

INFORMATION SHEET AND CONSENT FORM FOR DELPHI CONSENSUS BUILDING WITH CLINICIANS AND RESEARCHERS: Phase 2

ETH21-5966:

Development of a core outcome measurement set for studies of interventions to enable communication in adults requiring an artificial airway with or without mechanical ventilator support

What is the research study about?

To help patients, their family, doctors and other health professionals make decisions about treatments, we need evidence about what works best from research trials and in clinical practice. Treatments are developed and tested by researchers to make sure they work and are safe. In order to know if they work and are safe researchers look and measure the effects those treatments have on patients. This is done by using standard ways to measure effects, called outcomes. For example, in a study to see how well a new communication treatment works, outcomes used might be how soon a patient is able to speak, or how many patients have difficulty communicating during artificial ventilation.

This research aims to develop an international agreement on a core outcome set for treatments to enable communication in adults requiring an artificial airway. This core outcome set will be a set of main outcomes for all studies to measure. A core outcome set is a short list of patient outcomes that researchers agree to measure to help them see if a treatment has worked or not. At the moment, different studies looking at treatments for the same condition often measure different outcomes. This means when the two studies are finished, we cannot compare or combine their results because they have used different outcomes.

This research is being conducted over four (4) phases.

Phase 1: Patient and Family interviews.

Phase 2: Delphi study. A Delphi study is a way to get everyone's opinion on what to measure.

Phase 3: Consensus on core outcome set: A meeting to reach agreement on the most important outcomes to measure.

Phase 4: Measurement tools. A meeting to determine the best tools to measure the core communication outcome set.

We have completed Phase 1: Patient and Family interviews.

This information sheet and consent form relates to Phase 2: Delphi study. A Delphi study is a way to get everyone's opinion and try and reach agreement on the most important outcomes to measure.

What does this study involve?

You have been invited to participate in this study because we think it is important to include the opinions of patients, their family members and friends, expert clinicians, and researchers in developing the core outcome set. If you choose to participate, you will be asked to participate in a Delphi survey. A summary of how this process works is attached "*Comet Initiative: Delphi plain language summary*".

Who is conducting this research?

My name is Amy Freeman-Sanderson and I am an academic at UTS and the primary contact for the research team. I can be contacted on amy.freeman-sanderson@uts.edu.au if you have any questions about the study.

Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. To be included in this study we are looking for:

- Clinicians eligible for membership/registration of their designated professional society with at least 2 years clinical experience working with people with an artificial airway, and/or have a national standing/published research in this field; and
- Clinicians who understand, read and communicate in English; and
- Clinicians who have access to the internet for online meeting using Zoom.

Do I have to take part in this research study?

Participation in this study is voluntary. It is completely up to you whether or not you decide to take part. If you decide to participate, I will invite you to complete an online survey (approximately 20 minutes).

You can change your mind at any time and stop completing the survey without consequences.

Are there any risks/inconvenience?

We don't expect this survey to cause any harm or discomfort, however if you experience feelings of distress as a result of participation in this study you can let the researcher know and they will provide you with assistance. The survey is anticipated to take approximately 20 minutes.

What will happen to information about me?

Your survey responses will not be able to identified by the group. All identifying information will be removed and data will be aggregated (or reported together). De-identified data will be stored on STASH (UTS data repository). Your information will only be used for the purpose of this research project. In all instances your information will be treated confidentially.

We plan to present the results at conferences and publish in a peer-reviewed journal. In any publication, information will be provided in such a way that you cannot be identified.

What if I have concerns or a complaint?

If you have concerns about the research that you think I can help you with, please feel free to contact me on email (amy.freeman-sanderson@uts.edu.au).

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Officer on 02 9514 9772 or Research.ethics@uts.edu.au and quote this number **[UTS HREC 21-5966]**