



**Status Epilepticus Australasian
Registry for Children
(SEARCH)**

PREDICT

Paediatric Research in
Emergency Departments
International Collaborative

Overview

- A prospective, observational cohort study of children 4 weeks to 16 years of age, who have Convulsive status epilepticus (CSE) managed at a PREDICT emergency department.
- Data will be reported for a total for 24 months.
- SEARCH will be the first large prospective study of paediatric CSE in Australia
- A framework for ongoing monitoring of the appropriateness and effectiveness of specific healthcare interventions

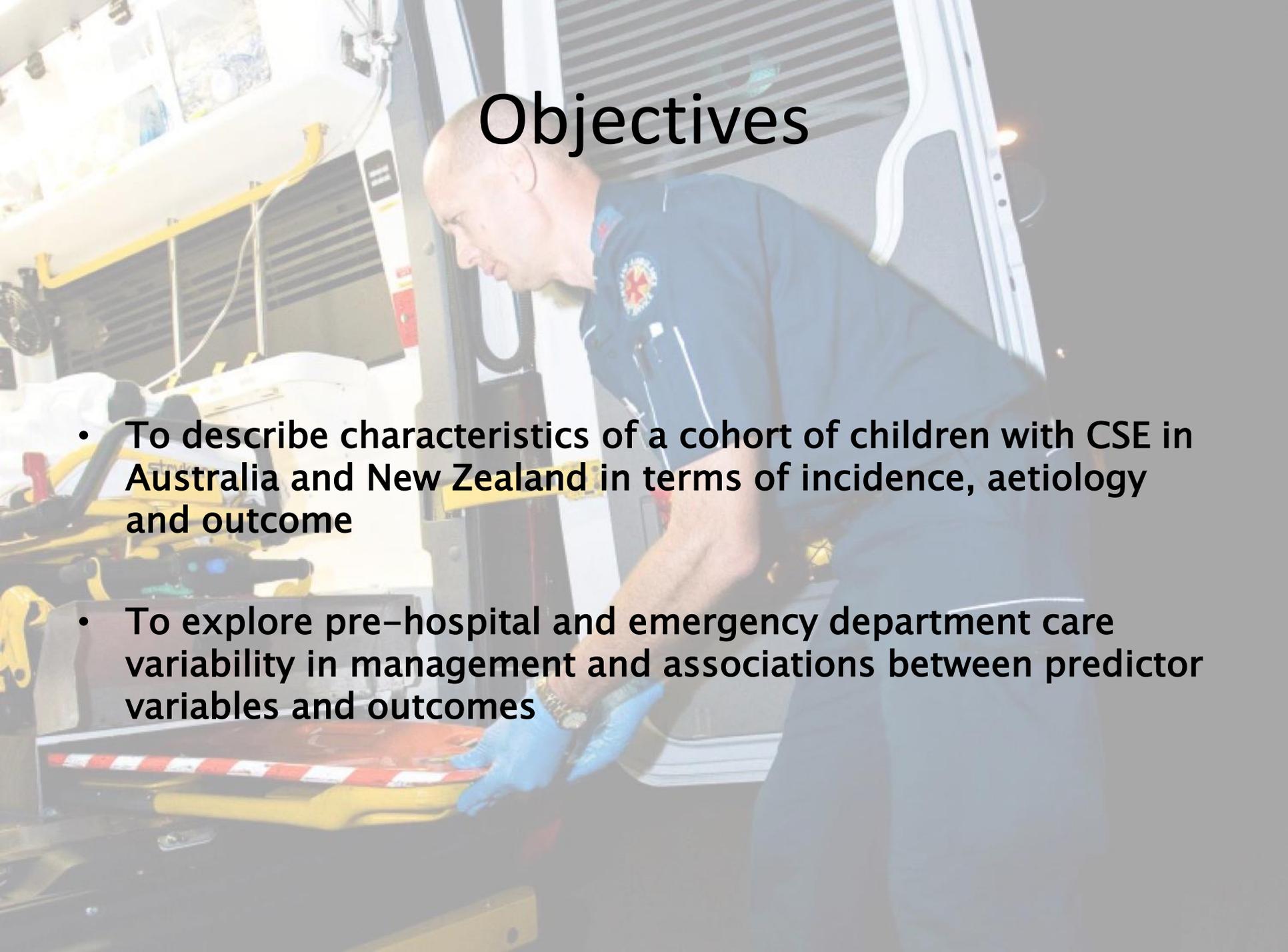


Overview continued...

