The SPINE Registry

Did you know?

- Back problems affect about 1 in 6 Australians.
- Back pain and neck pain are a leading cause of disability worldwide.
- Around 45,000 Australians undergo spinal surgery every year.
- Benefits from surgical treatment varies from person-to-person, even when individuals have the same diagnosis and same surgery.
- Clinical registries are a valuable tool to improve patient care by assessing both clinical outcome and outcomes from the patient's perspective.

Neurospine Foundation and Neurospine Institute have established a registry called 'The SPINE Registry' with the aim to optimise outcomes for patients with spine conditions by monitoring and evaluating the quality of spine care.

What is The SPINE Registry?

The SPINE Registry is a clinical registry which collects and stores health, clinical, and surgical information about patients who undergo spine surgery for treatment of their spine-related condition. The SPINE Registry also includes 'Patient-reported outcome measures (PROMs)' which are short questionnaires that collect information about pain, day-to-day function and quality of life from the patient's perspective. These PROMs allow us to understand treatment outcomes from a patient's point of view and drive patient centred care.

The SPINE Registry aims to:

1. Identify the most effective surgical techniques.
2. Identify patients most likely to benefit from surgery.
3. Identify which patients are at risk of complications and introduce suitable strategies to prevent complications.
4. Evaluate care against best practice standards and evidence-based medicine.

Who can participate in The SPINE Registry?

You are eligible to participate in The SPINE Registry if:

1. You have had a clinical assessment and treatment consultation with Dr Greg Cunningham, Dr Paul Taylor, Dr Andrew Miles or Dr Michael Kern at Neurospine Institute and you have consented to surgery for the treatment of your spine-related condition.
2. You are 18 years of age or older.
3. You understand what participating in The SPINE Registry involves and you are able to provide your informed consent to participate.

Choosing to participate or not to participate in the registry will not influence your treatment or relationship with the surgical team or other healthcare practitioners involved in your care. If you change your mind about participating in The SPINE Registry, you can withdraw your consent at any stage and this will not influence your treatment or relationship with those involved in your care.

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What does participation in The SPINE Registry involve?

Participation in The SPINE Registry is voluntary and very simple. We collect information about you, your health, your surgical procedure and your outcomes following surgery.
This information will be collected from you by asking you to complete questionnaires and also collected from your medical records at Neurospine Institute and from your surgeon.

This information is used to monitor surgical outcomes and for medical research which will allow us to improve patient care. At all times your health information will be kept confidential.

What information is collected in The SPINE Registry?

- **Patient information:** Your name, gender, date of birth and contact details. These details allow us to contact you for participation in The SPINE Registry and to link your surgery details with the results of your questionnaires.
- **Your health:** Other illnesses you may have, your height and weight, and whether you smoke cigarettes or drink alcohol. These details allow us to identify aspects of your health that may influence how helpful surgery is at treating your spine condition.
- **Information about your spine condition and your surgery:** Your surgeon will record the clinical details of your spine condition. This will include the region of your spine that is affected by your condition, the symptoms you are experiencing and the results from any scans you have had. Your surgeon will also record details of your surgical procedure such as the date and location of your procedure, the type or surgery and how it is performed, how long the surgery takes and if there are any complications during the procedure.
- **Patient Reported Outcome Measures or "PROMs" and satisfaction questionnaires:** You will be invited to complete questionnaires before your surgery and at standard time-points after your surgery at 6 weeks, 6 months and 1, 2, 5 and 10 years.

  Satisfaction questionnaires are a short survey about how satisfied you are with your care and the results of your surgery. Satisfaction questionnaires will be provided to you at 6 weeks and 6 months after surgery with your PROMs.

  These questionnaires will take a maximum of 10-15 minutes in total at each time point to complete. The answers to these questionnaires will allow us to monitor, from your perspective, how well your surgery has helped to treat your symptoms and improve your day-to-day function and quality of life.
- **Additional questionnaires from time-to-time:** If you consent, we may contact you outside the standard time-points to complete additional PROMs or other short questionnaires. This may be for specific research projects about your spinal condition and/or your spinal surgery.

How do I complete PROMs and Satisfaction Questionnaires?

