

SUPPLEMENTAL CONSENT AND INFORMATION: LUMBAR (LOW BACK) SPINAL SURGERY



Plans have been made for you to undergo **lumbar (low back) spinal surgery** as detailed below:

Procedure

.....

Other Procedure **Bone Graft**

Reason for Surgery.....

Surgeon's signature **Date**

It is important for you to understand the nature of your operative procedure, what to expect from your surgery and the risks which may occur with this operation and also rare, but significant, other complications which have been known to occur. These complications have been listed below, however, this is not an exhaustive and exclusive list and other unforeseen complications may occur. Please sign each of the sections below together with the formal Hospital Consent Form.

1. I understand the operation that my spinal surgeon is performing and I have been given the chance to ask any questions about the operation. I understand that the operation is not a "cure" and it is the nature of spinal surgery to expect a good percentage improvement and / or prevent progression of the underlying condition. I understand that improvements may not be immediate but may be gained over time. I understand there is the possibility that the surgery may not help and that my symptoms may worsen. I am aware of the likely outcome if I do not have surgery.

Signature: Date:

2. I understand that complications which may occur with this type of procedure include: bleeding; infection; nerve injury; scar (fibrous) tissue formation around the nerves; spinal cord injury (weakness, numbness, bladder and bowel problems); durotomy / spinal fluid leak; skin and nerve pressure problems; stiffness / reduced movement; failure to improve symptoms; recurrence of my problem; inadequate correction of any deformity; implant related problems including incorrect position, loss of position, loosening, breakage and non union (failure of the bones to fuse together); problems above and / or below the operated part of the spine; organ injury; sexual dysfunction; problems removing wound drains (if required). In addition, the complications of anterior spinal surgery include blood vessel injury, thigh numbness, warm leg and hernia. General anaesthetic and medical problems may include deep venous thrombosis / pulmonary embolism (blood clots), chest infections, urinary infections, acute confusional state, emotional distress and others. I understand that I may require a urinary catheter (tube in the bladder). A blood transfusion may be required. I understand that I will be exposed to radiation in the form of X-Ray or CT during the procedure.

Signature: Date:

3. Finally, I understand that there are also very rare but serious complications which have been recorded from this type of surgery which, in extreme circumstances, might include: death, paralysis, cauda equina syndrome, severe bleeding, organ injury, ureteric injury, eye complications including blindness, stroke, allergic reactions and other serious anaesthetic and medical problems. Very rarely wrong level and wrong side surgery can occur.