- SEARCH will be the first large data set including the new classification of CSE
- SEARCH will be instigated in conjunction with the Convulsive Status Epilepticus in Paediatrics Trial (ConSEPT).
- Data for SEARCH will complement data collected for ConSEPT

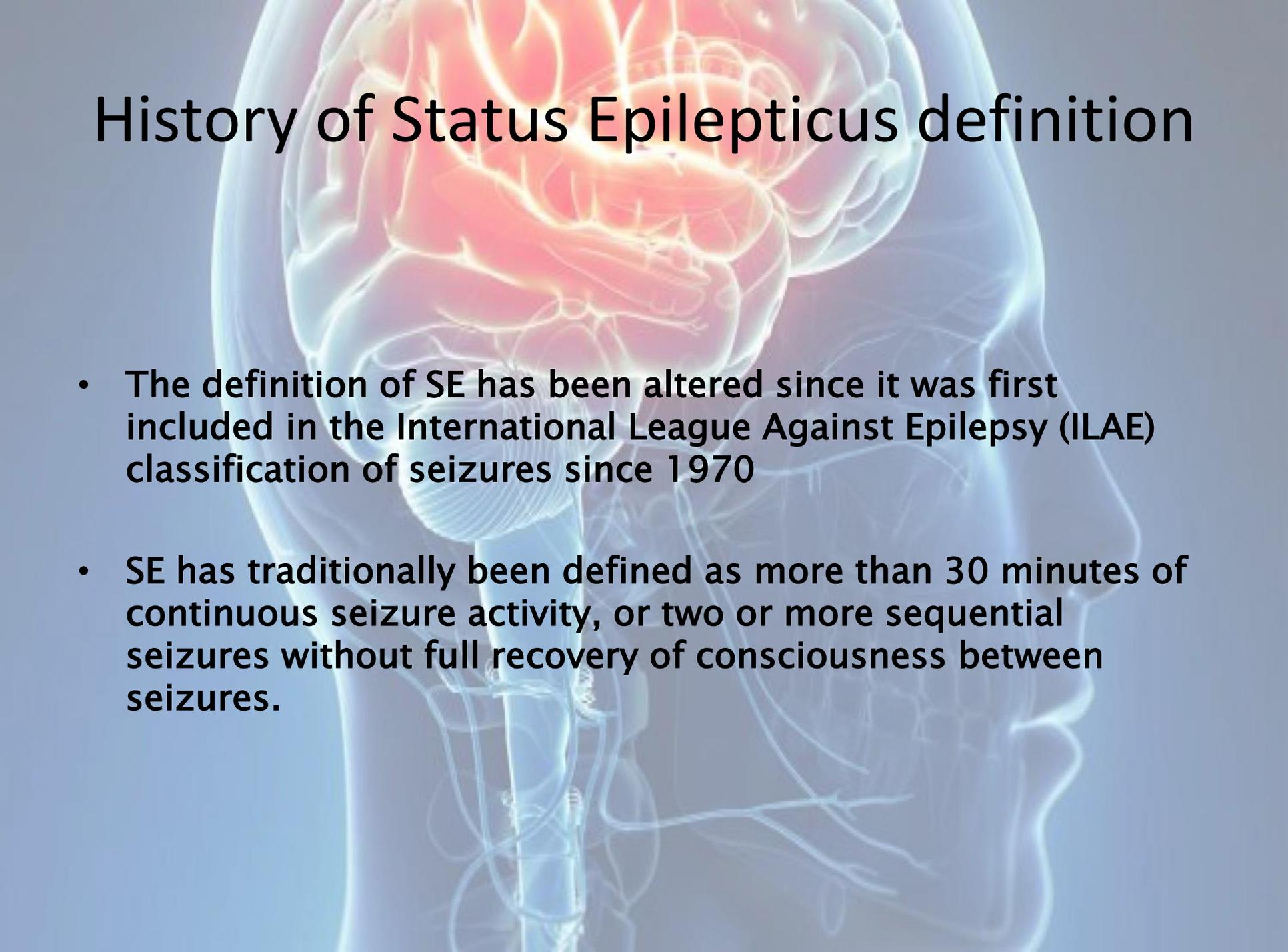


Objectives



- **To describe characteristics of a cohort of children with CSE in Australia and New Zealand in terms of incidence, aetiology and outcome**
- **To explore pre-hospital and emergency department care variability in management and associations between predictor variables and outcomes**

