GETTING IT RIGHT FIRST TIME

Spinal Services

GIRFT Programme National Specialty Report

by Mike Hutton
GIRFT Clinical Lead for Spinal Services

January 2019

GIRFT is delivered in partnership with the Royal National Orthopaedic Hospital NHS Trust and NHS Improvement

Foreword from Professor Tim Briggs GIRFT Programme Chair

I am delighted to recommend this Getting It Right First Time review of spinal surgery by Mike Hutton.

Mike's report brings the GIRFT approach to his own clinical specialty, combining a data-led view of outcomes and costs with real insight into what is and what is not working. I firmly believe that this review can empower clinicians and managers to substantially improve patients' outcomes and quality of life, and create significant cost efficiencies.

GIRFT and the other Carter programmes are already demonstrating that transforming provider services and investing to save can bring huge gains in improving care for patients.

The programme began following my review of orthopaedic surgery in 2012. That review was driven by a desire to ensure better care and outcomes for patients and to fix the issues faced by colleagues in my own specialty. With a small team, we visited over 200 sites, meeting more than 2,000 surgeons, clinicians, support staff and trust managers. Almost everyone acknowledged that the NHS must review all unwarranted variation in the quality and efficiency of the services we deliver.

Together we set out to understand the impact of that variation by reviewing data, discussing challenges and debating solutions. At the end of the process, we were able to make evidence-based recommendations and to share the good practice we found. Today, with the support of my fellow clinicians and the British Orthopaedic Association, those recommendations are helping to improve care and patient outcomes, as well as saving the NHS millions of pounds.

That support is crucial. GIRFT cannot succeed without the backing of clinicians, managers and all of us involved in delivering care. So I am most heartened to hear how supportive people have been as Mike has been carrying out his review.

My greatest hope is that GIRFT will provide further impetus for all those involved in the delivery of spinal surgery to work together, shoulder to shoulder, to create solutions and improvements that have appeared out of reach for too long.

GIRFT Programme Chair and
National Director of Clinical Improvement

Professor Tim Briggs is Consultant Orthopaedic Surgeon at the Royal National Orthopaedic Hospital NHS Trust, where he is also Director of Strategy and External Affairs. He led the first review of orthopaedic surgery that became the pilot for the GIRFT programme, which he now Chairs.

Professor Briggs is also National Director of Clinical Improvement.

Professor Tim Briggs *CBE*

Contents

Introduction from Mike Hutton **5**
Statement of Support from United Kingdom Spine Societies Board **6**
Statement of Support from the British Association of Spine Surgeons **7**
Statement of Support from the Society of British Neurological Surgeons **8**
Statement of Support from the British Orthopaedic Association **9**
Statement of Support from the National Backpain Pathway – Clinical Network **10**
Recommendations **11**

Executive Summary **13**
The GIRFT programme 13
What we found 14

1. Spinal Services Today **16**
1.1 Introduction 16
1.2 What leads to spinal surgery? 17
1.3 Progress to date 17
1.4 Looking ahead 17

2. Management of Lower Back and Radicular Pain **19**

3. Improving Emergency Access and Referral Protocols **27**
3.1 Cauda Equina Syndrome 27
3.2 Inappropriate Emergency Admissions 30
3.3 Spinal cord injury/Spinal Trauma 36

4. Strengthening the Network Model **43**

5. Specialist Spinal Services **45**
5.1 The provision of specialist spinal services 45
5.2 Surgical volumes and the provision of specialist surgery 48
5.3 Adult Spinal Deformity Correction 50

6. Management of Osteoporotic Fractures **52**

7. Paediatric Spinal Surgery **54**
7.1 The Distribution of Spinal Deformity Surgery 54
7.2 Type I & Type II Surgery 59
7.3 Theatre Efficiency and Cost 59
7.4 The Cost of Delivering Spinal Deformity Surgery 63

8. New Models of Care **65**
8.1 Vertebral Osteomyelitis/Infective Discitis 65
8.2 Supporting early discharge from elective spine surgery 66

9. Spotting Failure Earlier **70**
9.1 The use of new technologies 70
9.2 Iatrogenic infections 74

10. Training **76**

Contents

11. Independent Sector Providers **77**

12. Litigation **80**

13. Procurement **85**

13.1 Trends in Expenditure on Spinal Implants 85

13.2 Price Increases 86

13.3 Price Variation 87

Appendix A: The National Back Pain and Radicular Pain Pathway **93**

Appendix B: Standards of Care for Investigation and Management of Cauda Equina Syndrome **95**

Appendix C: Specialised Providers of Complex Spinal Surgery (2017/18) **96**

Appendix D: Beyond Compliance (Risk Assessment Framework) **97**

Appendix E: The GIRFT Categorisation for Spinal Constructs **98**

Acknowledgements **100**

Introduction from Mike Hutton

GIRFT National Clinical Lead for Spinal Services

In carrying out this review, I am fortunate to have been able to visit 127 spinal units in England. During my visits, I have been repeatedly struck by the passionate commitment of the clinical staff towards the NHS as a force for good in society. The majority of units expressed pride in their work, a sense of ownership of their unit, and a loyalty to the local communities they serve. They do so however under significant increasing demand on their services and financial constraints.

Before embarking on this journey, I spent considerable time researching what 'good looked like' in a spinal service. Reflections on my research were that in many aspects of spinal service provision, conflicting evidence existed within the published peer reviewed literature as to what represented the right thing to do with a particular spinal diagnosis. Moreover, with so many political stakeholders and specialist societies involved in the provision of care to patients with spinal conditions, offering guidance on how they should be managed, there were often conflicting views on what best practice is.

It did not take long on the journey however to formulate a robust view of what a good spinal service looked like. A good service is clinically led and working collaboratively with its management. It is not just about the provision of spinal procedures but about looking at a patient's journey from first presentation with a spinal problem, to exploring how to achieve the best possible outcome for a patient in the most cost-effective way.

A good service has a robust governance structure with clinicians meeting regularly locally and within a wider geographical network to discuss difficult clinical problems. The clinicians delivering an exemplar service had transparency regarding complications they encountered, and were able to demonstrate outcome data for the services and procedures delivered.

It transpired that most units were unable to justify their practices with their own outcome data and were often unaware of the types of data prepared and presented by this programme. This lack of data on outcomes and comparative performance provides some basis for the variations which were observed in practice across the country. It is for this reason that one of the key recommendations of this report is improving the quality of data that the NHS already records and mandating the recording of patient reported outcome data and implant use on the British Spine Registry. In this way clinicians can make informed decisions on their practice for the benefit of their patients and commissioners can designate services in centres that provide good outcomes for patients in a cost-efficient manner.

Where we have been able to identify examples of best practice and sound guidance associated with it, we have analysed to what extent this occurs throughout the country and these aspects form the basis of this national report. We have looked at the management of common spinal conditions that a patient presents to their general practitioner with, such as back and/or radicular pain (Sciatica) and found enormous geographical variation in patient pathways for this large group of patients. The solution I believe is universal adoption of the National Back & Radicular pain pathway. This evidence-based pathway involves the use of specialist spinal triage practitioners (e.g. specialist trained physiotherapists) and investment will be required to increase the numbers of this type of allied health care professional.

We have also concentrated on spinal emergency conditions such as Cauda Equina Syndrome, Spinal Cord injury, Spinal Infection and Spinal Trauma. Whilst rare, these conditions if not managed in a timely manner can have a devastating effect on a patient's life, result in years of disability and with this, great cost to patient and society alike. Cornerstone to the management of many of these conditions is rapid MRI imaging. Whilst MRI scanners are physically present in many hospitals they are not functional out of normal working hours in many trusts through a national shortage of radiographers. Many of the solutions to these problems I believe are straightforward.

I would like to acknowledge the significant contribution of Justin Nissen to the project. Justin is Consultant Neurosurgeon at Newcastle University Hospital. He attended 18 of the deep dive visits and gave valuable advice throughout the project. I am grateful to his trust for allowing him to do so.

I am excited to put forward the recommendations in this report. I firmly believe they offer the potential to achieve significant improvements in patient care and to create significant financial opportunities.

Mike Hutton

Mike Hutton is a Consultant Spine Surgeon and was the Spinal Clinical Lead at The Royal Devon and Exeter NHS Foundation Trust

He is a member of the executive of The British Association of Spine Surgeons as the Audit and British Spine Registry Lead, and spinal lead for the Department of Health Clinically Led Quality and Efficiency Programme.

Statement of Support
United Kingdom Spine Societies Board

The United Kingdom Spine Societies Board (UKSSB) welcome the publication of this report. We strongly endorse the GIRFT programme and the wide-ranging recommendations made in this report.

The GIRFT programme has enabled the collection, analysis and publication of a range of clinical and process measures. The many visits that have been made to individual trusts have provided new insights and been a powerful stimulus for improvements in patient care. Bringing these insights together in this national report shows where progress has already been made, gives examples of organisations that are leading the way in driving further improvements, and gives focus to areas where more work is needed.

The report highlights some areas of excellent practice, and also some areas where improvements can be made. For example, models of care are not always reflecting agreed and well-evidenced pathways, and the report highlights the need to strengthen how the NHS makes use of scarce specialist resources. In common with many specialties, there are substantial quality and efficiency improvements that can come from more consistent and coordinated delivery of services across primary, acute and community care. Many of the recommendations in this report point to the need to re-invest savings that can come from acute care into supporting the management of spinal conditions outside hospital.

This report also highlights the need for targeted investment in areas where there is a clear shortage of capacity, such as Spinal Cord Injury services, which we support.

We have no doubt that clinical staff will respond with vigour and passion to improve, where they can, the services provided for patients.

Patrick Statham
UKSSB Chair

Statement of Support
British Association of Spine Surgeons

The British Association of Spine Surgeons provides its full support to the GIRFT report and the recommendations within the document.

The report supports many of the improvements that have been advised by specialists for several years and will drive improvement in spinal care across the UK to elective and emergency spinal patients. The report will also help to support more consistent care and cost savings related to variable practices and procurement.

It is clear that the report and the work done so far by the GIRFT team has already stimulated improved working practices and more collaborative working in many NHS trusts across the country.

The British Association of Spine Surgeons fully supports mandatory outcome data on all patients undergoing a spinal surgical procedure. Data on spinal implants will allow us to identify failing devices early. It is essential that data is available to provide an accurate reflection of outcomes following spinal surgery to guide patients and commissioners in the future.

Stuart Blagg
President

Statement of Support
Society of British Neurological Surgeons

As the professional body representing neurosurgeons in the UK and Ireland The Society of British Neurological Surgeons (SBNS) welcomes and endorses this important Spinal GIRFT Report, the contents of which contains much of significance. This national assessment of spinal surgery services in England has followed detailed visits to all specialist and most non-specialist Units undertaking spinal surgery. Great variability is noted in clinical workload volume and complexity, in procurement arrangements and in the recording of the spinal surgical practice outcomes in Units by the use of Registries. Analysis of the findings will provide great stimulus to decision makers to improve standards of spinal surgery practice and to ensure the right operations are being performed in the right hospitals by the right surgeons.

