Patient information and consent to posterior spinal instrumented fusion

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- If you have any questions or concerns about this procedure or your appointment, please call the clinical nurse practitioner or secretary for your consultant. Any concerns regarding the organisation of your admission date may be dealt with by the neuroscience admissions office on 01223 217100.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know
Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.
About posterior spinal instrumented fusion

An unstable spine often causes pain and there may be pressure on the spinal cord or spinal nerves in your neck or back. This pressure results in pain, numbness or weakness and possibly disturbance to your bladder/bowel function. Without surgery, the spine will remain unstable and your symptoms might progressively worsen. This operation involves the insertion of metal screws and rods to stabilise your spine. It may also be necessary to remove (decompress) small portions of bone which are causing pressure on the spinal cord or nerve roots.

Intended benefits

The aim of the surgery is to stabilise your neck or back. For most patients, this will prevent further deterioration of their symptoms as a result of spinal instability and compression of nerve tissue. The success rate for this operation is high with regards to stabilisation of the spine. However, the recovery of function is unpredictable. A small proportion of patients will continue to have pain after their surgery.

Who will perform my procedure?

This procedure will be performed by a consultant neurosurgeon or consultant orthopaedic spinal surgeon or neurosurgery specialist registrar operating under the supervision of a consultant.

Before your procedure

Most patients attend a pre-admission clinic, when you will meet either the consultant neurosurgeon or his specialist registrar and the clinical nurse practitioner At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

We need to know if you are taking any of the following tablets as they thin the blood which may cause excessive bleeding at the time of surgery:

- Aspirin
- A prescription for Warfarin, Aspirin Rivaroxaban, Dabigatran, Apixaban or Clopidogrel (Plavix®)
- Or any other medication which may thin your blood
Patient Information

If to your knowledge the answer to any of the following is yes, it is important that you tell us:

- Have you ever received Human Growth Hormone;
- Have you had brain surgery prior to 1992 or;
- Has anyone in your family been diagnosed with CJD?

A positive answer will not prevent any treatment, it will however allow us to take Infection Control advice and plan your procedure so as to minimise any risks.

This procedure involves the use of general anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

When you are admitted to hospital the nurses will let you know when to stop eating and drinking; this is usually from midnight the day before your operation.

The time that you spend in hospital after the operation will depend on the reason for having the operation and whether a minimally invasive approach is used. We will discuss this with you prior to the operation.

During surgery, you may lose blood. If you lose a considerable amount of blood your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause you harm. The blood transfusion can involve giving you other blood components such as plasma and platelets which are necessary for blood clotting. Your doctor will only give you a transfusion of blood or blood components during surgery, or recommend for you to have a transfusion after surgery, if you need it.

Compared to other everyday risks the likelihood of getting a serious side effect from a transfusion of blood or blood component is very low. Your doctor can explain to you the benefits and risks from a blood transfusion. Your doctor can also give you information about whether there are suitable alternatives to blood transfusion for your treatment. There is a patient information leaflet for blood transfusion available for you to read.

**During the procedure**

An incision will be made in the skin of your neck or back over the region of the unstable spine. Small portions of the bones may then be removed to create more space for the compressed spinal cord or nerve roots. Metal screws and rods are inserted into the normal spine above and below the unstable area to stabilise the spine and prevent any abnormal movement of the spine. Sometimes it is necessary to take a bone graft from the edge of your pelvis through a separate incision.
After the procedure

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too. You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your ward. Another small, plastic tube attached to a drainage container will exit just next to the wound. This will be removed one to two days after surgery.

After certain major operations you may be transferred to the intensive care unit (ICU/ITU), high dependency unit (HDU), intermediate dependency area (IDA) or fast track/overnight intensive recovery (OIR). These are areas where you will be monitored much more closely because of the nature of your operation or because of certain pre-existing health problems that you may have. If your surgeon or anaesthetist believes you should go to one of these areas after your operation, they will tell you and explain to you what you should expect.