History of Status Epilepticus definition



- The definition of SE has been altered since it was first included in the International League Against Epilepsy (ILAE) classification of seizures since 1970
- SE has traditionally been defined as more than 30 minutes of continuous seizure activity, or two or more sequential seizures without full recovery of consciousness between seizures.

Current Status Epilepticus definition

- This lead to a revised operational definition of CSE
- Recently the ILAE task force on the classification of SE released a report outlining a proposed new definition, which is:

“SE is a condition resulting either from the failure of the mechanisms responsible for seizure termination or from the initiation of mechanisms which lead to abnormally prolonged seizures (after time point t1). It is a condition that can have long-term consequences (after time point t2), including neuronal death, neuronal injury, and alteration of neuronal networks, depending on the type and duration of seizures.”

Status Epilepticus definition continued...

- **This new system acknowledges that at least half of patients presenting in SE will not have epilepsy, and therefore previously used seizure classifications are probably not appropriate.**
- **In their report on the classification of SE in 2015, the ILAE task force proposed a system incorporating 4 axes**
 - **1. Semiology**
 - **2. Aetiology**
 - **3. Electroencephalographic correlates**
 - **4. Age**
- **We will use this newly developed classification system to characterise children presenting with SE to participating SEARCh emergency departments. This will be the first large study to utilise this specifically developed system internationally.**

Recruitment

Inclusion criteria

- Aged between 4 weeks and 16 years
- Patient experienced an episode of status epilepticus
- Eligible patients will be prospectively identified by clinical staff at participating PREDICT hospital Eds
- Either the treating clinician or research staff will approach the parents/carers of the child to discuss inclusion on the registry. The clinician or researcher will provide the parent/carer with a Participant Information Form and Opt Out Form

Recruitment continued...

- **A research assistant at each site will check standard hospital databases (weekly) for patients who present with seizures to their site**
- **ED medical records will be examined to identify children who had a seizure of more than 5 minutes duration**
- **On occasions where a patient has left hospital prior to being identified for inclusion in the study a letter will be sent to the patient's parents**