The SBNS agrees that Spinal Registry use should be mandated and considerable resource will be required to achieve the long term goal of accurately knowing spinal surgical outcomes across the country.

Issues surrounding emergency spinal rotas, spinal trauma and imaging in possible cauda equina syndrome have been rightly highlighted and will need addressing despite the complexities. The wealth of data in this report will take time to digest but the 22 recommendations now need to be acted upon.

Neil Kitchen
President

Statement of Support
British Orthopaedic Association

The British Orthopaedic Association (BOA) welcomes the first National Spinal GIRFT Report as a natural continuation of the process started by the BOA in orthopaedics.

The results clearly show significant variation in provision and results for spinal surgery, and we welcome the recommendations as proposed to reduce this inequality.

The BOA has always maintained that surgeons should contribute to any available national audit, and as such has supported the British Spine Registry as the leading source of clinical spinal data.

Orthopaedic GIRFT has already highlighted the opportunity for greater efficiency and value in clinical delivery, and we welcome the suggested implementation of the Regional Spinal Networks programme which will empower local clinical teams to improve their service delivery in the most appropriate manner.

Phil Turner
President

Statement of Support

National Backpain Pathway – Clinical Network

The National Backpain Pathway – Clinical Network (NBP-CN) welcomes the publication of this GIRFT Spinal Services report which recognises the importance of improving quality of care across the whole pathway. We strongly endorse the recommendations and will continue to work closely with GIRFT to drive implementation through the National Back and Radicular Pain Pathway (NBRPP) *https://www.ukssb.com/improving-spinal-care-project*.

The report found enormous geographical variation in the pathways of patients with back pain. It emphasises the role of Specialist Spinal Triage Practitioners and the importance of early screening, with rapid access to diagnostics and spinal services, for suspected serious spinal pathologies. The report provides evidence that implementation of the NBRPP results in fewer admissions for back pain (with or without radicular pain) and reduces admission for therapeutic injection. The report also found that Allied Health Professionals can contribute to reducing length of stay and readmissions.

High quality early management of back pain however is dependent on investment in Specialist Spinal Triage Practitioners, who bring consistency to the back pain pathway. Further, commissioning of Combined Physical and Psychological Programmes is essential in reducing back pain disability and discontinuing use of less cost effective invasive treatments.

The potential to deliver substantial improvements in patient outcomes and quality of life is why the NBP-CN believes that this GIRFT report will be central in transforming back care in the UK.

Elaine Buchanan
NBP Chair

Recommendations

In this report, we make a series of recommendations that will strengthen the quality and efficiency of spinal services across the NHS and reduce unwarranted clinical variation. Specific actions and their owners are highlighted in the main text of this report. The key recommendations are:

1. CCGs and trusts to agree local plans to implement and adhere to the National Back & Radicular Pain Pathway.

2. Mandatory use of National Neuromodulation Registry for Spinal Cord Stimulators.

3. Trusts to follow SBNS and BASS guidance on the management of patients with suspected cauda equina syndrome, including urgent referral by a senior decision-maker to a 24-hour MRI scanning service performed locally in the hospital of presentation, ensuring no delay.

   Radiologists must prioritise these patients in light of the syndrome's severity and the time-critical nature of effective treatment.

4. Spinal hubs (a spinal hospital with 24/7 spinal consultant on-call) to implement electronic emergency referral systems, that allow effective two-way communication between and within trusts.

5. All major trauma centres to have 24/7 ability to stabilise and decompress patients with fractured and/or dislocated spines.

6. Additional SCI beds, including ventilation beds, to be funded in the system.

7. Develop a standardised mobilisation protocol for patients with a SCI, based on international recognised practice, and improve recording and monitoring of outcomes through the National Spinal Cord Injuries Database.

8. All providers, including Independent Sector providers, to be part of a Regional Spinal Network. Clinicians, including allied health care practitioners, to actively engage in their Regional Spinal Networks.

9. Review the list of trusts that are designated specialist spinal surgery centres and that non-specialist trusts are not remunerated for undertaking specialist work. Specialist top-ups phased out and tariff restructured so that specialist centres are appropriately remunerated for the specialist activity they undertake and are not incentivised to perform non-specialist work.

10. Review of minimum surgeon and provider volumes for a range of rare spinal conditions and complex spinal surgeries, including adult spinal thoracolumbar degenerative deformity surgery and paediatric spinal deformity surgery. Spinal societies asked to make recommendations.

11. BASS to review NICE guidance and recommendations on the appropriate use of vertebroplasty and kyphoplasty and timing of intervention.

12. The BSS and the Spinal Services CRG asked to define criteria in the 16-18 age group that should be treated as a paediatric case.

13. CCGs to ensure that all primary care referrals for paediatric deformity surgery go through their local paediatric deformity unit. A central paediatric deformity referral management tool is used to ensure that cases go to the correct geographical centre with appropriate skill sets and shorter waiting times.

14. Spinal Services CRG (NHSE) asked to review service specification for Type I and Type II Paediatric Scoliosis Surgery.

15. SBNS, BASS and BSS asked to collate and disseminate evidence on best practice in reducing hospital length of stay and supporting early discharge.

16. All spinal surgical interventions to be recorded on the British Spine Registry.

17. Implement a range of specific measures to ensure that spinal surgery implants are introduced and adopted in line with emerging evidence and best practice, and that comprehensive data is collected to support appropriate dissemination.

18. Mandatory requirement for trusts to participate in Public Health England's surveillance of SSI post-spinal surgery.

19. Training across the spinal specialties and within trusts to be strengthened by funding the Spinal Training Interface Groups and reviewing the ongoing training provided by trusts in relation to spinal services.

20. Urgently implement measures to reduce litigation costs by applying GIRFT's five-point plan, adopting best-practice consenting processes, and adhering to guidance on the management of suspected CES.

21. Instigate pricing transparency in procurement for spinal surgery and use the resulting insight to deliver more cost-effective procurement.

22. Industry to publish details of financial and non-financial support they provide directly or indirectly to individuals or units.

Executive summary

The management of spinal problems involves disciplines from across primary and secondary care providers. These include general practitioners, chiropractors, osteopaths, physiotherapists, combined physical and psychological rehabilitation programmes, pain physicians (usually from an anaesthetic background), rheumatologists, and neurosurgical and orthopaedic spine surgeons.

Currently, 150 NHS trusts and 79 Any Qualified Providers (Independent Sector providers) undertake spinal services in England. Of these, 40 are designated as specialist providers of adult spinal surgery and 24 are designated to undertake paediatric spinal surgery. Thirty-four trusts provide spinal pain services only (injections and pain modulations). In 2017/18, the NHS undertook almost 211,000 pain injections and 52,523 surgical procedures of the spine, of which 9,424 were defined as specialist.

Many of the conditions that the specialty deals with are not life-threatening but can have a major impact on quality of life. In other instances, rapid intervention is required to prevent serious and life-changing disability. In any event, many clinical groups will be involved in the delivery of care, meaning it is critical that teams work for the common good, rather than in silos. For many patients, spinal services are delivering high quality care, but further improvements can still be made. This report summarises the most important variations and service developments that can be addressed within spinal services.

The GIRFT programme has examined in detail the way that spinal services are currently provided in England. In 2017/18, the GIRFT team has carried out 127 visits to NHS trusts in England that provide spinal services. This report builds on those visits to set out 22 recommendations to improve the way services are provided in the NHS in England. Our review identifies significant opportunities to improve patient care and outcomes, including a notional direct financial opportunity of £27m.

The recommendations focus on how spinal services can make better use of resources, improve patient experience and improve outcomes for patients. Many of the recommendations will have direct resource savings and can be implemented easily, such as stopping the delivery of interventions that are of limited clinical value and are proven to not be value for money.

Implementation of the national lower back and radicular pain pathway is an example where significant savings could be made from greater cross-team working, in line with established national guidance. In other examples, we have made recommendations where improved coordination of care has the potential to achieve efficiencies and enhance patient experience. Across spinal services, there are examples where scarce clinical and financial resources are not being targeted appropriately, and this report highlights where there are opportunities to make improvements. These will come through removing financial incentives to undertake certain activities, addressing issues in how caseload is distributed across different provider types, and ensuring clinical teams are managing volumes of activity so that they have the required critical mass of skills and expertise.

The rate of technical innovation in spinal services is high. New implants are constantly emerging, offering new and exciting opportunities to improve outcomes for patients, but the evidence suggests that the adoption of these technologies is sub-optimal. They are not introduced in a planned way, and opportunities to collect and disseminate evidence on benefits and appropriate use are missed. We have made recommendations about how the dissemination of new technologies can be coordinated and evaluated more rigorously to improve value for money and patient outcomes.

This report also makes a series of recommendations aimed at reducing litigation claims. In keeping with other specialities, there are simple steps that trusts can take to mitigate the risk of litigation (e.g. the three-legged stool model to getting fully informed consent) and learn from their claims experience.

The recommendations have been reviewed and considered by relevant stakeholders before publication, securing strong support for both the overall direction and the specific detail of implementation. The aim is that they should serve as the catalyst for further discussion and action at national, trust and individual surgeon level.

The GIRFT programme

Funded by the Department of Health and jointly overseen by NHS Improvement and the Royal National Orthopaedic Hospital NHS Trust, GIRFT seeks to identify variation within NHS care and then learn from it. GIRFT is one of several ongoing work streams designed to improve operational efficiency in NHS hospitals. In particular, it is part of the response to Lord Carter's review of productivity and is providing vital input to the Model Hospital project. It is also closely aligned with programmes such as NHS RightCare, acute care collaborations (ACCs) and sustainability and transformation partnerships (STPs)/integrated care systems – all of which seek to improve standards while delivering efficiencies.

Under the GIRFT programme, data from many NHS sources is consolidated and analysed to provide a detailed national picture of a particular area of practice. This process highlights variations in care decisions, patient outcomes, costs and other

factors across the NHS. The data is reviewed by experienced clinicians, recognised as experts in their field, who visit individual hospital trusts to discuss the data with senior management and the clinical teams involved in the specialty under review. This is an opportunity for both parties to learn; the individual trust can understand where its performance appears to be below average and draw on clinical expertise to identify ways to address that, while the visiting clinicians can gain an insight into emerging best practices, to feed into the national picture and make recommendations for service-wide improvement. The analysis and visits lead not only to targeted action within individual trusts, but also to the production of this national report and its recommendations, backed by an implementation programme to drive change and address unwanted variation.

What we found

Management of Lower Back and Radicular Pain

We found wide variation in the management of lower back and radicular pain across NHS trusts. In many instances, lower back and radicular pain is managed with interventions of limited clinical value (e.g. facet joint injections) and at treatment intervals that are inappropriate (e.g. nerve block injections that are repeated within a few months). We also found significant variation in the use of expensive Spinal Cord Stimulators and are recommending mandatory submission of data to the national Neuromodulation Registry so that data on their use and benefits can be systematically collected.