If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.

**Eating and drinking.** After this procedure, you should be able to eat and drink until your medical team considers it to be safe - this is usually about two to four hours after the procedure provided you do not feel sick.

**Getting about after the procedure.** After this procedure, we will get you mobile as soon as we can to help prevent complications from lying in bed. Typically most patients are able to get out bed one to two days after the operation. If we feel that further physiotherapy is necessary we will advise you.

**Leaving hospital.** The actual time that you stay in hospital will depend on the reason for doing the surgery, your general health, how quickly you recover from the procedure and your doctor's opinion.

**Resuming normal activities including work.** This will depend on the reason for doing the surgery. When you will be ready to return to work will depend on your usual health, how fast you recover and what type of work you do. Please ask your doctor for his/her opinion.
**Special measures after the procedure:** Your medical team will give you further information about any special measures you need to take after the procedure. We will also give you information about things to watch out for that might be early signs of problems (e.g., infection).

**Check-ups and results:** We will organise some x-rays prior to you being discharged and also for your subsequent outpatient appointments. You will be reviewed six to 12 weeks following the operation to make sure that your progress is satisfactory. We usually perform further x-rays at this stage.

**Significant, unavoidable or frequently occurring risks of this procedure**

- At the time of surgery, there is a risk of damage to the spinal cord or nerve roots. This risk is less than 1% (one in 100). If it occurs, you might notice increased numbness in parts of your arm or leg and/or increased weakness in movement. In some cases there could be complete loss of function of your arms or legs and loss of your bladder and bowel.
- Sometimes during the operation, we find that the waterproof membrane surrounding the nerves is very adherent (sticky) to the surrounding structures. If it is torn during the operation, there is a risk of leakage of fluid from the wound. If the membrane is torn, this can be repaired during the operation.
- The risk of a blood clot on the wound that requires a second operation to remove it is between 1 and 2%.
- The risk of wound infection is less than 5%, but this can sometimes need prolonged treatment with antibiotics.
- There is a small risk of requiring a further operation if the bone does not heal or if it is necessary to remove the implants.

**Alternative procedures that are available**

- If the instability of your spine is due to a fracture, the bones and ligaments will often heal if given enough time. You would have to remain in bed for several weeks and may then need to wear a spinal brace for several weeks.
- If the instability in your spine is due to a tumour, radiotherapy treatment may be offered instead but this cannot stabilise the spine.

**Information and support**

You can contact the clinical nurse practitioner for your consultant via the main hospital switchboard or via the neurosurgical secretary if you have further concerns. Further information on spinal conditions is available via the website [www.brainandspine.org.uk](http://www.brainandspine.org.uk).
Anaesthesia

Your operation will be carried out under general anaesthetic

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. **The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness.** Sometimes different types of anaesthesia are used together.

**Before your operation**
Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

**Pre-medicine**
You may be prescribed a ‘premed’ prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. **Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.**

**Moving to the operating room or theatre**
You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room and **before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.**

Once that is complete, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.
General anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects if local anaesthesia has been injected close to your wound whilst you are unconscious. When the effects of the local anaesthesia wear off you may need pain relieving medicines.

What are the risks of anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

Very common (1 in 10 people) and common side effects (1 in 100 people)

Feeling sick and vomiting after surgery
Sore throat
Dizziness, blurred vision
Headache
Bladder problems
Damage to lips or tongue (usually minor)
Itching
Aches, pains and backache
Pain during injection of drugs
Bruising and soreness
Confusion or memory loss
Uncommon side effects and complications (1 in 1000 people)
Chest infection
Muscle pains
Slow breathing (depressed respiration)
Damage to teeth
An existing medical condition getting worse
Awareness (becoming conscious during your operation)

Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications
Damage to the eyes
Heart attack or stroke
Serious allergy to drugs
Nerve damage
Death
Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

For more information about anaesthesia, please visit the Royal College of Anaesthetists’ website: www.rcoa.ac.uk
Information about important questions on the consent form