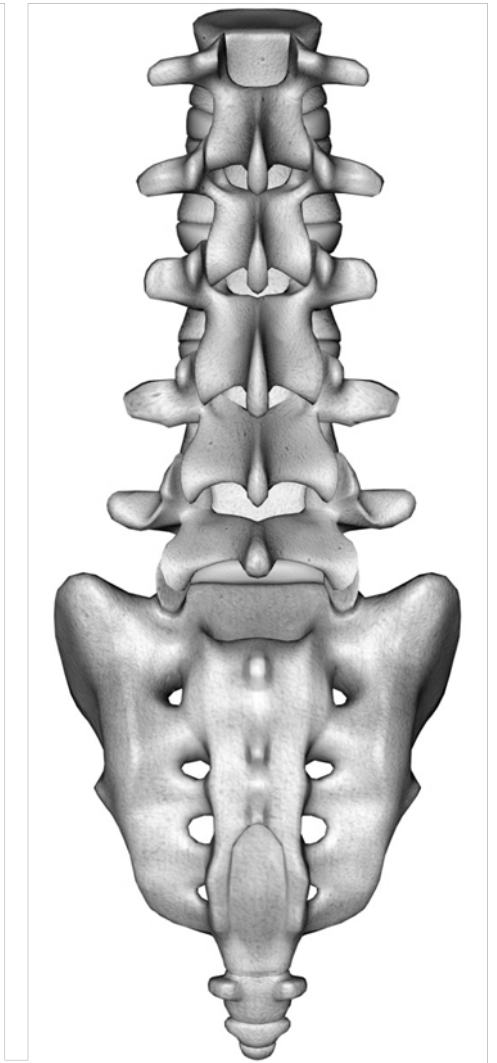
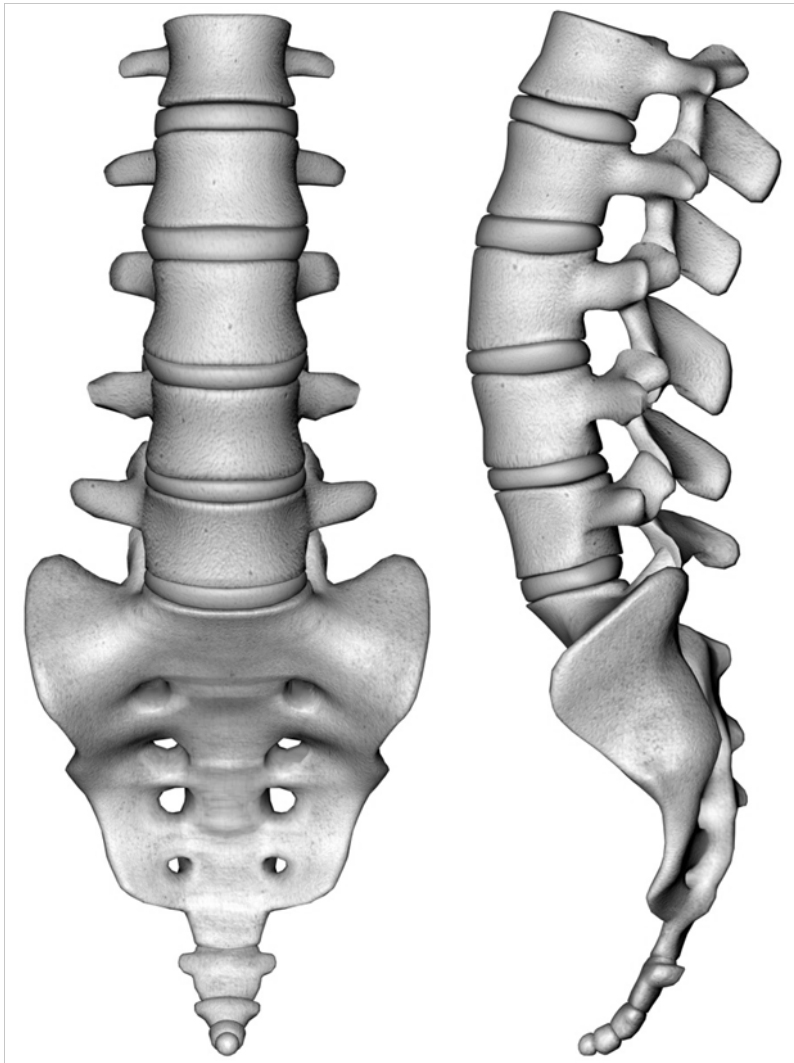
Signature: Date:

4. I consent to blood virology testing in the event of a staff needle stick injury	Yes / No
I consent to medical photography for educational and teaching purposes and	Yes / No
my anonymized medical data to be used for educational and teaching purposes	Yes / No
I consent to being entered on the British Spinal Registry	Yes / No
I understand that I will be required to complete outcome questionnaires	Yes / No

Signature: Date:

5. I understand that there are risks regarding COVID19 (and other pandemic infections) and I will follow the current guidelines and advice given to me by the hospital including social distancing, isolation and COVID19 testing.

Signature: Date:



PUT PHOTO OF CONSENT FORM HERE



British Spine Registry Consent Form

Helping to improve patient care through knowledge

Please tick to confirm that you have been given / read the 'BSR patient information leaflet'

Surname: _____

First Name: _____

Date of Birth: ____/____/____

Postcode: _____

Email address (if you are happy for us to send you email links to questionnaires):

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.

Patient / Parent agreement to data collection for Registry and Research:

Signature: _____ **Date:** ____/____/____

To be completed by the person accepting patient consent

Name: _____ **Position:** _____

Signature: _____ **Date:** ____/____/____

This form should be retained.

Last name:	
First name:	or Patient label
DOB:	
Hospital Number:	

Risk Assessment for Venous Thromboembolism (VTE)

All patients will be risk assessed at pre-operative assessment or no later than on admission and if the clinical situation changes.

STEP ONE

Assess all patients admitted/to be admitted to hospital for level of mobility (tick one box). All surgical patients, and all medical patients with significantly reduced mobility, will be considered for further risk assessment.

STEP TWO

Review the patient-related factors shown on the assessment sheet against **thrombosis risk**, ticking each box that applies (more than one box can be ticked). Any tick for thrombosis risk should prompt thromboprophylaxis according to NICE guidance. The risk factors identified are not exhaustive. Clinicians may consider additional risks in individual patients and offer thromboprophylaxis as appropriate.