Improving Emergency Access and Referral Protocols

There are opportunities to improve pathways of care for patients with emergency spinal conditions. For example, evidence suggests that many patients with suspected Cauda Equina Syndrome (CES) – a condition that can lead to a range of severe permanent disability including permanent limb paralysis, permanent loss of bowel, bladder and sexual function—are not being referred in line with agreed treatment protocols.

We also observed large numbers of patients being admitted to specialist trusts that do not require surgery, and we saw large number of patients staying in acute beds with non-emergency conditions for long lengths of stay. We also found variations in the protocols for referring and rehabilitating patients following a spinal cord injury.

Regional Spinal Networks

The Spinal Services Clinical Reference Group, with the support of the spinal societies, is championing the establishment of Regional Spinal Networks (RSNs). The goal is to establish networks where there are rules regarding how cases are managed and each provider's role (including Independent Sector providers) within the networks is clear.

The variations identified in this report indicate compelling evidence of the opportunity to improve consistency in how spinal cases are allocated and managed by different types of provider.

Specialised Spinal Services

The data suggest that a significant amount of specialised spinal surgery activity is being undertaken by trusts that are not designated as specialised. We also found some inconsistencies in how trusts are remunerated for specialised activity. We are recommending that the definitions used to identify specialised procedures and designate providers as specialised be reviewed.

We also found wide variations in the volumes of highly complex specialised procedures being undertaken by providers. In this report, we ask the spinal societies to assess the clinical case for setting minimum volume thresholds for a small number of highly complex procedures.

Management of Osteoporotic Fractures

We found wide variations in the use of the kyphoplasty and vertebroplasty, both of which are interventions that aim to improve symptoms of pain associated with benign and malignant osteoporotic fractures. The evidence suggests there is no difference in outcomes between the two procedures when used to manage pain associated with these fractures, although there is a four-fold difference in costs. We are asking BASS to recommend to NICE to review and update their guidance on when intervention should occur in benign osteoporotic fractures, if at all.

Paediatric Spinal Deformity Surgery

Many patients receiving paediatric spinal deformity surgery face long waiting times and have a relatively high risk of their surgery being cancelled. There are opportunities to provide paediatric spinal deformity surgery in a way that reduces the risk of cancellation. This includes preferentially scheduling surgery during summer months for cases requiring paediatric

high dependency/intensive care units, enhanced ward recovery for cases of adolescent idiopathic scoliosis and directing referrals to centres with shorter waiting times and low cancellation rates.

Previous GIRFT reports have emphasised the clinical advantages of having dedicated (ring-fenced) cold site elective hospital beds. In orthopaedics, they have been shown to reduce infection, shorten length of stay and reduce cancellations.

Similar principles applied to paediatric spinal deformity surgery could support trusts in reducing their on-the-day cancellation rates for children undergoing this complex surgery.

We also established that there were varying practices regarding the use of HDU and length of stay on HDU following surgery for adolescent idiopathic scoliosis (AIS). We saw examples of trusts that had reduced their on-the-day cancellation rate for AIS by providing appropriate levels of nursing care in a non-HDU environment.

New Models of Care

During our visits we saw numerous examples of local providers and health systems working together and in different ways to improve the quality and effectiveness of patient care. These include working with community services to manage conditions such as spinal infections with specialist teams at home, greater use of day case surgery where appropriate, and supporting early discharge from acute care. There is wide variation in how these new models of care are being used across providers and scope for greater and rapid adoption of promising new approaches.

Spotting Failure Earlier

There is a big opportunity to improve the way new technologies are introduced, disseminated and appraised in spinal services. Spinal surgery lags behind other specialties, which have made greater progress in controlling the uptake of new technologies, collecting data on their benefits, and using the learnings to inform appropriate clinical practice. In particular, there is an opportunity to routinely collect and analyse data through existing infrastructures so that innovations that represent poor value for money, or are adverse for patients, are spotted and stopped earlier.

Similarly, spinal services are behind other specialties in collecting and monitoring data on surgical site infections. These are serious adverse events. Improved and consistent data collection on their incidence would allow local surgical teams to identify potential problems and implement local plans to reduce surgical site infection rates.

Independent Sector (IS) Providers

The data suggest that the casemix managed by Independent Sector providers is very different to that managed by NHS trusts, even after controlling for specialised services that would not typically be managed by IS providers. We also found that IS providers are more likely than NHS trusts to undertake repeat facet joint injections (which are of limited clinical value). We are recommending that IS providers become part of the Regional Spinal Networks, so that they have the same opportunity as NHS providers to be part of local referral pathways and contribute local spinal services in a consistent and coordinated way.

Litigation

The data indicates that the costs and risk of litigation in spinal surgery are greater now than they ever have been in the past. NHS Resolution data suggest claims related to spinal surgery average over £100m per year, whilst the largest UK medical defence organisation has decided to withdraw cover for spinal surgeons working in the private sector. It is clear from the data on litigation that greater awareness of the drivers of litigation, as well as adherence to existing policies, guidance and best practice, could go a long way to improving patient care and managing litigation costs.

Procurement

Since the onset of GIRFT, total implant costs for spinal surgery have fallen by around 10% (without a reduction in surgical procedure volumes). Despite progress, there is significant further opportunity to strengthen procurement practices in spinal surgery and deliver cost efficiencies. Data suggest there is still wide variation across providers for the same implant, that these variations are unrelated to the volumes being purchased, and that it is common for trusts to purchase comparable implants from competing suppliers at very different prices. In this report, we call for greater transparency in pricing (e.g. using the standard GIRFT categorisation for spinal constructs), greater clinical involvement in procurement, and more transparency on the financial and non-financial support that the medical device industry provides directly or indirectly to individuals or units.

1. Spinal Services Today

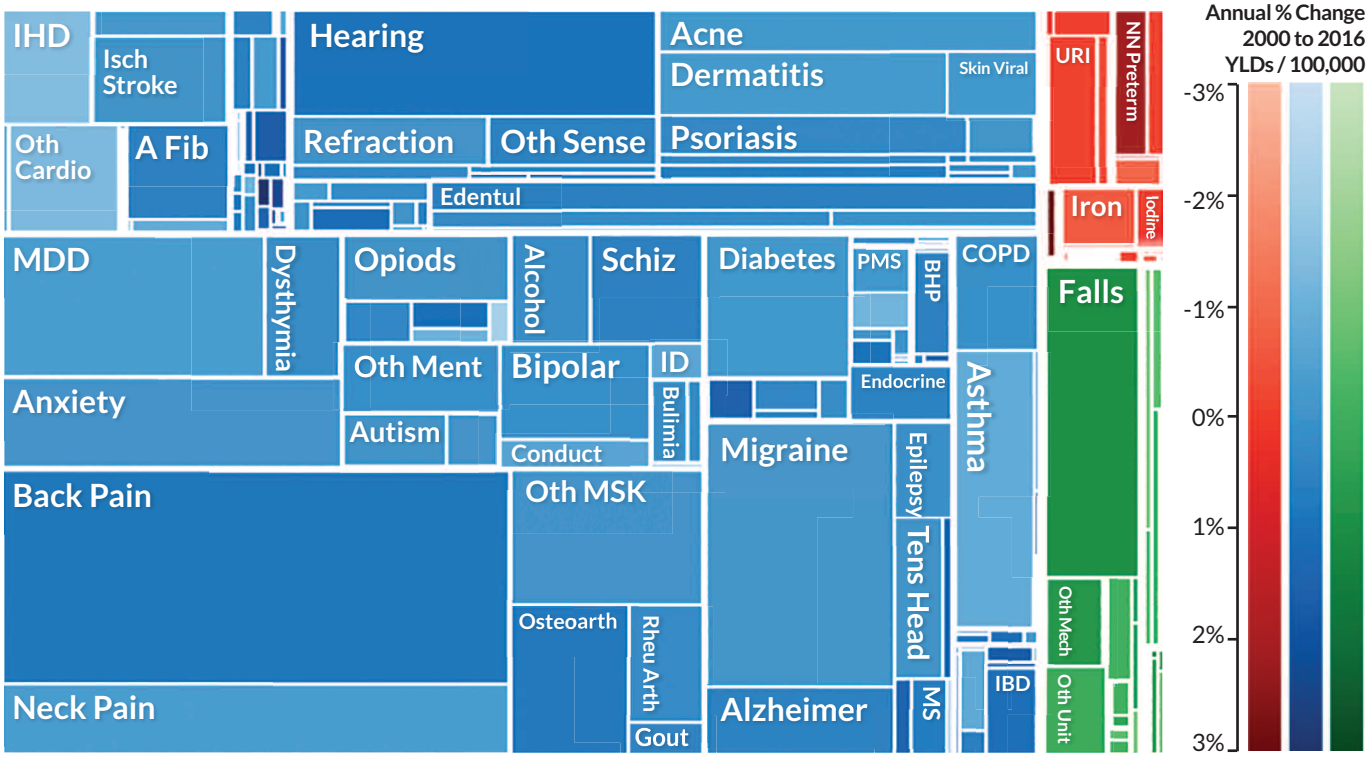
1.1 Introduction

The management of spinal problems within England involves a number of disciplines from primary care to secondary care providers. These include general practitioners, chiropractors, osteopaths, physiotherapists, combined physical and psychological rehabilitation programmes, pain physicians (usually from an anaesthetic background), rheumatologists, and neurosurgical and orthopaedic spine surgeons. With so many groups involved in the care of these patients, it is easy to understand how services can easily work in isolated silos rather than the common good.

Currently, 150 NHS trusts and 79 IS providers undertake spinal services in England. Of these, 40 are designated as specialist providers of adult spinal surgery and 24 are designated to undertake paediatric spinal surgery. Thirty-four trusts provide spinal pain services only (injections and pain modulations). In 2017/18, the NHS undertook almost 211,000 pain injections and 52,523 surgical procedures of the spine, of which 9,424 were defined as specialist.

Spinal services most commonly deal with patients who suffer with lower back pain. Lower back pain is a condition which affects most of the population at some point in our lifetime. One third of the population will suffer with it at any point in time, with a lifetime prevalence of 84%.[1] Of the patients who suffer with back pain, approximately one in 15 will attend their general practitioner and unfortunately some of these will develop chronic back pain making back pain the largest cause of disability in the UK.[2] Figure 1 uses data from the Global Burden of Disease[3] study to estimate the total number of years lived with disability for all causes of disability. Disability from back and neck pain are the largest causes of disability in the UK. A good spinal service should seek to empower first-contact practitioners with the confidence to identify rare but important emergency/urgent spinal conditions referring into an emergency service when suspected. Practitioners should have the tools to identify and manage patients at a high risk of chronicity, including referral for further imaging, expert assessment and timely intervention when appropriate. Support from specialist spinal triage practitioners to arrange, scan and interpret information is key. If any part of this chain has a significant delay then the service will have failed in its objective to reduce pain, disability and chronicity for a patient and enable a rapid return to work.

