical services, within the PREDICT research network to compare and validate current paediatric CPS and clinician gestalt in a continuously collected prospective cohort.
Primary outcome:	Performance accuracy as measured by the aggregate measure of AUC (composed of sensitivity and specificity) for the ROC curves in identifying surgically confirmed appendicitis for PAS, AS and pARC CPSs.
Current study status:	NHMRC Clinical Trial and Cohort Study Application under consideration.

ED EPIDEMIOLOGY

CURRENT PROJECTS

Project Title:	Quality Improvement in the Pre-Hospital Setting (Amb. Vic. Audits)
Co-ordinating PI:	Franz Babl, Sandy Hopper, Tom Solan, Natalie Phillips, Elyssia Bourke
Study coordinator:	Cate Wilson
Project aim/s:	This study aims to understand more about current pre-hospital practice in Victoria for the management of paediatrics with: <ul style="list-style-type: none">• Convulsive status epilepticus• Intraosseous access• Asthma• Airway management/intubations• Neck injuries• Acute severe behavioural disturbance
Study design:	Retrospective audit of Ambulance Victoria data for paediatrics 0-<18 in a 12-month period. Primary outcome: For all groups broadly: <ul style="list-style-type: none">• Description of epidemiology of patients• Assessment of paramedic interventions provided• Assessment of gross outcome of patients/interventions during transport• Assessment of adverse events
Current study status:	Convulsive status epilepticus <ul style="list-style-type: none">• Data cleaned, analysed. Publication submitted Intraosseous access <ul style="list-style-type: none">• Data cleaned, analysed. Publication to be submitted soon. Airway management <ul style="list-style-type: none">• Data cleaning and analysis underway Asthma <ul style="list-style-type: none">• Data cleaning and analysis underway Neck injuries <ul style="list-style-type: none">• Data cleaning and analysis underway Acute severe behavioural disturbance <ul style="list-style-type: none">• To commence
Publications:	CSE paper submitted.

Project Title:	Emergency department data to assess the impact of COVID-19 restrictions
Co-ordinating PI:	Simon Craig
Study coordinator:	Marietta John-White
Project aim/s:	To describe patterns of presentations to EDs across Australia and New Zealand during the study period (1st January 2017 to 31st December 2022).
Study design:	Retrospective observational study using routinely collected ED data.
Primary outcome:	Changes in ED presentation patterns across the COVID-19 pandemic.
Current study status:	Progressing with ethics and governance. Some delays with data-sharing agreements. Data imports have commenced from some sites.

ED EPIDEMIOLOGY

CURRENT PROJECTS

Project Title:	Electronic Medical Record (EMR) use to assess application of new evidence for convulsive status epilepticus, bronchiolitis and head injury management.
Co-ordinating PI:	Franz Babl
Study coordinator:	Cate Wilson
Project aim/s:	To determine the implementation of new evidence from three Evidence based guidelines in the acute care setting in relation to CSE, bronchiolitis and head injury management in the acute care setting.
Study design:	This is a multi-centre study that will collect retrospective data directly from electronic medical records or electronic prescribing systems at eligible hospitals within the PREDICT network in relation to the following conditions in paediatrics, CSE, bronchiolitis and head injury.
Primary outcome:	The outcomes for the retrospective data collection are: <ol style="list-style-type: none">1. The use of leviracetam in single or combined usage as a second line AED during ED management for CSE.2. The lack of use of chest x-ray, salbutamol, glucocorticoids, antibiotics and adrenaline in management of bronchiolitis in ED and during hospitalisation within 24 hours of ED triage.3. The use of CT brain and ED length of stay for children presenting with head injury.
Current study status:	Protocol in early development stage. Some funds available.

OTHER

SEDATION/PAIN MANAGEMENT

CURRENT PROJECTS

Project Title:	Pain Management and Sedation in Pediatric Ileocolic Intussusception: A Global, Multicenter, Retrospective Study (PAINT Study)
Co-ordinating PI:	Simon Craig, Itay Shavit (PERN)
Study coordinator:	Marietta John-White
Project aim/s:	<ul style="list-style-type: none">• To explore current global practices related to the provision of analgesia and sedation for reduction of intussusception• To examine the association of sedation with outcomes in the reduction of intussusception.
Study design:	Retrospective cohort study
Primary outcome:	Differences in the provision of analgesia and sedation for reduction of intussusception.
Current study status:	Data collection completed in March 2021 (85 participating sites). N=3,790 (3,160 met inclusion criteria). Manuscripts being prepared. One on pain relief, one on sedation.

CONSENT

CURRENT PROJECTS

Project Title:	Deferred Consent Projects
Co-ordinating PI:	Jeremy Furyk
Study coordinator:	Jeremy Furyk
Project aim/s:	To explore the attitudes and experiences of parents to research with deferred consent in paediatric emergency research.
Study design:	Qualitative, participant interviews.
Primary outcome:	To explore the attitudes and experiences of parents to research with deferred consent in paediatric emergency research.
Current study status:	<p>The Deferred Consent project consisted of two discrete projects, the first involving hypothetical patients from multiple centres presenting with simple febrile seizures and bronchiolitis to the emergency department. This component has been analysed, presented at scientific meetings and published.</p> <p>The second study consisted of patients enrolled in the CONCEPT and PARIS high flow trial, exploring experiences of involvement in the study, and specifically with deferred consent process. Data from approximately 40 patients has been collected, transcribed and imported into Nvivo software. Coding and analysis is ongoing, with anticipated completion this year. Delays have been due to lead investigator taking substantial leave for family reasons over the last 2 years. Was not feasible for other team members to complete the required analysis.</p>
Publications:	<p>Furyk J., McBain-Rigg K., Watt K., Theophilus I Emeto, Franklin RC., Franklin D., Schibler S., Dalziel SR., Babl FE., Wilson D., Phillips N., Ray R., on behalf of PREDICT. Qualitative evaluation of a deferred consent process in paediatric emergency research: a PREDICT study. BMJ Open 2017 Nov 15;7(11):e018562. doi:10.1136/bmjopen-2017-018562. [Link]</p>

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HEAD INJURY

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RESPIRATORY CONDITIONS

BRONCHIOLITIS

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