STEP THREE

Review the patient-related factors shown against **bleeding risk** and tick each box that applies (more than one box can be ticked). Any tick will prompt the Consultant to consider if the bleeding risk is sufficient to preclude pharmacological intervention.

This section to be completed by Consultant on admission

<p>NAME:.....</p> <p>DATE:.....</p> <p>CLINICAL DECISION</p> <p>Tick</p> <p><input type="checkbox"/> No Prophylaxis required (please state rationale for this).....</p> <p><input type="checkbox"/> Mechanical prophylaxis only (please state instruction).....</p> <p><input type="checkbox"/> Pharmaceutical prophylaxis only (please state).....</p> <p><input type="checkbox"/> Combined prophylaxis (please state).....</p> <p><input type="checkbox"/> Variance to NICE guidelines clinically recommended. Please state instruction and confirm discussion with patient AND document in medical record</p> <p>.....</p> <p>.....</p>	<p><i>Signature Designation</i></p>
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Last name:	
First name:	or Patient label
DOB:	
Hospital Number:	

Risk Assessment for Venous Thromboembolism (VTE)

MOBILITY – all patients (tick one box)

Surgical patient <input type="checkbox"/>	Medical patient expected to have ongoing reduced mobility relative to normal state <input type="checkbox"/>	Medical patient NOT expected to have significantly reduced mobility relative to normal state <input type="checkbox"/>
Assess for thrombosis and bleeding risk below		Risk assessment now complete

THROMBOSIS RISK

Patient related	Tick	Admission related	Tick
Active cancer or cancer treatment		Significantly reduced mobility for 3 days or more	
Age > 60		Hip or knee replacement	
Dehydration		Hip fracture	
Known thrombophilias		Total anaesthetic + surgical time > 90 minutes	
Obesity (BMI >30 kg/m ²)		Surgery involving pelvis or lower limb with a total anaesthetic + surgical time > 60 minutes	
One or more significant medical co morbidities (e.g. heart disease; metabolic, endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions)		Acute surgical admission with inflammatory or intra-abdominal condition	
Personal history or first-degree relative with a history of VTE		Critical care admission	
Use of hormone replacement therapy		Surgery with significant reduction in mobility	
Use of oestrogen-containing contraceptive therapy		Varicose veins with phlebitis	
Pregnancy or < 6 weeks post partum (see NICE guidance for specific risk factors)			

BLEEDING RISK (known or suspected conditions)

Patient related	Tick	Admission related	Tick
Active bleeding		Neurosurgery, spinal surgery or eye surgery	
Acquired bleeding disorders (such as acute liver failure)		Other procedure with high bleeding risk	
Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR >2)		Lumbar puncture/epidural/spinal anaesthesia expected within the next 12 hours	
Acute stroke		Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hours	
Thrombocytopenia (platelets < 75x10 ⁹ /l)			
Uncontrolled systolic hypertension (230/120mmHg or higher)			
Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)			

Nurses Name	Signature	Date
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Approximate Recovery Times in Weeks for Spinal Operations

The following is a guide for recovery times following spinal surgery. It is important to note that recovery times will vary between patients and that this is only a guide.

	Lumbar Microdiscectomy / Decompression	Multilevel Lumbar Decompression	Lumbar Decompression and Fusion	Thoracolumbar Fusions: PLF / TLIF / XLIF / ALIF and #s*
Wound Healing	2 to 4	2 to 4	2 to 4	2 to 4
Office / Desk Job	4 to 6+	6+	6+	6+
Manual Job	6+	6 to 12	12+	12+
Driving	Approximately 4 to 6 weeks when you are comfortable getting into and out of a car, can turn your body to look out of the back window and can safely perform an emergency stop.			
Walking	As soon as able. This is an excellent form of gentle exercise to aid your recovery. It is important to slowly pace yourself and build up distances gradually.			
Showering	Initially the wound should be covered by a waterproof dressing whilst taking brief showers. Once it has healed fully longer showers and bathing are permitted.			
Housework	When comfortable. Avoid bending at the back and use your knees. Avoid twisting when hoovering and when ironing make sure the board is set at an appropriate level or you can sit down to iron. Avoid over stretching.			
Lifting	Lifting light objects and shopping can be performed when comfort allows. Avoid bending at the back and use your knees. Use both arms to carry shopping and avoid carrying for long periods.			
Swimming	Your wound must have healed fully before you can swim. If you have been fused please wait until you have had a follow up X-Ray. In line strokes are best following lumbar spine surgery (front crawl and back stroke).			
Gardening	6+	6+	12+	12+
Cycling	6+	6+	6+	6 to 12+
Racquet sports, golf, cricket, jogging	6+	12+	12-24+**	12-24+**
Yoga, Pilates, tai chi, aerobics, gentle aerobic gym activity	6+	6+	12+**	12+**
Weight lifting, contact sports, gymnastics (including football and rugby)	12+	12+	26-52 (if at all)**	26-52 (if at all)**

