

SUPPLEMENTAL CONSENT AND INFORMATION: SPINAL SURGERY



Plans have been made for you to undergo **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 cervical (neck) spinal surgery include voice changes, swallowing difficulties, breathing difficulties, organ / blood vessel injury; the complications of anterior thoracic surgery include organ / blood vessel injury and or dysfunction, pneumothorax (collapsed lung); the complications of anterior lumbar (low back) 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, severe bleeding, organ 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.

Thromboprophylaxis Recommendations

Specialty specific advice

Acute spinal injury (T&O): Patients should receive mechanical prophylaxis. Please discuss with the consultant spinal surgeon if enoxaparin should be prescribed as they may require surgical intervention.

Elective spinal surgery (T&O): Prescribe mechanical prophylaxis (stockings, plus foot impulse devices). Do not prescribe enoxaparin pre-operatively. Discuss with consultant spinal surgeon before starting enoxaparin post-operatively. Patients with ruptured cranial/spinal vascular malformations or acute traumatic/non traumatic haemorrhage must not be offered enoxaparin prophylaxis until the lesion is secured or the patient's condition stabilised


Cardiac surgery: Patients should be prescribed enoxaparin pre-operatively *unless contraindicated*, but enoxaparin should be omitted for at least 24 hours prior to surgery. Patients should be prescribed mechanical prophylaxis. Prescribe prophylactic enoxaparin post-operatively until discharge, unless patient is receiving therapeutic anticoagulation (either IV heparin or therapeutic enoxaparin) or acquires a contraindication.

Head and Neck surgery: Prophylaxis is not routinely used for this patient group

Ophthalmology: Day case / SSSU patients do not require VTE prophylaxis if (1) LA (2) GA less than 90mins. Patients with GA > 90mins should receive AES prophylaxis. This does not apply to paediatric cases.

Trauma: There is an increased **initial** risk of haemorrhage in patients following poly-trauma, multi part or unstable pelvic fractures and potentially unstable spinal pathology pending MRI scan. Discuss with consultant

Nephrology and transplant: For this patient group refer to **appropriate** risk assessment form

Patient details (affix addressograph)	 Cardiff and Vale University Health Board Bwrdd Iechyd Prifysgol Caerdydd a'r Fro	Weight:kgs Date weight recorded:..... <div style="text-align: center; border: 1px solid black; padding: 5px;">COMPLETE AND FILE IN PATIENT'S NOTES</div>
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THROMBOPROPHYLAXIS FOR TRAUMA ADMISSIONS

Prescribe both enoxaparin and below-knee anti-embolism stockings for all patients who are not walking OR undergoing surgery IF they have any of the following risk factors for venous thromboembolism

DOES THE PATIENT HAVE RISK FACTORS FOR VENOUS THROMBOEMBOLISM? (VTE) (✓)

Age ≥ 60 years	Acute respiratory failure or exacerbation of COPD
Spinal patient for surgery, bed-rest, brace, halo or hard collar	Acute exacerbation of heart failure
Pelvic surgery, stable pelvic fracture or pubic ramus fracture	Active cancer or cancer treatment
Intracapsular and two-part trochanteric hip fracture	Dehydration
Prolonged (>90 minutes) lower-limb surgery	Obesity (BMI > 30kg/m ²)
Long-leg cast, brace, or traction	Personal or first degree relative with history of VTE
Other (specify)	Pregnancy or < 6weeks post partum
	Use of HRT or oestrogen-containing contraceptive therapy

Risk identified?	Y/N	Thromboprophylaxis indicated?	Y/N	Sign	Name	Date
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PATIENT AGE: _____ **If patient > 70 years old request an eGFR since they may have undiagnosed renal impairment**

DOES THE PATIENT HAVE A CONTRAINDICATION TO:

