Relative Information Sheet

Australia and New Zealand Fragility Fracture Registry

This Registry is the collection of information about the care of people with a broken bone caused by a low impact injury such as a fall from a standing height.

The Registry and Fracture Liaison Services are funded by Accident Compensation Corporation

Coordinating Principal Investigator, New Zealand: Dr Frazer Anderson, Geriatrician, Northland

Study Site: ____

Site Coordinator: ____

Ethics committee ref.: 11797

Voluntary participation, withdrawal and opt-out

Information about your relative will be automatically included in the Registry unless it is decided not to include their information (Opt Out).

Participation in the Registry is voluntary, and information about your relative may be withdrawn from the Registry at any time. Their clinical care will not be affected.

Your relative may opt-out and withdraw their information from the Registry at any time. Refer to the Opt-Out section at the end of this document.

Purpose

Fragility fractures are when bones break after low impact injury like after a fall from a standing height.

- The purpose of the Registry is to improve the quality, safety, and effectiveness of fragility fracture care and to reduce further fractures.
- This will be done by measuring and reporting how fracture care is delivered, how further fractures are prevented and comparing this to the Clinical Standards for Fracture Liaison Services in New Zealand.
- The Registry aims to record information about the care of everyone in New Zealand with a fragility fracture.

Who can take part?

The Registry includes people aged 50 years and over, who have had a fragility fracture (a broken bone from a low impact injury).

What does participation in the Registry involve?

The only difference from usual care is that information about the care of your relative will be collected into a national registry. This allows easier comparison of care to the Clinical Standards. All the information we are collecting is already recorded in your relative's DHB health records as part of the usual care of people with a fragility fracture.

Usual care involves

- An interview to understand the risk factors for future fractures.
- Possibly blood tests (to look for causes of bone weakness) and a scan to gauge the strength of your relative's bones.
- If medication is recommended, a phone call at 16 weeks and 52 weeks after your relative's fracture to see how they are going.
- A referral may be made for an exercise programme
- Your relative and their GP will receive a long-term plan of care.

Risks, benefits, and costs

There are no additional risks to the usual care for people with fragility fractures.

Participation will help improve future care of people with fragility fractures.

There are no additional costs. There are no payments.

What will happen to your relative's information?

Identifiable information

Identifiable information is any data that could identify your relative (e.g., name, date of birth, or address). Only the local clinical team and the Registry Data Manager will have access to this.

In this study, we will submit your relative's identifiable information into a registry where it will be converted into de-identified (coded) information. The only way we will use your relative's identifiable information is to compare our record about your relative with other health records held in the Ministry of Health Mortality Collection, and the Hip Fracture Registry. This is called 'data-linking'. Data-linking in this study is essential to make sure our records are complete and accurate. We cannot use your relative's identifiable information for any other purpose without additional Ethics Committee approval.

De-identified (coded) information

To make sure your relative's personal information is kept confidential, information that identifies your relative will not be included in the main database used by the registry to create its reports. The registry will keep a separate list linking your relatives code with their name, so that your relative can be identified by their coded data if needed.

The following people may access coded information in the registry:

- Researchers from within the Steering Committee to write reports on the care that has been delivered to people with fragility fractures
- External researchers may request access to coded data for independent research, but they will require ethics approval from an independent Ethics Committee for this and they will sign a confidentiality agreement.

The results of the Registry may be published or presented, but not in a form that would identify your relative.

Future research using your relative's coded information.

Your relative's coded information may be used for future research related to fragility fractures. This future research may be conducted overseas by researchers who have received independent Ethics Committee approval. The coded information may also be added to information from other studies, to form much larger sets of data. There will not be notification when future research is undertaken using this coded information.

You will not receive any results that directly relate to your relative's participation in the Registry. Annual Registry reports will be available on the registry website www.fragilityfracture.co.nz. The reports will be the percentage of people that meet each of the clinical standards in each service. All data in these reports will not identify your relative.

Risks.

The information in the registry will be kept secure by the registry complying with all New Zealand and Australian standards and guidelines for cloud-based storage and by using encryption to submit information to the registry.

The registry data including your relative's information will be stored on secure cloud-based storage in Australia. When storage of the same security is available in New Zealand the data set will be relocated to New Zealand. Your relative's information stored in the Registry will be stored indefinitely.

The management of the data is supervised by a Steering Committee comprising clinicians and researchers from both Australia and New Zealand.

Every effort will be made to protect your relative's privacy. Coded and anonymised information does not provide an absolute guarantee that your relative cannot be identified, however the risk of people accessing and misusing your relative's information (via illegal means) and accidental disclosure is very small.

What happens if I want more information, or have a complaint?

Please contact your local Site Coordinator if you:

- Would like more information or have a complaint,
- Want to access and review your information,
- Want to request that any information you disagree with is corrected.

Site Coordinator ____

You may also contact the Registry by email admin@fragilityfracture.co.nz

How does my relative Opt-Out?

If you do not wish to have your relative's information included in the Registry you can:

- Inform the clinician who is working with your relative.
- Inform the person who provided this information sheet.
- Contact the local Site Coordinator
- Email opt-out@fragilityfracture.co.nz
- Visit the Registry website www.fragilityfracture.co.nz
- To formally record your relative's Opt-Out request you may wish to complete an opt-out form.