1 Creutzfeldt Jakob Disease ('CJD')
We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings
As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in training
Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4 Use of Tissue
As a leading bio-medical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
Privacy & dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site.
For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.information@addenbrookes.nhs.uk.
Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history
Authors Neurosurgical team
Pharmacist Fran Smith
Department Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ www.cuh.org.uk
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Version number/Ref 5/CF388/Document ID 8852

Posterior spinal instrumented fusion, CF388, V5, July 2017
Consent Form

Patient agreement to investigation or treatment for neurosurgery, spinal surgery or vitreoretinal surgery

Interpreter's statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed (Interpreter): ................................................................. Date: ...........................................

Name (PRINT): ........................................................................

Or, please note the language line reference ID number: .........................................................
Posterior spinal instrumented fusion

The aim of the surgery is to stabilise your neck or back.

Risk of damage to the spinal cord or nerve roots; risk of leakage of fluid from the wound; blood clot on the wound; wound infection; requiring a further operation if the bone does not heal or if it is necessary to remove the implants.

The following information leaflet has been provided: **Posterior spinal instrumented fusion**

Version reference and date: CF388 version 5 July 2017

or I have offered the patient information about the procedure but this has been declined.

This procedure will involve:

- [ ] General and/or regional anaesthesia
- [ ] Local anaesthesia
- [ ] Sedation
- [ ] None

Signed (Health professional): ___________________________ Date: ____________
Name (PRINT): ___________________________ Time (24hr): ____________
Designation: ___________________________ Contact/bleep no:
C Consent of patient/person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information on ‘Consent’ and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
   a) Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional. □ Yes □ No
   b) Have you had a history of CJD or other prion disease in your family? □ Yes □ No
   c) Have you ever received growth hormone or gonadotrophin treatment? □ Yes □ No
      If yes, please give details below:
      Please specify:
      (i) whether the hormone was derived from human pituitary glands □ Yes □ No
      (ii) the year of treatment
      (iii) whether the treatment was received in the UK or another country □ UK □ Other

   d) Have you ever had surgery on your brain, eye or spinal cord? □ Yes □ No
      If yes, please give details below:

   e) Since 1980, have you had any transfusions of blood or blood components (red cells, plasma, cryoprecipitate or platelets)? □ Yes □ No
      If yes, please answer questions below:
      Have you either:
      (i) received more than 50 units of blood or blood components, □ Yes □ No
      or
      (ii) received blood or blood components on more than 20 occasions □ Yes □ No
      Where possible, please provide the names of all the hospitals where you received blood or blood components:

In the case of a positive reply to any CJD question, staff should immediately inform Infection Control on ext 3497 (bleep numbers 152-198 or 151-803) and the theatre co-ordinator (24 hour bleep number 152-585); out of hours contact the on call medical microbiologist via the hospital contact centre.

2 Photography, Audio or Visual Recording
   a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment. □ Yes □ No
   b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting. □ Yes □ No

3 Medical Training
   I agree to the involvement of medical and other students as part of their formal training. □ Yes □ No
Use of Tissue

a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research. □ Yes □ No

b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records. □ Yes □ No

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information entitled Consent and the above additional information. I agree to the procedure or treatment.

Signed (Patient): _______________________________ Date: _______D.D./M.M./Y.Y.Y.Y.____

Name of patient (PRINT): ____________________________

If signing for a child or young person; delete if not applicable.

I confirm I am a person with parental responsibility for the patient named on this form.

Signed: _______________________________ Date: _______D.D./M.M./Y.Y.Y.Y.____

Relationship to patient: ______________________________

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): _______________________________ Date: _______D.D./M.M./Y.Y.Y.Y.____

Name of witness (PRINT): ____________________________

Address: ________________________________

Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): _______________________________ Date: _______D.D./M.M./Y.Y.Y.Y.____

Name (PRINT): ____________________________ Job title: ______________________________

Please initial to confirm all sections have been completed:

Withdrawal of patient consent

□ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): _______________________________ Date: _______D.D./M.M./Y.Y.Y.Y.____

Signed (Health professional): _______________________________ Date: _______D.D./M.M./Y.Y.Y.Y.____

Name (PRINT): ____________________________ Job title: ______________________________
British Spine Registry – Patient Information

Helping to improve patient care through knowledge

What is the British Spine Registry (BSR)?