Enoxaparin?														
Assessment	1	2	✓	1	2	✓	1	2	✓	1	2	✓	1	2
Increased initial risk of orthopaedic haemorrhage: - poly-trauma / SPINAL SURGERY - potentially unstable spinal pathology pending MRI - multipart or unstable pelvic fracture - multipart trochanteric or subtrochanteric hip fracture - Pagetic hip fracture														
Epidural/spinal in past 4 hours or expected in next 12 hours														
Risk of central nervous system bleed (eg. new-onset stroke, head injury or previous subarachnoid haemorrhage)														
Uncontrolled systolic hypertension > 180mmHg														
Currently receiving therapeutic anticoagulation														
Severe liver disease														
Known bleeding disorder**														
Thrombocytopenia: platelet count < 70 x 10 ⁹ /l														
Clopidogrel therapy continuing through pre-operative period*														
Heparin induced thrombocytopenia or heparin allergy**														
Renal impairment with eGFR < 30ml/min **														
Other (specify)														

*discuss with Dr Johansen, or (if coronary stent or recent coronary syndrome) on-call cardiologist ** discuss with coagulation registrar

Contraindication?	Assessment 1	Y/N	Assessment 2	Y/N	Contraindication?	Assessment 1	Y/N	Assessment 2	Y/N
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PRESCRIBE THROMBOPROPHYLAXIS, ACCORDING TO RISK ASSESSMENT, ON DRUG CHART
N.B. Reassess risk of bleeding and venous thromboembolism within 24 hours and if clinical situation changes

On admission	Consultant:				Post-operatively	Consultant:					
Enoxaparin (Clexane) sub-cutaneously	Weight (Kg)	Dose	✓	Mechanical prophylaxis	✓	Enoxaparin (Clexane) sub-cutaneously	Weight (Kg)	Dose	✓	Mechanical prophylaxis	✓
< 50	Seek advice**			Calf length anti-embolism stockings		< 50	Seek advice**			Calf length anti-embolism stockings	
50 - 100	40mg od					50 - 100	40mg od				
101- 150	40mg bd					101- 150	40mg bd				
> 150	60mg bd					> 150	60mg bd				
Contraindication present				Contraindication present		Contraindication present				Contraindication present	

If using b.d. dose omit on the day of surgery

If no contraindications exist and thromboprophylaxis is not prescribed state reason

Sign	Name	Date	Sign	Name	Date
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PRESCRIBING ADVICE

TIMING of enoxaparin administration:

- **if given day before surgery:** administer **no later** than 18:00hrs
- **day of surgery:** administer at 18:00hrs OR 6 hours post-op for afternoon cases (d/w consultant surgeon/anaesthetist)
- **subsequent post-op days:** prescribe at 18:00hrs

Following surgery under spinal/epidural anaesthesia: Wait at least 4 hours before giving enoxaparin

Patients with epidural analgesia post-op: Do not remove epidural catheter within 12 hours of enoxaparin
 Following removal of epidural catheter wait 4 hours before giving next dose of enoxaparin

Heparin induced thrombocytopenia (HIT): Recheck platelet count following 5-7 days of treatment

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

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.

	Anterior Cervical Discectomy and Fusion	Posterior Cervical Decompression and Fusion	Adult Deformity Correction	Paediatric Deformity Correction
Wound Healing	1 to 2	2 to 4	2 to 4	2 to 4
Office / Desk Job	4 to 6	6+	8 to 12+	6+
Manual Job	12+	12+	26+**	12+ N/A**
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	12+	12+	26+	12+ N/A
Cycling	6 to 12+	6 to 12+	12+	12+
Racquet sports, golf, cricket, jogging	12+	12+	26+	26+**
Yoga, Pilates, tai chi, aerobics, gentle aerobic gym activity	12+**	12+**	26 to 52 (if at all)**	26+**
Weight lifting, contact sports, gymnastics (including football and rugby)	26 to 52 (if at all)**	26 to 52 (if at all)**	52+ (if at all)**	52+**

** 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