Figure 1: Years lived with disability, all causes, UK (2016)



United Kingdom - Both sexes, all ages, 2016, YLDS

Source: Institute for Health Metrics and Evaluation, Global Burden of Disease Study (2016) – www.healthdata.org

[1] *Walker BF. The prevalence of low back pain: a systematic review of the literature from 1966 to 1998. J Spinal Disord. 2000;13(3):205–217*

[2] *Macfarlane GJ, Jones GT, Hannaford PC. Managing low back pain presenting to primary care: where do we go from here? Pain. 2006;122(3):219–222*

[3] *Institute for Health Metrics and Evaluation, Global Burden of Disease Study (2016) – www.healthdata.org*

The organisation of spinal services in England has been the subject of previous national reviews[4] yet many have ignored the guidance given preferring to continue to work in silos. Many commissioners still struggle with commissioning spinal services.

The most common group of spinal conditions are associated with the aging spine. The natural history in these conditions in most cases is usually favourable (i.e. patients get better given time). Most spinal injections are used either in a diagnostic role to identify the source of a patient's pain when uncertain or to provide a period of effective pain relief in the hope the condition improves. These injections are provided by surgeons, pain clinicians, radiologists and, on occasion, rheumatologists and increasingly allied health professionals.

1.2 What leads to spinal surgery?

The circumstances that lead to spinal surgery are varied.

In the acute hospital setting presentations are often urgent and may require immediate or expedited intervention (e.g. management of CES, metastatic spinal cord compression, acute neurological deterioration in spinal infection, and traumatic dislocation of the spine). In these circumstances, timely surgical intervention stops irreversible loss of a patient's function.

Other attenders will be acute exacerbations of back and or radicular pain, the majority of which will never require surgery. This is an extremely common reason for attendance at emergency departments (the biggest category presenting is musculoskeletal at 22%, with back pain as the most common symptom[5]) and hospital admission.

Elective spine surgery seeks to improve pain, function and address deformity in spinal conditions and, in the case of young children, ensure they develop as normal a spine as possible to avoid thoracic insufficiency syndrome and early death.

With an ageing population and given how common spinal complaints are (estimates suggest around 33% of the population have lower back pain at any point in time[6]), the management of spinal conditions presents a challenge to the NHS. Patient populations are broad, including patients with first-time back pain, those with intermittent acute exacerbations and chronic long-term patients. Consistent triaging and onward management is vital, be it community, specialist or highly specialist. Small variations in the initial triaging, streaming and management of patients, have a significant impact on the consequential demands on providers of surgical care. This variation, and the resulting impact on providers, forms the principal focus of this report.

1.3 Progress to date

A lot of work has been undertaken to improve consistency of decision-making and to support clinicians. For example, the National Low Back and Radicular Pain Pathway was recently updated to its third revision and has been instrumental in providing clarity to clinicians about the management of these common complaints. NICE issued guidance in 2009 and 2016 on the management of lower back pain and sciatica. NHS England's Spinal Surgery Clinical Reference Group provides clarity about the procedures that are specialist and which should only be undertaken by centres and surgeons meeting clear minimum standards. The establishment of Regional Spinal Networks is moving forward, aiming to ensure that activity is distributed across providers of spinal surgery in a way that the NHS makes best use of limited specialist resources, whilst also providing clinical support to non-specialist providers of spinal surgery.

There are also many examples where individuals and organisations have developed local solutions that have a significant impact on the quality of treatment that patients receive. Some of these are highlighted in this report.

Despite these, and many other positive steps, the data collected by GIRFT show that significant opportunities remain to reduce unwarranted variations, improve outcomes for patients, and reduce waste.

1.4 Looking ahead

This report sets out the actions that individuals and organisations involved in supporting the delivery of spinal services need to take to improve consistency in the delivery of care, reduce variation and improve value for money. The areas covered include adherence to established treatment protocols, the distribution of specialist activity and the mechanisms that need to be in place to support the same.

[4] *See, for example: National Spinal Taskforce, Commissioning Spinal Services – Getting the Service Back on Track: A guide for commissioners of spinal services, January 2013*

[5] *https://www.myhealth.london.nhs.uk/sites/default/files/Rapid%20review%20-%20Behavioural%20insights.pdf*

[6] *https://www.ncbi.nlm.nih.gov/books/NBK11709/*

An important area of focus is information. Other specialties are ahead of spinal surgery in respect of the collection of data on activity and outcomes, as well as using that data to inform clinical practice and motivate change. This is important in all specialties, but particularly so in spinal surgery where the pace of change in medical device technology is high, and the NHS has an opportunity to streamline how it collects, consolidates and disseminates data to inform best practice.

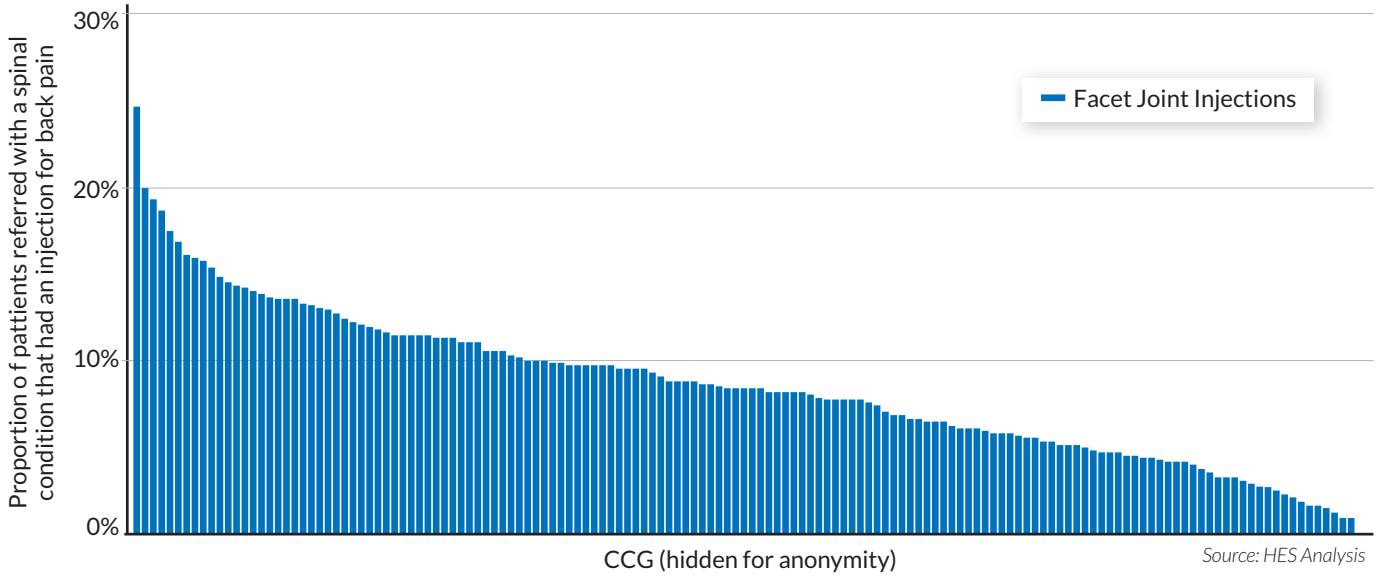
2. Management of Lower Back and Radicular Pain

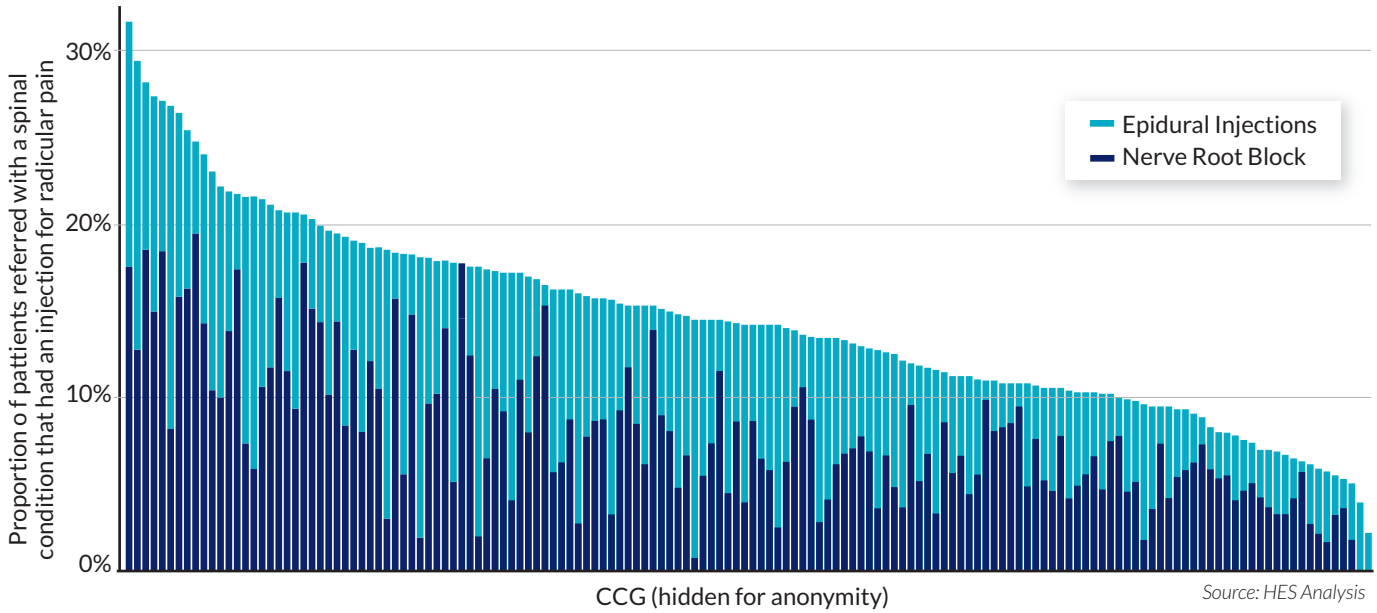
Lower back pain is a common patient symptom and the largest single cause of loss of disability adjusted life years in England. In 2013, a clinical group was established by NHS England to develop an agreed pathway for the management of patients with lower back pain and radicular pain (pain that radiates from buttock to leg). The group agreed guidance, which was first published in 2014. The guidance has since been updated twice to incorporate the latest evidence from NICE. The third edition of the National Low Back and Radicular Pain Pathway was published in 2017.[7] It has been endorsed by NICE[8] and actively promoted by NHS Right Care.

The guidance includes a clear recommendation to *"de-commission treatments which are recommended against by NICE 2016 such as, acupuncture, therapeutic injections for back pain including facet joint injections, TENS and other treatments".*[9]

Data on the use of injections suggests there is still both high and varied use of injections to manage back pain – contrary to national guidance. Figure 2 shows the proportion of patients referred with a spinal condition who have had an injection for back/radicular pain. The data are grouped by Clinical Commissioning Group (CCG).