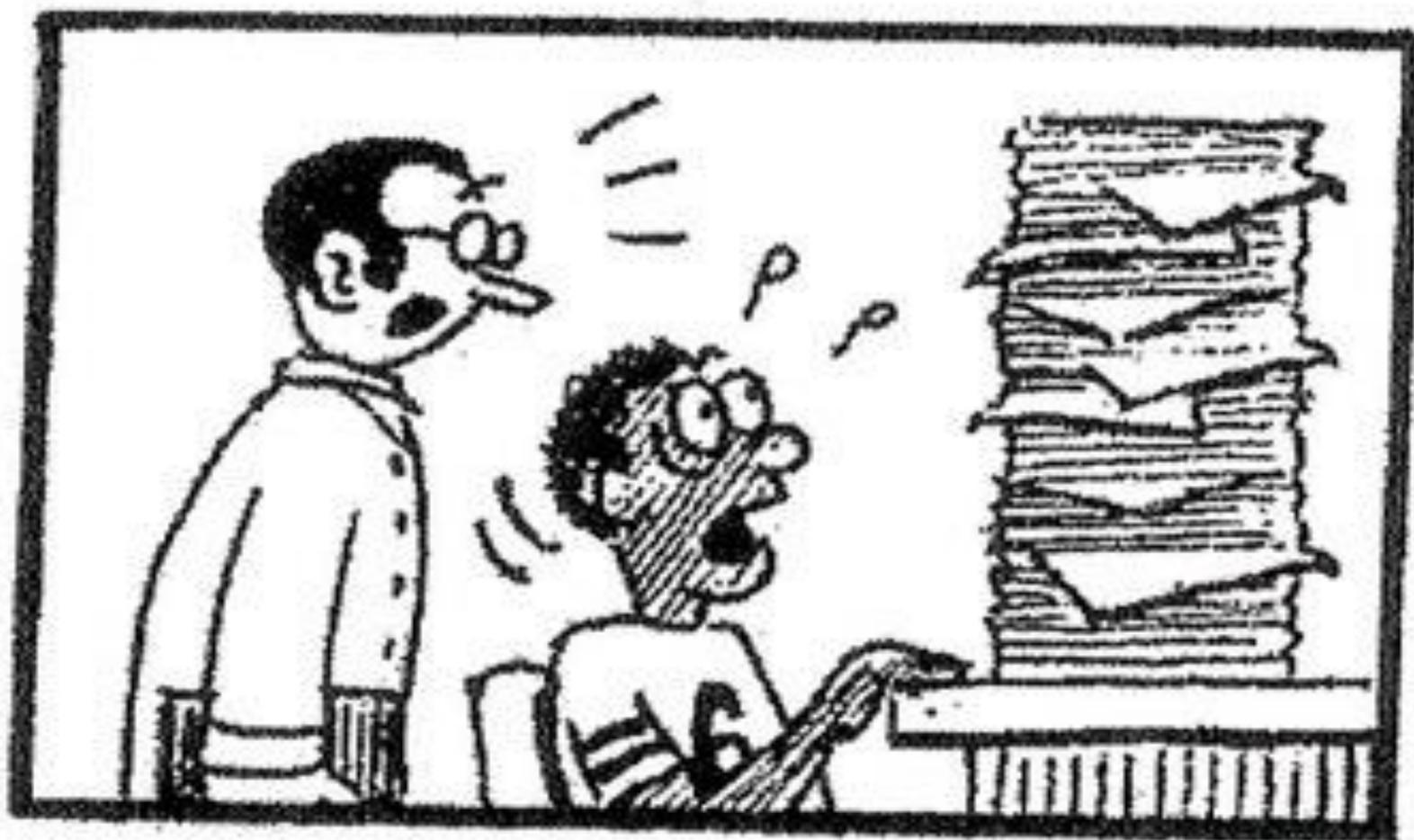


Consent

- **The study will use a repeated opt out approach to recruiting patients**
- **Parents whose children are identified for the study while still in hospital will be approached and receive both a verbal description of the study and a Patient Information Form. In addition, they will be provided with an Opt Out Form.**
- **One week after the child's initial contact with the hospital, parents will again be sent a further Patient Information and Opt Out Form**

Consent continued...

- **If consent cannot be obtained prior to hospital discharge, parents will be sent Patient Information and Opt Out Forms and be invited to participate in the study.**
- **During each follow-up phone call made at one month and 12 months, the research nurse will briefly confirm the parent's verbal consent to continue participating in the study, before proceeding with CRFs 3 and 4.**



“The biggest risk in this study is just reading the consent form!”

OPT OUT FORM

| | |
|-------------------------|--|
| PRINCIPAL INVESTIGATOR: | Dr Jeremy Furyk, The Townsville Hospital |
| PROJECT TITLE: | Status <u>Epilepticus</u> Australasian Register for Children - <u>SEARCH</u> |

This form allows you to OPT-OUT of the research study: **Status Epilepticus Australasian Register for Children** By opting out of this study, you have indicated to the research team that you do not wish to participate in the research, and that you do not wish to be contacted any further about the study.

Please indicate your wishes below:

I do not want to participate in this research

I do not want to be contacted by the research team for this study

We are asking parents who have chosen to opt out, if we can retain the information we have already collected about your child for our research. Please indicate below if you would like to opt out of this as well:

I do not want my child's information to remain on the research register

| | |
|-----------------|-------|
| Name: (printed) | |
| Signature: | Date: |

Case Report Forms

- **Data will be recorded on specifically designed paper CRFs**
- **Core data will include: exact onset and duration of seizure; clinical assessment of type of seizure; presumed aetiological diagnosis; and management given**
- **Follow up data, and detailed demographics will be collected by research assistants at the earliest possible opportunity after admission, at which time consent will be sought for retention of data, hospital follow up, and follow up at 12 months**