It aims to collect information about spinal surgery across the UK. This will help us to find out which spinal operations are the most effective and in which patients they work best. This should improve patient care in the future.

The Registry will allow patient outcomes to be assessed using questionnaires. These will allow surgeons to see how much improvement there has been from treatment.

This has worked for hip and knee joint replacements through the National Joint Registry. We need your help to improve spinal surgery in the UK.

What data is collected?

Your personal details allow the BSR to link you to the surgery you have had. They also allow us to link together all the questionnaires you complete. If you need any further spinal surgery in the future, details of previous operations will be available to your surgeon.

Personal details needed by the BSR are: Name, Gender, Date of birth, Address, Email, NHS number

Your personal details are treated as confidential at all times and will be kept secure. This data is controlled by the British Association of Spine Surgeons (BASS) and held outside the NHS. Personal details will be removed before any data analysis is performed retaining only age and gender. Your personal data and e- mail address will not be available to anyone outside BASS and its secure IT provider. Anonymised data may be released to approved organisations for approved purposes but a signed agreement will restrict what they can do with the data so patient confidentiality is protected.

Your personal data is very important as this will allow us to link details of your diagnosis and surgery with any problems or complications after surgery. You may also be asked to complete questionnaires before and after surgery to work out how successful the surgery has been. These will only be possible if we can connect you to the questionnaires through your personal details.
Do I have to give consent?

No, your participation in the BSR is voluntary and whether you consent or not, your medical care will be the same. Your personal details cannot be kept without your consent. This will be obtained either by getting you to physically sign a consent form or electronically sign one through an email link to a questionnaire or at questionnaire kiosk in the outpatient clinic.

You can withdraw your consent at any time or request access to your data by contacting your Consultant.

Research

Your consent will allow the BSR to examine details of your diagnosis, surgical procedure, any complications, your outcome after surgery and your questionnaires. These are known as ‘service evaluations’ or ‘audits’.

Operation and patient information including questionnaires in the BSR may be used for medical research. The purpose of this research is to improve our understanding and treatment of spinal problems. The majority of our research uses only anonymised information that means it is impossible to identify individuals. From time to time researchers may wish to gather additional information. In these cases, we would seek your approval before disclosing your contact details. You do not have to take part in any research study you are invited to take part in and saying no does not affect the care you receive.

All studies using data from the Registry will be recorded on the BSR website: www.britishspineregistry.com

Children

Parents are asked to consent for data to be collected from their child. Looking at the outcome of spinal surgical procedures is just as vital in children as it is in adults.

Can I find out more information?

The BSR website (www.britishspineregistry.com) contains more information including details of any studies and any information obtained through the Registry data.

If you want to see what data is stored on you, please write us at the BSR Centre (see below).

Contact Details:

Visit our website at:
www.britishspineregistry.com

Send an email to:
Customer.support@amplitude-clinical.com
## British Spine Registry Consent Form

*Helping to improve patient care through knowledge*

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**I CONSENT to:**

- Personal details being recorded in the British Spine Registry.
- I understand information in the Registry will be used to look at the outcomes of treatment and may be used for research purposes and results will be published.
- I understand that data identifying me will not be released to anyone unless required by law or where there is a clear public need to do so.
- Your data may be accessed by other spinal medical professionals in the future who are involved in your medical care.
- I understand that I may ask for my details to be removed at any time and may request access to my personal data.
- I understand that my health data may be linked to other national health databases.

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| **Signature:** ________________________ | **Date:** _____/_____/_____ |

This form should be retained.