Figure 2: The proportion of patients referred with a spinal condition that had an injection for back/radicular pain by CCG (April 2016-March 2018)





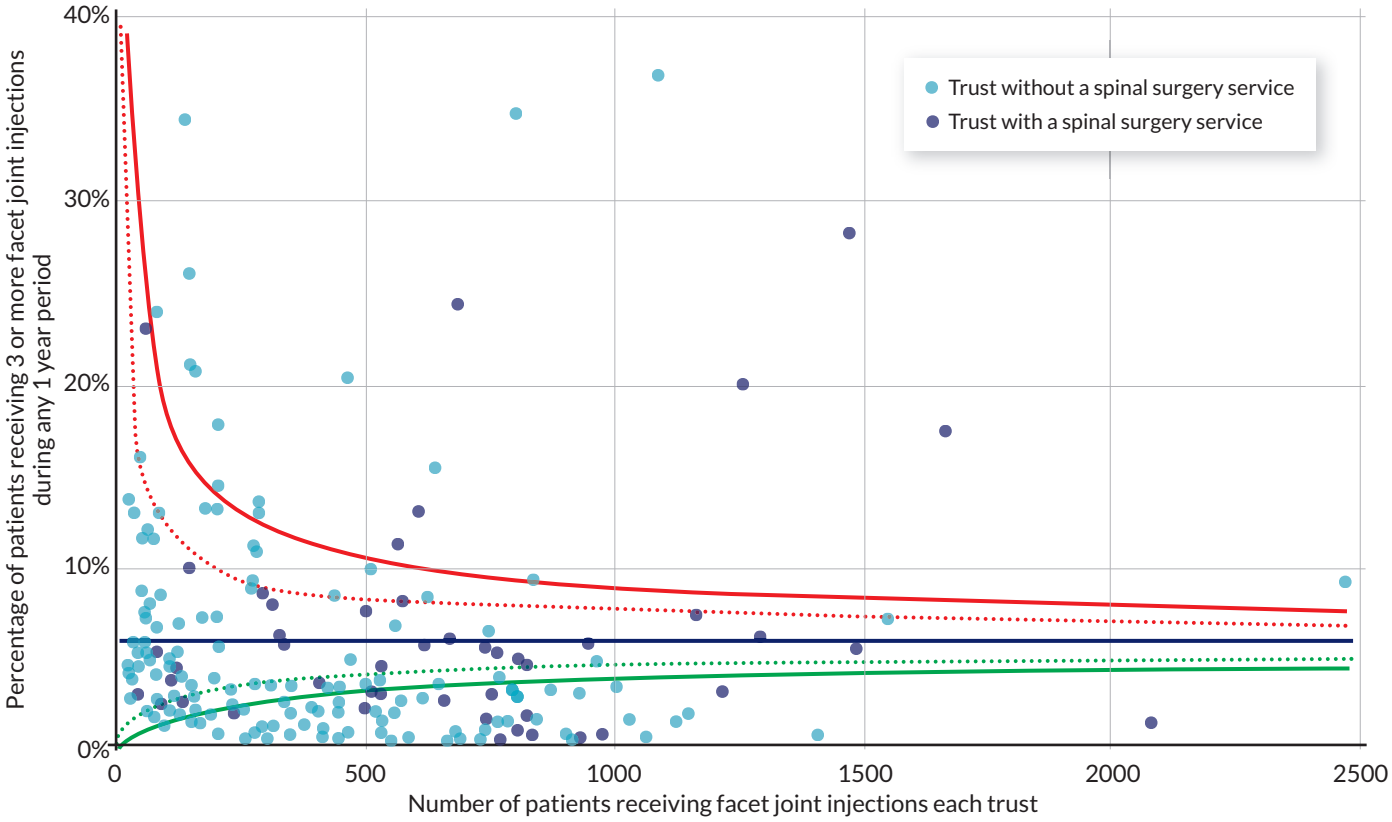
[7] *National Low Back Pain and Radicular Pain Pathway, Third Edition 3.0 30th June 2017 (accessed via https://www.ukssb.com/improving-spinal-care-project)*

[8] *www.nice.org.uk/guidance/ng59/resources*

[9] *National Low Back Pain and Radicular Pain Pathway, Third Edition 3.0 30th June 2017, pg. 5 (accessed via https://www.ukssb.com/improving-spinal-care-project)*

A significant proportion of these patients are receiving facet joint injections, despite guidance to the contrary. Figure 3 shows the proportion of patients with a spinal condition receiving 3 or more facet joint injections within a 12-month period, and the number of patients affected, by trust. On average, 5.7% of patients receive three or more facet joint injections within a 12-month period (April 2015 - March 2018), despite the evidence and guidance suggesting there should be none. The annual cost of repeat injections is estimated to be £10.5m. Figure 3 also distinguishes between trusts that provide surgery and those that do not provide surgery. Whilst the overall picture is mixed, the highest rates of repeated injections are seen in the trusts that do not have surgery as an option.

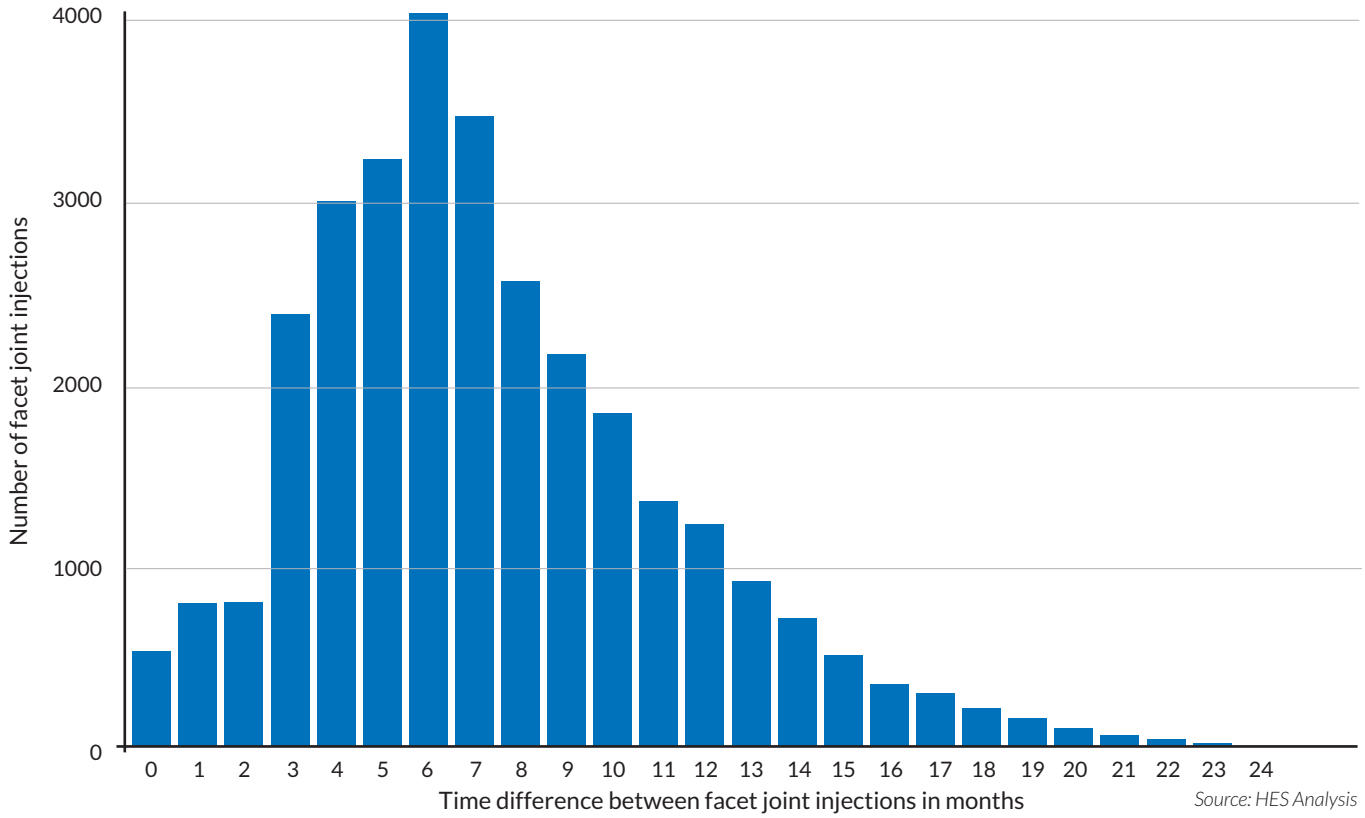
Figure 3 Number of patients with three or more repeated facet joint injections within 12 months, by trust (April 2015-March 2018)



Source: HES Analysis. The denominator is the number of patients receiving at least one facet joint injection in April 2015 to March 2017. The numerator allows an extra year of data to search for repeats April 2015 to March 2018.

Figure 4 shows the distribution of time between repeated facet joint injections. Nationally, the median time between consecutive repeated injections is 6 months.

Figure 4: Time differences between consecutive facet joint injections across all trusts (April 2016-March 2018)



Source: HES Analysis

Nerve root block or epidural injections are used in the management of radicular pain. These injections are either used diagnostically, to establish that a patient is suffering with nerve root pain when the cause is not clear, or they are administered looking to a provide a period of effective pain relief in the hope that the radicular pain caused usually by foraminal or lateral recess stenosis or disc protrusion settles. If an injection does not provide prolonged pain relief then surgery is often an effective alternative option. With a sound evidence base, surgery is a cost effective alternative and patients recover quickly.[10, 11, 12, 13] There should therefore be very few patients requiring 3 or more of these injections within a 12-month period. Figure 3 illustrates how the use of these injections varies by trust, showing the proportion and number of patients with a spinal condition receiving nerve block or epidural injections to manage radicular pain. Their use varies considerably by trust, and on average 5.2% of patients are receiving three or more of these injections in a 12-month period (April 2015 - March 2018). As with facet joint injections, the trusts with the highest rates of repeated nerve block or epidural injections are those that do not also undertake spinal surgery.