Patient's initials (first, last): _____

Patient UR: _____

Study ID No.: _____

Status Epilepticus Australian Registry for Children

CASE REPORT FORM 2 – TO BE COMPLETED BY RESEARCH STAFF IN WEEK FOLLOWING ADMISSION

1. Developmental History

- 1.1 What was the mother's age at childbirth? ___ years
- 1.2 What was the father's age at childbirth? ___ years
- 1.3 Was the patient born premature? (Gestation <37 weeks)
- Unsure
 - No
 - Yes
- 1.4 Did the mother smoke during pregnancy?
- Unsure
 - No
 - Yes
- 1.5 Was there any alcohol consumption during the pregnancy of the patient?
- Unsure
 - No
 - Yes
- 1.6 Were there any complications during the pregnancy of the patient?
- Unsure
 - No
 - Yes
- 1.7 Delivery type:
- Vaginal
 - Forceps
 - Vacuum delivery
 - Breech birth
 - Elective caesarean delivery
 - Emergency caesarean delivery



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Affix patient label here

Patient's initials (first, last): _____

Patient UR: _____

Study ID No.: _____

Status Epilepticus Australian Registry for Children

CASE REPORT FORM 3 - TO BE COMPLETED BY RESEARCH STAFF AT ONE MONTH

1. Follow Up - One Month

1.1 Is the patient still in hospital?

- No
Yes (if yes, please discontinue)

1.2 Is the patient contactable?

- No
 Yes

1.3 How frequently have the seizures occurred since discharge?

- Daily
Weekly
1-2/month
Nil seizures in the last month
Unknown

1.4 Has the patient had any further episodes of status epilepticus? (Seizure lasting >5 minutes or requiring medication to stop) since discharge, both admitted to hospital or managed at home?

- Unsure
 No
 Yes
If yes, number of episodes of status epilepticus _____

1.5 Is the patient taking any regular medication?

- Unsure
 No
 Yes
If yes, please list below

1. _____
2. _____
3. _____
4. _____
5. _____

Patient's initials (first, last): _____

Patient UR: _____

Study ID No.: _____

Status Epilepticus Australian Registry for Children

CASE REPORT FORM 4 – TO BE COMPLETED BY RESEARCH STAFF AT 12 MONTHS

1. Follow Up – Twelve Months

1.1 Is the patient still in hospital?

- No
Yes (if yes, please discontinue)

1.2 Is the patient contactable?

- No
 Yes

1.3 How frequently have the seizures occurred since discharge?

- Daily
Weekly
1-2/month
Nil seizures in the last month
Unknown

1.4 Has the patient had any further episodes of status epilepticus? (Seizure lasting >5 minutes or requiring medication to stop) since discharge, both admitted to hospital or managed at home?