* PLF = Posterolateral Fusion, TLIF = Transforaminal Lumbar Interbody Fusion, XLIF = Extreme Lateral Interbody Fusion, ALIF = Anterior Lumbar Interbody Fusion, #s = Fractures

** After discussion with your surgeon

Anticipated Times and Information for Spinal Operations

	Anaesthetic	Operative	Recovery	Length of Hospital Stay	Urinary Catheter
<i>Cervical Surgery</i>					
ACDF IVDR 1-2 Levels	<30 mins	1-2 hours	30-45 mins	1 day	No
ACDF IVDR ≥ 3 Levels	<30 mins	2-3 hours	30-45 mins	2 days	No
Anterior Cervical Corpectomy	30-45 mins	2 hours	60 mins	2-3 days	No
Posterior Cervical Decompression +/- Fusion / Laminoplasty	30-45 mins	2-3 hours	60 mins	3 days	No
<i>Lumbar Surgery</i>					
Microdiscectomy / microdecompression	<30 mins	1-2 hours	30 mins	1 day	No
Decompression 1-2 Levels	<30 mins	1-2 hours	30-45 mins	1-2 days	No
Decompression ≥ 3 Levels	<30 mins	2-3 hours	45-60 mins	2-3 days	Not Routinely
Decompression and Instrumented Fusion 1-2 Levels	<30 mins	2-3 hours	45-60 mins	3-4 days	Not Routinely
Decompression and Instrumented Fusion ≥ 3 Levels	<30 mins	3 hours	60-90 mins	4-5 days	Likely
PLIF / TLIF 1-2 Levels	30-45 mins	3-4 hours	60-90 mins	3-5 days	Likely
XLIF 1-2 Levels	30-45 mins	1-2 hours	60-90 mins	1-2 days	Possible
XLIF 1-2 Levels plus Posterior Surgery	30-45 mins	3-4 hours	60-90 mins	3-4 days	Possible
ALIF 1-2 Levels	30-45 mins	2-3 hours	60-90 mins	3-4 days	Yes
ALIF 1-2 Levels plus Posterior Surgery	30-45 mins	4 hours	60-90 mins	3-5 days	Yes
<i>Deformity Surgery / Other</i>					
Paediatric Posterior Scoliosis Correction	45-60 mins	3-4+ hours	60-90 mins	5 days	Yes
Adult Posterior Spinal Deformity Correction with osteotomy / cages	45-60 mins	5+ hours	60-90 mins	1+ week	Yes
Posterior Thoracolumbar Fracture / Tumour / Infection Fixation	45-60 mins	2-3+ hours	60-90 mins	1+ week	Yes (Possible for Fracture)
Anterior Thoracolumbar Fracture / Tumour / Infection Fixation	45-60 mins	3+ hours	60-90 mins	1+ week	Yes

Useful Links:

American Academy of Orthopaedic Surgeons

<http://www.orthoinfo.org/menus/spine.cfm>

Backcare

<https://backcare.org.uk>

British Association of Spine Surgeons

<http://www.spinesurgeons.ac.uk>

British Pain Society

<http://www.britishpainsociety.org>

Education Programs for Patients in Wales

<http://www.eppwales.org>

Eurospine Patient Information

<https://www.eurospine.org/patient-line-spine-diseases.htm>

Getting It Right First Time

<https://gettingitrightfirsttime.co.uk>

National Institute of Clinical Excellence

<http://www.nice.org.uk>

NHS Wales

<http://www.wales.nhs.uk>

North American Spine Society Patient Information Leaflets

<http://www.knowyourback.org/Pages/Brochures/Default.aspx>

Patient.info

<http://www.patient.info>

Scoliosis Association UK

<http://www.sauk.org.uk>

Scoliosis Research Society

http://www.srs.org/patient_and_family

Spine Dragon:

<http://www.spinedragon.com>

Spine Health:

<https://www.spine-health.com>

Spine Universe:

<http://www.spineuniverse.com>

Understand Spine Surgery

<http://understandspinesurgery.com>

WebMD:

<https://www.webmd.com>



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