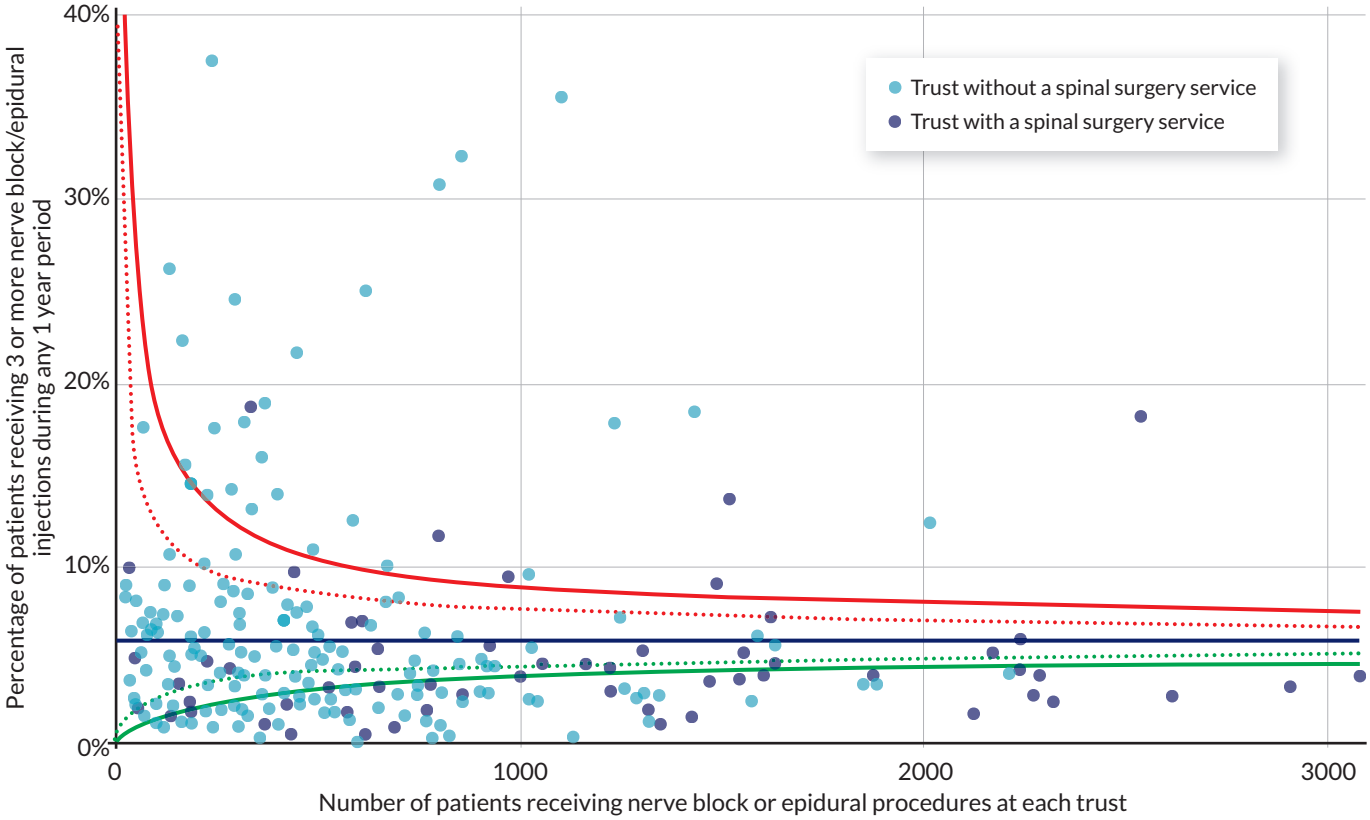
[10] *Weinstein JN et al, Surgical versus Non-Operative Treatment for Lumbar Disc Herniation: Eight-Year Results for the Spine Patient Outcomes Research Trial (SPORT), Spine (Phila Pa 1976). 2010 Jun 15; 35(14): 1329–1338*

[11] *Lurie JD et al, Surgical versus Non-Operative Treatment for Lumbar Disc Herniation: Eight-Year Results for the Spine Patient Outcomes Research Trial (SPORT), Spine (Phila Pa 1976). 2014 Jan 1; 39(1): 3–16*

[12] *Tosteson ANA et al, The Cost Effectiveness of Surgical versus Non-Operative Treatment for Lumbar Disc Herniation over Two Years: Evidence from the Spine Patient Outcomes Research Trial (SPORT), Spine (Phila Pa 1976). 2008 Sep 1; 33(19): 2108–2115*

[13] *Tosteson ANA et al, Comparative Effectiveness Evidence from the Spine Patient Outcomes Research Trial: Surgical vs. Non-Operative Care for Spinal Stenosis, Degenerative Spondylolisthesis and Intervertebral Disc Herniation, Spine (Phila Pa 1976). 2011 Nov 15; 36(24): 2061–2068*

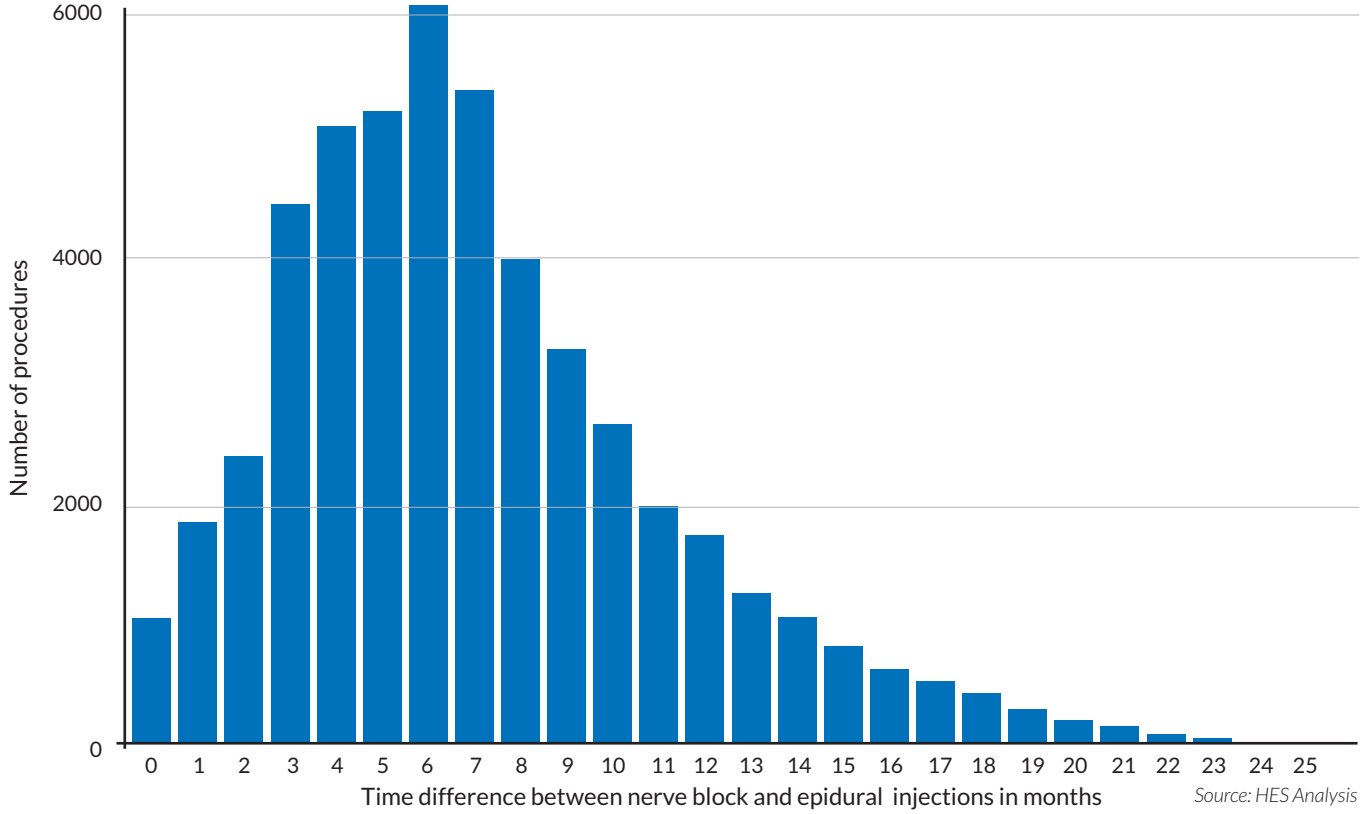
Figure 5: Number of patients with three or more repeated nerve block or epidural injection within 12 months, by trust (April 2015-March 2018)



Source: HES Analysis. The denominator is the number of patients receiving at least one epidural injection or nerve block in April 2015 to March 2017. The numerator allows an extra year of data to search for repeats April 2015 to March 2018.

Nationally, the median length of time between repeated injections for nerve block or epidural injections is six months. Around 9,500 of these injections are repeated in under six months, with a total annual cost of £6.7m. Figure 6 shows the distribution of time between these injections nationally.

Figure 6: Time differences between consecutive nerve block and epidural injections across all trusts (April 2016-March 2018)



Source: HES Analysis

This evidence suggests there is widespread non-compliance with established guidance on the use of injections, with a significant cost impact on the NHS £17.2m per year. Our recommendation is that clinicians should adhere to the National Back Pain and Radicular Pain Pathway, which has been endorsed by NICE. This is also consistent with recommendations of the Evidence Based Interventions Programme.[14] Trusts and commissioners should ensure that this is happening within their localities. (The National Back and Radicular Pain Pathway is attached at Appendix A.)

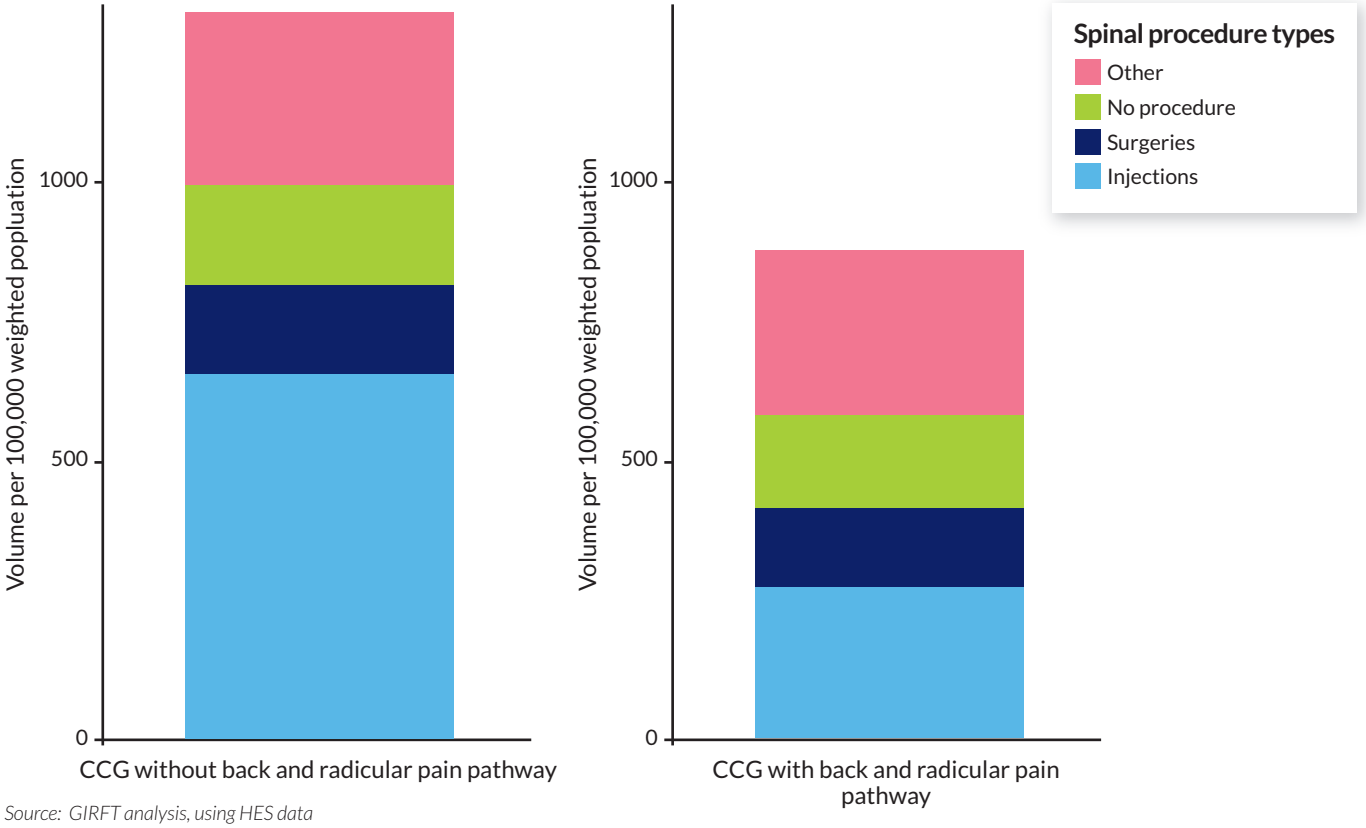
In conjunction, we also recommend that there is investment in combined physical and psychological rehabilitation programmes, so that patients with back pain without a sinister history have access to best practice management. NICE's assessment is that there will be no net additional significant resources required to implement its guidance on improved management of lower back pain.[15]

