Government of **Western Australia**
Department of **Health**
Child and Adolescent Health Service

PARENT INFORMATION SHEET

Preterm Infants

Thank you for your interest in the study that we are conducting called:

Predicting the safety of air travel in ex-premature infants

Information regarding the study is given below. You may ask any questions that you have.

Background and purpose of the study?

Each year many infants born prematurely travel vast distances to return home after treatment at KEMH or PMH or for holiday travel. Although air travel for these journeys is convenient, it exposes babies to reduced oxygen levels on the aircraft. Normal air that we all breathe contains 21% oxygen, while aeroplanes travelling at high altitude are pressurised to provide the equivalent 15% oxygen only. Whilst for most of us this is well tolerated, the precise effect on babies, particularly those born premature, of this reduced oxygen level has not been scientifically evaluated. This study will investigate that question, together with the accuracy of pre-flight "safe to fly" testing, called a Hypoxia test. The hypoxia test is widely used in infants, children and adults, however it is not known if it is an accurate predictor of needing oxygen to fly or of not needing oxygen to fly in infants following their discharge from hospital.

Who is being asked to take part in this study?

We are asking all parents with babies aged 1 to 12 months corrected and born prematurely (less than 35 completed weeks gestation age) who are undertaking air travel to attend outpatient clinics at PMH or KEMH or for personal holiday travel to participate.

What will happen in the study?

Prior to air travel: In this study we will test (using a hypoxia test) for any potential decrease in oxygen saturation that might occur when your baby is exposed to 15% oxygen during a flight. The hypoxia test is performed by having your baby breathe a mixture of 14% oxygen via a face mask, during which time your baby will have continuous saturation monitoring. In ex-premature infants, if the saturation falls to less than 85% during the test, additional oxygen will be administered through nasal cannulas whilst still applying 14% oxygen. Oxygen will then be titrated to maintain oxygen saturation above 94% so that we can determine the amount of oxygen that your baby should receive during their flight. The test takes 30 minutes to complete.

You will be provided the results of the hypoxia test including its implications and limitations. This is the current standard of practice in the department for clinically referred patients for hypoxia testing.

Irrespective of the results of the hypoxia test, we will train you in the use of supplemental oxygen during the flight. The use of oxygen in-flight is common in premature infants undertaking air travel and can be easily managed by parents. While we believe that air travel without supplemental oxygen is safe in premature infants this has not been scientifically

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studied. We will provide you with an air travel pack that includes an oxygen cylinder, regulator and nasal prongs. We will also provide you with small oxygen saturation monitor (the size of a large wrist watch) for use during the flight.

In Flight: During flight the oxygen saturation monitor will continuously monitor heart rate and oxygen saturation levels of your baby. If your baby desaturates on the flight below 85% for 2 minutes, or less than 75% for one minute, we will ask you to commence the supplemental oxygen therapy. We will also ask you to record take off and landing times as well as your impression of the baby's behaviour (awake, asleep, feeding and crying).
We will arrange to contact you after your first flight and depending on your flight arrangements the same procedure will be used for your return flight.

Potential risks and/or side effects

The hypoxia test as we apply it mimics the environment encountered by your baby during flight and is considered a safe test. Your baby will be closely monitored during the test and if any signs of hypoxia noted then supplemental oxygen will be commenced. This test is standard practice at PMH and confirms with international guidelines.
It is possible even if your baby passes the hypoxia test that during flight your baby may exhibit lowered oxygen saturation or other signs of clinical hypoxia. We will provide you with an oxygen saturation monitor and a small oxygen cylinder and you will be trained in their use. To date there are no reports of side effects or adverse advents in infants who have under taken air travel with supplemental oxygen.

Voluntary participation

This study does not involve any needles or any additional procedures other than described above. Participation in the study is completely voluntary and you may withdraw from the study at any time, without any effect on any future care your child may require. The results of this study may be published; however neither your child nor family will be identified in any way.

Consent

If you agree to take part, you will be asked to sign a Study Consent Form. This is a standard form, based on one developed by the Ethics Committee at PMH, and it will be witnessed by one of the Study staff. You should only sign the consent form once you are satisfied that you have read and understood the information leaflet and that any questions you have asked have been answered to your satisfaction. It does not take away any of your normal legal rights. The Princess Margaret Hospitals Ethics Committee has approved this study and the confidentiality of all participants is assured.

Complaints

If you have any complaints about any aspect of the study you can contact the Executive Director Medical Services of PMH on 9340 2222

Further information and contacts

If you have any questions about this study that and you would like further information or you have any concerns now or at any time about the study, please contact Ms Maureen Verheggen on (08) 9340 8990.