- Unsure
 No
 Yes
If yes, number of episodes of status epilepticus _____

1.5 Is the patient taking any regular medication?

- Unsure
 No
 Yes
If yes, please list below

1. _____
2. _____
3. _____
4. _____
5. _____

Database

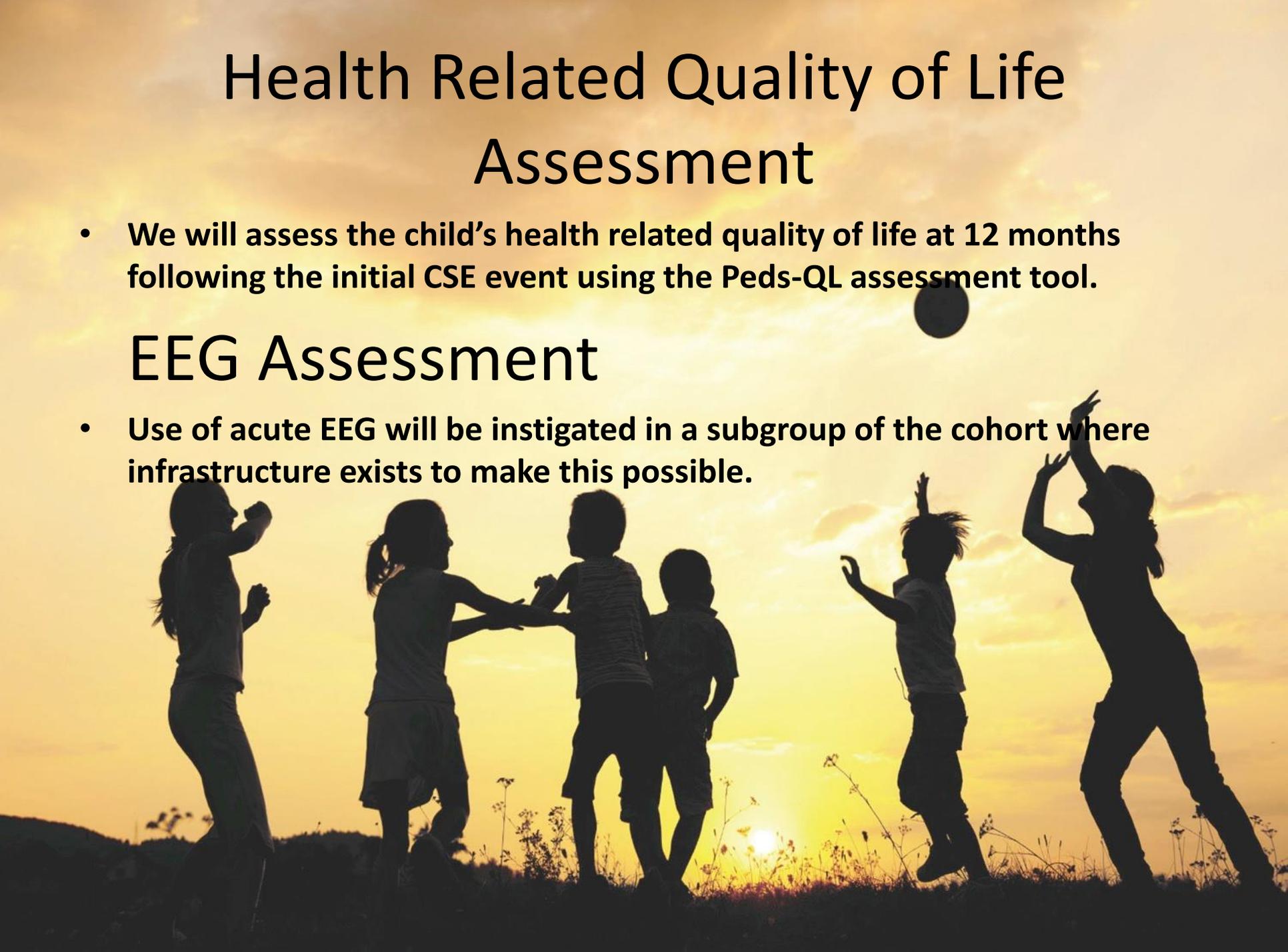
- **Data will be electronically entered into trial specific electronic data entry forms**
 - **Research Electronic Data Capture (REDCap)**
- **A secure web-based application designed to support data capture for research studies, and hosted through the Murdoch Childrens Research Institute**

Health Related Quality of Life Assessment

- We will assess the child's health related quality of life at 12 months following the initial CSE event using the Peds-QL assessment tool.

EEG Assessment

- Use of acute EEG will be instigated in a subgroup of the cohort where infrastructure exists to make this possible.