[14] *https://www.england.nhs.uk/evidence-based-interventions/*

[15] *www.nice.org.uk/guidance/ng59/resources/resource-impact-statement-2726444413*

Figure 7 shows an example of the impact that the national back and radicular pain pathways can have on the management of these conditions. It uses data aggregated from a collection of CCGs and trusts in the North of England, where some CCGs have implemented the national back and radicular pain pathways, whilst others have not. The Figure shows the rates of admission to hospital for back and radicular pain by CCG for those CCGs with a triage service versus those without. The rates are expressed as a rate per 100,000 weighted population to control for demographic characteristics.

Figure 7: Illustration of the impact the national back and radicular pain pathway on intervention rates for back and radicular pain (April 2016-March 2018)



Source: GIRFT analysis, using HES data

The data is consistent with the evidence in the National Low Back and Radicular Pain Pathway, which suggests that triage has a significant impact on lowering the rates of admission for spinal injection. It reinforces the established case for decommissioning facet joint injections and re-investing savings into local combined physical and psychological rehabilitation programmes.

Recommendation	Actions	Timescale
1. CCGs and trusts to agree local plans to implement and adhere to the National Back & Radicular Pain Pathway	Facet joint injections are decommissioned. Diagnostic medial branch blocks commissioned but not repeated, and there are no payments for repeat medial branch blocks. There should be investment in local combined physical and psychological rehabilitation programmes in line with established pathways	
	• Clinicians and trust management to assess their use of facet joint injections and agree local processes to decommission their use and replace with Diagnostic Medial Branch Blocks.	For immediate action
	• CCGs and trusts to agree local plans for improving access to local combined physical and psychological rehabilitation programmes	For immediate action
	• High injection rates observed in non-spinal partner trusts managed by involvement in the Regional Spinal Networks	When Regional Spinal Networks are fully operational
	Facet Joint Denervation is only repeated after relapse if there is a patient reported outcome measure demonstrating significant improvement in pain relief and function at 12 months post initial denervation procedure	
	• NHSI and NHSE to work with GIRFT to develop payment mechanism to support appropriate behaviour in the use of Facet Joint Denervation	For immediate action
	• Mandatory recording of the use of Facet Joint Denervation on the British Spinal Registry including completion of outcome metrics to demonstrate improvements in pain relief	For immediate action
	• Evaluation of impact, once established	
	Radicular pain injections are only repeated if six months of pain relief and functional improvement is achieved	
	• Mandatory recording of patient reported outcomes of radicular pain injections at six months on the British Spine Registry including completion of outcome metrics to demonstrate improvements in pain relief	April 2020
	• Trusts to fund the administrative support required to ensure this happens	
	• NHSI and NHSE to review data and take appropriate action to ensure best practice is being followed	April 2021

Spinal cord stimulators (SCS) are used to modify pain in patients with chronic neuropathic pain, usually without a reliable alternative medical or surgical option. They are surgically placed over the neural structures in the spine and send a mild electric current to this tissue. SCS are expensive devices, costing approximately £19,000 each, and the estimated spend on SCS in 2017-2018 was £6m.[16] There is wide variation in their use across the NHS. Figure 8 shows data on insertions of SCS by CCG (expressed as a rate per 100,000 weighted population), which demonstrates their wide variation in use across England. The data also show that there appears to be large amounts of surgical activity undertaken to remove or revise the SCS.[17]

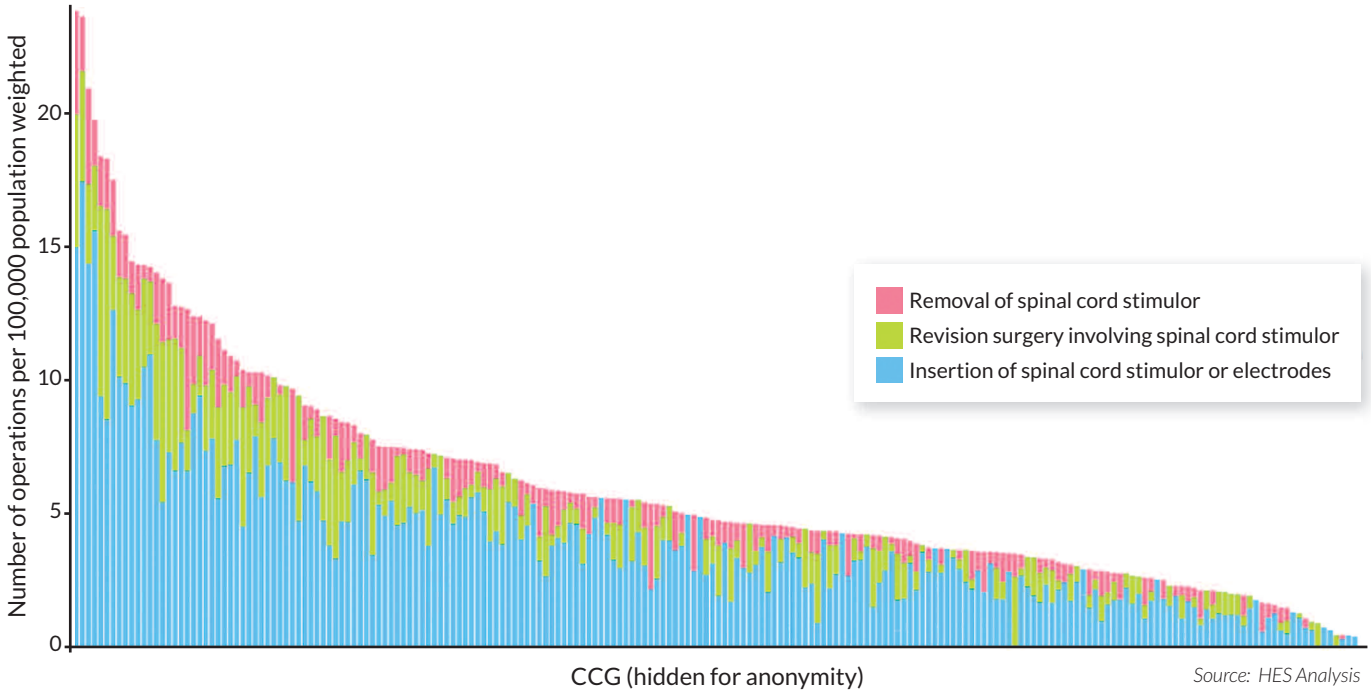
Like any other technology, it is important to have contemporaneous data on the use of SCS so that we learn about clinical practice and its impact. In 2018, the UK Neuromodulation Registry was established with the aim of achieving this, learning lessons from other areas of implant use such as orthopaedic surgery. We are recommending that recording data on the use of SCS on the UK Neuromodulation Registry should be mandatory. Prior to their insertion they should be assessed by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, with spinal opinion sought as required (consistent with NICE guidance[18]).

[16] *Source: Purchase Price Index Benchmarking Tool Data Analysis: Adviseinc*

[17] *We acknowledge a difficulty with this data because a battery change to continue to power and deliver ongoing therapy can be coded as a removal of SCS*

[18] *NICE Guidance, TA159*

Figure 8: Spinal Cord Stimulators – insertions, revisions and removals – by CCG (rate per 100,000 weighted population, April 2017-March 2018)



Source: HES Analysis

Recommendation	Actions	Timescale
2. Mandatory use of National Neuromodulation Registry for Spinal Cord Stimulators	• SCS moved to remit of Specialised Commissioning (rather than be CCG-commissioned)	April 2020
	• NHS England Specialised Commissioning mandate collection along with other pain interventions that have a limited evidence base	April 2020
	• Review the data and take appropriate action	April 2021

3. Improving Emergency Access and Referral Protocols

3.1 Cauda Equina Syndrome

Cauda Equina Syndrome (CES) is a spinal surgical emergency that requires urgent specialist assessment and intervention. If the condition is not managed in a time efficient manner, it can lead to a range of severe permanent disabilities including permanent limb paralysis, permanent loss of bowel, bladder and sexual function. This is devastating to a patient's quality of life.

Given the potential severity, the Society of British Neurological Surgeons (SBNS) and the British Association of Spine Surgeons (BASS) has developed standards of care for patients presenting with suspected CES. The cornerstone of these recommendations includes access to emergency MRI scanning, as this often dictates whether emergency surgery needs to take place.

The SBNS/BASS standards (attached at Appendix B) set out that:[19]

i. The reliability of clinical diagnosis of threatened or actual CES is low and there should be a low threshold for investigation with an emergency MRI scan at the request of the examining clinician and MRI must be available at the referring hospital 24/7.

ii. The decision to perform an MRI does not require discussion with the local spinal services.

iii. The MRI must be undertaken as an emergency in the patient's local hospital and a diagnosis achieved prior to any discussion with the spinal services.

iv. The MRI must take precedence over routine cases and any reasons for a delay or a decision not to perform an emergency scan should be clearly documented.

v. If MRI is contraindicated, discussion with local spinal services is appropriate.

A recent national audit – ENTICE (Evaluation of National Treatment and Investigation of Cauda Equina)[20] – collected data across 28 spinal emergency units in the UK. 4,441 referrals were made across a 6-month period (1st October – 31st March 2017). The study found that the SBNS/BASS standards are not currently being met, with potentially life-changing impacts on patients. Considering that 23% of litigation claims for spinal surgery in England relate to CES (based on GIRFT's assessment of litigation claims in England between 2013/15 -15/16), this is unacceptable.

