



*Please take
me home.*



Eastern Heart Clinic and Sutherland Heart Clinic Outcome Data Information Sheet

The doctors and staff of Eastern Heart Clinic, (located within Prince of Wales Hospital), and Sutherland Heart Clinic, (located within Sutherland Hospital), are dedicated to improving our clinical results and we can only do this with your assistance. In order to improve the immediate success and long-term outcomes of cardiac procedures, we need to know what factors increase a patient's risk of complications. By knowing this we hope to improve procedural success and long-term outcomes for all patients.

Section 1 – Information for Patients Having A Balloon/ Stent Procedure (All Other Patients See Section 2 overleaf)

The following information describes our outcomes clinical database. All patients who have a balloon/stent procedure are enrolled in this database unless they elect to opt out. All that we ask is that you allow us to contact you at 30 days, one year and two years, to ascertain how much you have benefited from your procedure. The information that we collect allows us to improve our care to future patients.

There are no additional blood tests, chest X-rays or angiograms required.

As you would reasonably expect, many hospitals already have databases on the in-hospital outcome of cardiac procedures, but there is little group data available about long-term outcomes in Australia. To obtain this important information Eastern Heart Clinic and Sutherland Heart Clinic have set up a database that will record information on every adult coronary artery interventional procedure. The success of the database depends on the amount of information we get, and to be truly representative we want to include all patients.

If your doctor found that you had significant narrowing or blockage in one or more of your coronary arteries causing you pain and other symptoms, it is likely that we will wish to include your information in our outcomes database, so please read the following information.

The coronary arteries are the main blood vessels feeding your heart. When they are blocked or narrowed the blood flow to your heart is reduced. Your doctor will look for these narrowed arteries using X-ray (an angiogram) and then give you appropriate treatment to open up the blood vessels or to reduce your symptoms. The treatment you will receive involves inflation of a small balloon inside the artery to widen it. This is called an angioplasty. During this procedure, a stent is often implanted. A stent is a hollow, flexible, metal tube which is placed inside the newly opened artery to hold it open and keep it open.

Generally, these procedures are successful and improve the quality of the patient's life, with a small risk of death or major complications. Your doctor will have explained these risks to you. Some people, however, can have a recurrence of their original symptoms, usually due to re-narrowing of the vessel (restenosis). There are continuous improvements in techniques and equipment that reduce the risk of complications and restenosis in clinical trials, but whether these improve outcomes in "real life" is often unknown.

We are asking you to participate in our outcomes database by allowing us to document information about your cardiac condition after your procedure. We are interested in how you progress over time by collecting follow-up information about your cardiac health.

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What Information Do We Need?

We are required already to collect information about your care such as your name, date of birth, hospital identification number, the name of your hospital, the reason you are having a coronary intervention, technical details of the procedure, and any complications that you have in hospital. Additionally we would like to collect follow-up (outcome) information from you. All of your information will be freely available to you from your treating hospital.

We Will Keep Your Information Confidential

Please note that any personal information you provide will be used for clinical research purposes only and will be treated confidentially. No information which could lead to your identification will be released without your written permission or used in any reports on this study. Your records will be stored confidentially under the direction of the researchers on a password protected computer at Eastern Heart Clinic, Prince of Wales Hospital. After the study, these may be stored in a secure location at a document storage company outside the hospital. All trials records must be stored for 15 years and may then be disposed of by shredding and file erasure.

How Will We Collect the Information?

The hospital staff will complete the forms that contain the relevant details during your hospital stay. You will be sent a questionnaire 30 days, 1 year and 2 years after your procedure to briefly obtain information about your cardiac health. This questionnaire will ask you about any new heart symptoms, any further procedures that you have had, and what medications you are taking. Your information will then be entered into a secure database computer. If we do not receive your completed questionnaire within a few weeks, you will be contacted via telephone and given the opportunity to answer the questions.

Risks and Benefits to You

Your information is protected and we are not allowed to identify you by law. The database will produce general reports on the short-term and long-term success of coronary procedures, which we anticipate will improve the quality of procedures in the future.

You Can Choose Not to be in the Outcomes Database

We understand that not everyone is comfortable about having details related to their ongoing heart health entered into a database. If you feel this way, and do not want to be contacted for follow-up, please contact our Outcomes Researcher on 9382 0705 at any time. If you decide you do not wish to participate, this will be respected and your decision will not affect any medical or nursing treatment from us in the future.

Section 2 – Information for All Patients

In order to ensure the greatest standard of care possible for our patients, we ring a sample of our patients to check on their condition post-operatively and ask them if they have any suggestions for improvement of any aspects of our service. We may also invite your participation in research; however any participation is always entirely voluntary.

Please note that any personal information you provide will be used for clinical research purposes only and will be treated confidentially. No information which could lead to your identification will be released without your written permission.

If you do not want to be contacted for follow-up, please contact our Outcomes Researcher on 9382 0705 at any time. If you decide you do not wish to participate, this will be respected and your decision will not affect any medical or nursing treatment from us in the future.



EASTERN HEART CLINIC
Level 3, Campus Centre Building, Prince of Wales Hospital, Barker St, Randwick, 2031
Phone (02) 93820700; Fax (02) 93820799

SUTHERLAND HEART CLINIC
Level 2, Sutherland Hospital, The Kingsway, Caringbah, 2229
Phone (02) 9540 8555; Fax (02) 9540 8550