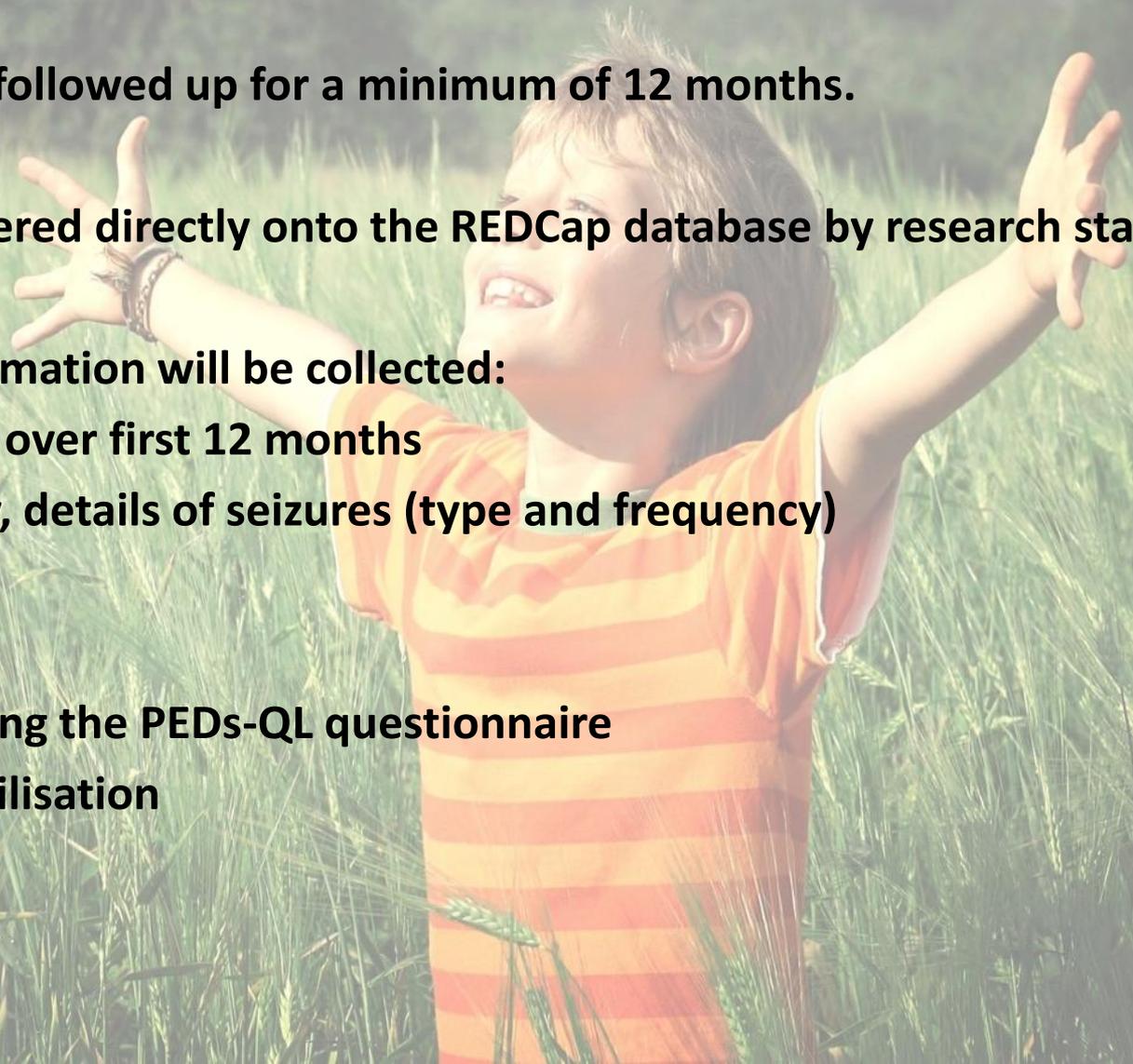


12 month follow up

- **Patients will be followed up for a minimum of 12 months.**
- **Data will be entered directly onto the REDCap database by research staff**

The following information will be collected:

- 1. Case fatality rate over first 12 months**
- 2. Ongoing epilepsy, details of seizures (type and frequency)**
- 3. Recurrence of SE**
- 4. Global Outcome**
- 5. Quality of life using the PEDs-QL questionnaire**
- 6. Health service utilisation**



Ethics

- **Awaiting ethics confirmation from Children's Health Queensland Human Research Ethics Committee (CHQ HREC)**
- **Governance approvals sought from all participating sites**

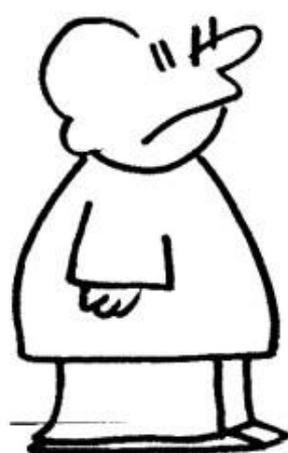


Ethics

Grant money



- **Queensland Emergency Medicine Research Foundation (QEMRF) grant approved for 70k over 2 years**
- **Applying for National Health and Medical Research Council (NHMRC) grant next month**



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“It’s a foolproof formula for writing grant applications.”

