Interview Schedule:

Qualitative analysis of parental attitudes to a deferred consent process in paediatric emergency research.

Survey Information (used to augment existing information within EDIS):

- Demographic data:
  - Guardian Sex: Male Female
  - Guardian Age range: 18-24 25-34 35-44 45-54 55-64 65+ (or you could have them state their age, whichever you prefer).
  - Ethnicity? (Self-identify)
  - Religious Denomination? (Self-identify)
  - What is the highest level of education you have completed? Completed primary completed year 10 (school certificate) completed year 12 (higher school certificate) post school non-university completed an undergraduate university degree completed a postgraduate university degree
  - What is your approximate annual household income? Less than $25k 25k-49k 50-74k 75-100k >100k
  - Are you supportive of medical research? Yes / No / Unsure
  - Are you supportive of research on emergency care? Yes / No / Unsure
  - Have you participated in a research study before? Yes / No / Unsure
    - If yes, Why did you participate?
      Personal interest in the topic
      Someone asked
      Might help others
      Might advance science/medicine
      Unique personal experience
      Financial compensation
      Other benefits
      Other
  - Have you ever refused to participate in a research study? Yes / No / Unsure
    - If yes, Why the refusal?
      Prompts: Too much of a time investment
      Inconvenient time or place
      Concerned about the risk
      Information was not clear or complete
      Concerned about confidentiality
      Insufficient compensation
      Other

Do you understand why medical research is conducted, such as clinical trials?

Do you understand what randomization is, and why scientists use this to test out potential treatments?

Interview questions:

Attitudes toward consent concepts. Each scenario will be applied according to the presenting complaint.

We want to discuss this idea about consent with you, based on the kind of experiences you had in your presentation to the Townsville Hospital Emergency Department.

Scenario 1 - Simple febrile seizures: Your child presented to ED with a simple febrile seizure. You have probably now had it explained that this condition is very common, and most children recover completely without any consequences. Regardless we also know that this is often very frightening for parents at the time. Status Epilepticus, which is an emergency condition where seizures do not stop by themselves and require medication to be administered to stop the seizures to try to prevent long term consequences. As emergency doctors we do not know for sure which drug is the best at stopping these seizures. Research into emergency situations like this sometimes use a "deferred consent" process because of the need to start treatment without delay, whereby the doctor will treat the patient in the standard manner, or will treat the patient with an alternative method that is believed to be of equal or better standard to the standard treatment method. Due to the time required to treat, they do this, without asking the consent of the patient or in this case the parent / guardian beforehand. Consent is sought as soon as is practical afterwards so that information already collected can be used, and to continue in the trial.

Scenario 2 – Bronchiolitis: Your child presented to ED with a bronchiolitis. You have probably now had it explained that this condition is very common, and most children recover completely without any consequences. Regardless we also know that this is often very frightening for parents at the time. Bronchiolitis can also be a life threatening emergency in some circumstances when oxygen levels can fall very low, and some children require additional oxygen to help them breath. Emergency doctors do not know for sure which way of giving oxygen is better for children with bronchiolitis. Research into emergency situations like this sometimes use a "deferred consent" process because of the need to start treatment without delay, whereby the doctor will treat the patient in the standard manner, or will treat the patient with an alternative method that is believed to be of equal or better standard to the standard treatment method. Due to the time required to treat, they do this, without asking the consent of the patient or in this case the parent / guardian beforehand. Consent is sought as soon as is practical afterwards so that information already collected can be used, and to continue in the trial.

Questions

Thinking back on your recent visit to the Townsville Emergency Department, would you have been willing for your child or a child in your care to have participated in research and then for consent being sought at a later stage? Discuss

Can you describe to me how you were feeling at the time of the visit.

Do you think you would have been able to make a quick informed decision about participating in a research study? Based on this do you think you would have participated. Why / Why not

How do you feel about the idea of deferred consent, in time critical health care situations when gaining consent up front is not an option? Bear in mind that deferred consent is used in regards to research in emergency settings, not clinical care. How do you feel about this? Are you able to make a distinction between the clinical care and research?

How do you feel about using deferred consent in research situations that are considered low risk? How would you feel if it were a high risk situation?

In a time pressured situation, do you think you would be in the right frame of mind to provide prospective informed consent (that is informed consent before the procedure is carried out)?

When do you think is the most appropriate time to approach a parent about deferred consent for a study?

Do you think that this deferred consent process should be carried out, even if a child dies?

Do you think that, in the event of a child death, that consent should be waived, and any data collected are used in the study?

Would you be happy for a study to have deferred consent where there is a group of similar people helping to review and provide feedback. E.g. consumer advocate

Do you feel satisfied and reassured by the knowledge that the research project has undergone a review process by an ethics committee, who approved this study as being appropriate. Is this safeguard sufficient to protect the individuals rights?

(If not in agreement with deferred consent as a concept – prompt questioning on why they are uncomfortable with it, and ask question as above about the role of the ethics committee in safeguarding individual rights and safety – or what would make it more acceptable to them if ever).