Information in The SPINE Registry is collected and stored using a secure online platform called Amplitude Clinical Outcomes (Amplitude). We will create your online patient portal in Amplitude for you if you agree to participate in the registry. Your patient portal is secure and can only be logged into using your personal details, your password and the answer to your secret security question. You can update your information and security details at anytime through your patient portal.

If you have access to the internet and have an email address, you can complete your questionnaires online via your patient portal.

You will automatically receive an email and/or SMS from Amplitude at the standard time-points to let you know you have questionnaires ready to be completed and this will contain a link to log into your patient portal so you can complete your questionnaires.

If you do not have access to the internet or email, or prefer not to use your online portal, you can complete the questionnaires over the phone with one of our trained research personnel.

Alternatively, we can arrange for your questionnaires to be posted to you along with a reply-paid envelope so the questionnaires can be returned at no cost to you. If you wish to change the way you receive questionnaires at any time, this can be arranged by contacting the research team at Neurospine Institute.

What are the benefits of participating in The SPINE Registry?

Objectively collecting and monitoring outcomes from the patient's perspective has the potential to improve patient care. For example, reasons for poor outcomes from the patient's perspective can be evaluated and management strategies implemented.

The overall aim of the registry is to improve patient care and treatment of spine-related conditions. This may be of future benefit to other people undergoing treatment for their spine condition.

Are there any risks to participating in The SPINE Registry?

There is no physical risk to you by participating in The SPINE Registry. The registry collects and stores information that is routinely collected as part of standard patient care.

However, if you have any concerns about your participation or experience any distress completing the questionnaires you can contact your surgeon or the research team to discuss these concerns or to withdraw your participation at any time.

Ethical approval for The SPINE Registry

The SPINE Registry has been approved by the St John of God Health Care Human Research Ethics Committee (SJGHC HREC – 1776). The SPINE Registry is coordinated and managed by the research team at Neurospine Institute. If you have any questions or concerns, please get in contact with St John of God Health Care or the research team at Neurospine Institute (contact details below).

Privacy and confidentiality

Trained research personnel directly involved in the collection of data will have access to your personal information in The SPINE Registry and medical records. However, the privacy of your information is very important to us and we ensure the security and confidentiality of your information at all times.

- Amplitude has strict data privacy and security procedures and undergoes frequent cyber security testing.
- Amplitude complies with the Australian Privacy Act of 1988, Australian Privacy Principles, and The Government of WA Health Department Patient Confidentiality Policy.

- Amplitude has expertise in safeguarding private information. Amplitude houses the well-established British Spine Registry and therefore complies with strict European standards including the General Data Protection Regulation.
- Access to your information in Amplitude is restricted to your treating surgeon and temporary, limited access is granted to medical support staff involved in your care and trained research personnel at Neurospine Institute.
- Any information that could identify you as an individual such as your name and contact details will be removed before any data is analysed for quality assurance, outcome reporting or medical research.

Access to your information

You can access and review your personal information through your Amplitude patient portal at any time. You can also contact your surgeon or the research team at Neurospine Institute to access your information and results.

You can find out about the status of The SPINE Registry or the results of future medical research studies using data collected in The SPINE Registry by contacting the Coordinating Principal Investigator or visiting our website at www.nsiwa.com.au/foundation

Consent to participate and withdrawal from The SPINE Registry

If you are eligible to participate in The SPINE Registry, you will be provided with a Patient Information and Consent Form. If you agree to participate, you can provide written consent by signing and returning the consent form while at the Neurospine Institute rooms after your consultation with your surgeon or you can complete the form at home and return it at a later day after discussing participation with your family, friends, or regular doctor.

You can also provide electronic consent to participate in The SPINE Registry via your Amplitude patient portal.

If you wish to withdraw from The SPINE Registry, you can complete the Form for Withdrawal of Participation provided within the Patient Information and Consent Form and return this to the research team at Neurospine Institute. Alternatively, you can log into your Amplitude patient portal and withdraw your consent electronically. You can also contact Neurospine Institute any time to discuss your concerns with participating or to request to withdraw from The SPINE Registry and a trained research personnel will update your consent on your behalf.

Questions or concerns

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Concerns or complaints

If you have any complaints about this project or how it is being conducted,
or have any questions about being a research participant you may contact:

St John of God Health Care
Human Research Ethics Committee
(08) 6116 0542