In particular, the study found that:

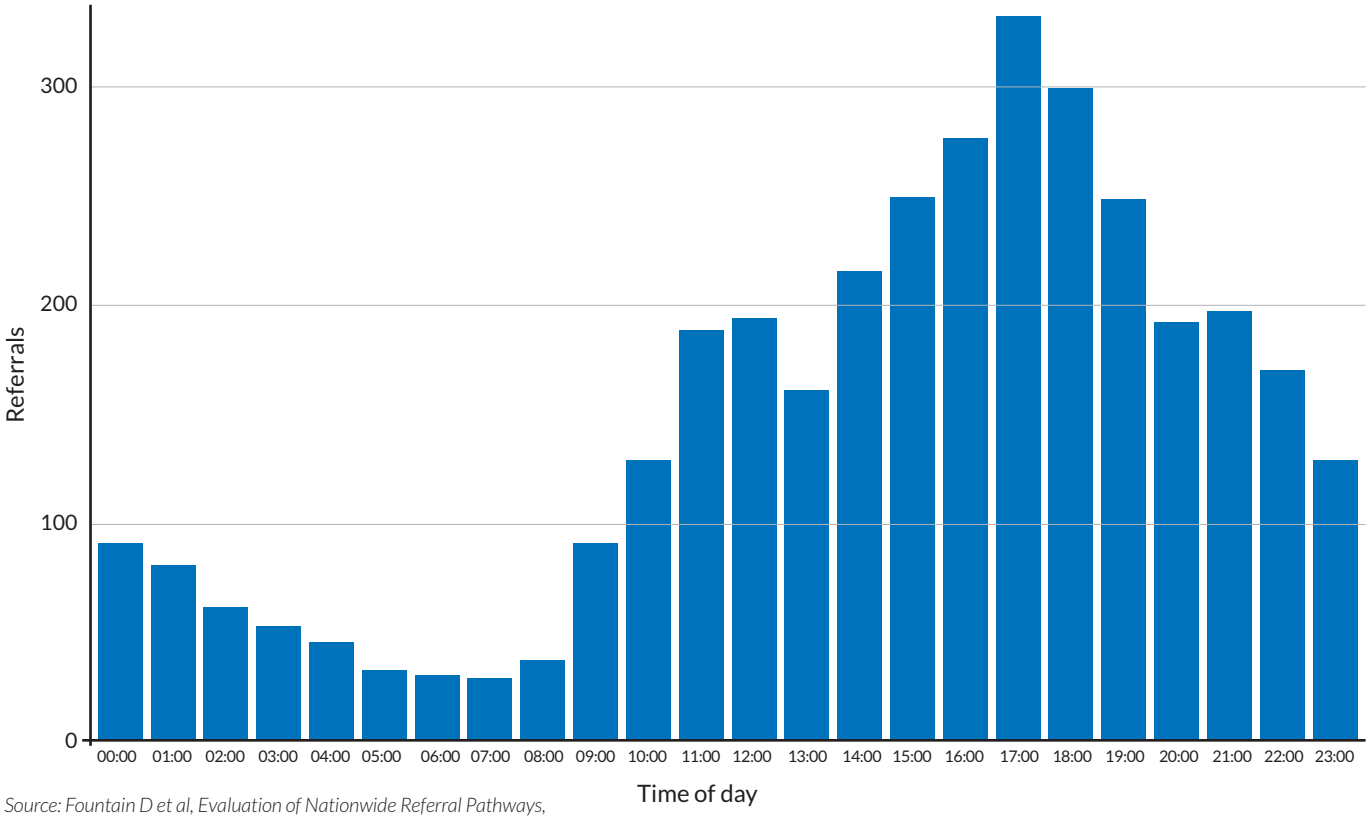
- 63% of referrals to emergency spinal units for suspected CES were made without an available MRI, meaning that many of these cases did not have a confirmed diagnosis of CES but were still being discussed with emergency units;
- 23% of referrals without an MRI were transferred to emergency spinal units for an emergency MRI; and
- when an emergency MRI was indicated there was a significant difference in the time that the MRI was acquired. The median time to MRI at an emergency spine unit was 4 hours if referred from another speciality within the spine unit, 7.2 hours if transferred from outside and 13.3 hours if performed at a referring hospital.

The study's analysis of referrals to spinal units by day of week and time of day demonstrates that there are underlying difficulties in how out-of-hours services are organised. Figure 9 shows data from the ENTICE study on referrals to spinal units for suspected CES by time of day. A significant portion of referrals are happening from late afternoon and through the night – suggesting trusts are more likely to refer cases on to emergency spinal units outside core hours.

[19] *Standards of Care for Established and Suspected Cauda Equina Syndrome, available at www.sbns.org.uk*

[20] *This study was undertaken through the British Neurosurgical Trainee Research Collaborative (BNTRC). It is due to be published as: Fountain D et al, Evaluation of Nationwide Referral Pathways, Investigation and Treatment of Suspected Cauda Equina Syndrome in the United Kingdom. Submitted for publication European Spine Journal.*

Figure 9: Number of referrals over a six-month period to spinal units for suspected Cauda Equina Syndrome, by time of day

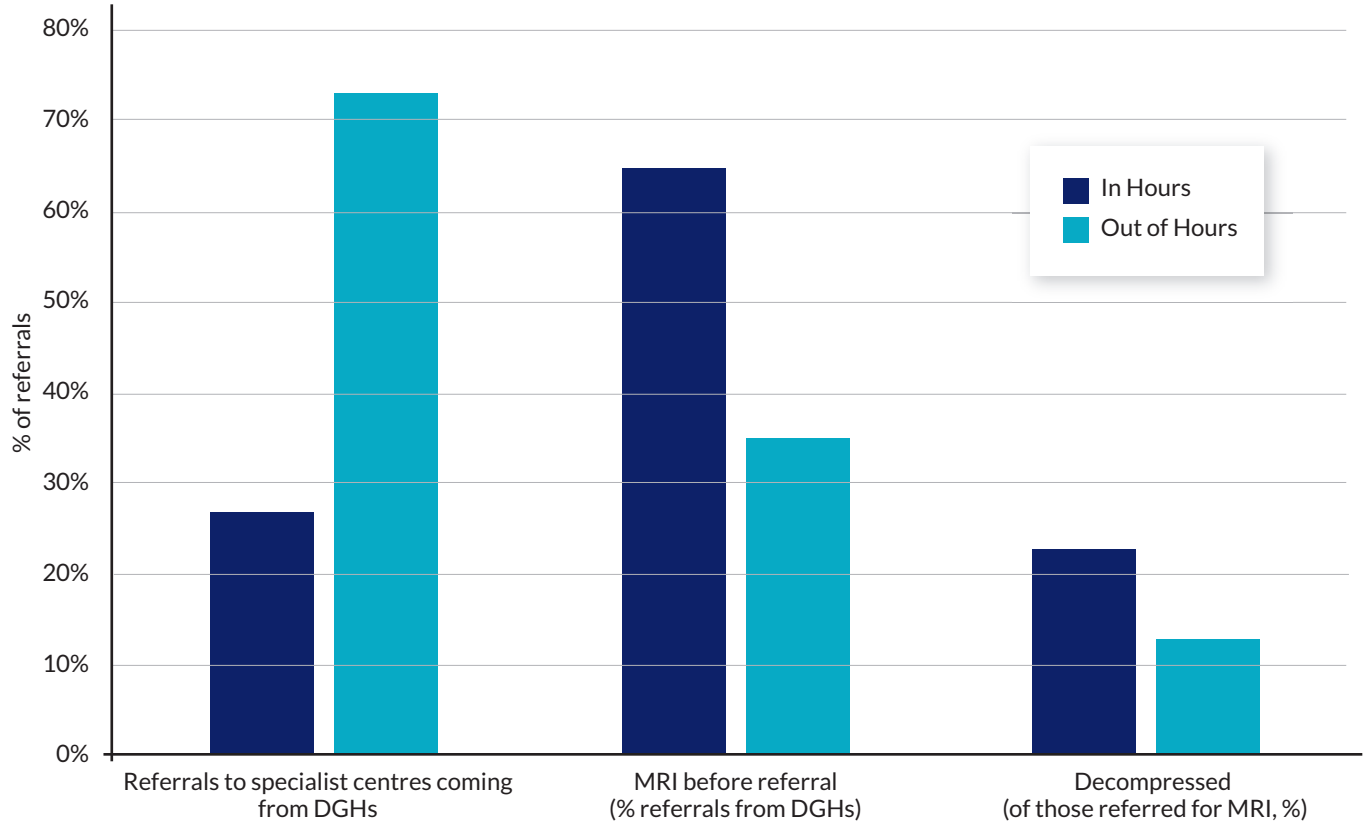


Source: Fountain D et al, Evaluation of Nationwide Referral Pathways, Investigation and Treatment of Suspected Cauda Equina Syndrome in the United Kingdom, European Spine Journal (Submitted for publication)

Figure 10 uses the ENTICE data to show referrals from district general hospitals (DGHs) to emergency spinal units both within core hours (defined in the study as 9am-5pm, Monday to Friday) and outside these hours. They find that:

- most referrals from DGHs were made out-of-hours (72.7%);
- these out-of-hours referrals are significantly less likely to have had an MRI before referral; and
- out-of-hours referrals are more likely to require transfer for an MRI.

Figure 10: Comparison of Referrals from DGHs Within and Outside Core Hours



Source: Fountain D et al, Evaluation of Nationwide Referral Pathways, Investigation and Treatment of Suspected Cauda Equina Syndrome in the United Kingdom, European Spine Journal (Submitted for publication)

Evidence collected during visits indicates that the principal reason for patients with suspected CES not receiving timely MRI scans is a lack of out of hours radiography support in referring units. Even though MRIs are switched on out of hours, in many instances a radiographer may not be available to operate the scanner.

Without exception, emergency units who performed surgery for CES were happy to accept and interpret an out-of-hours MRI without a radiologist's report of the scan (this is something which could occur the following day).

There are costs involved in transferring patients with suspected CES for an MRI. Typically:

- costs are incurred in connection with the transfer of a patient to another provider;
- the receiving trust will incur costs associated with undertaking the MRI;
- there are costs associated with out-of-hours nursing and medical staffing;
- in cases where CES is ruled out, patients ordinarily will be transferred back to the referring trust; and
- the referring trust should keep a bed available in the event that CES is ruled out and the patient is repatriated.

These costs are significant. Cambridge University Hospitals NHS FT estimates a cost of £6,000 per referral for cases of suspected CES where MRI subsequently rules out this diagnosis. They estimate that only two referrals per year would make it more cost effective for a referring trust to have their own local provisions to have radiographers on call.

A reluctance to interrupt elective scanning lists with emergency cases was also observed. Some trusts that we visited countered this by staffing machines from 7.30am, prior to the start of elective lists, to deal with emergencies that arrived overnight. A study published from the John Radcliffe Hospital in Oxford referred to their practice of training all band 6 radiographers in basic MRI so when working in out-of-hours CT, they can cross-cover. The authors state this usually requires

3 weeks in MRI without any previous experience and continual rotations through MRI every 12-15 weeks. Such an approach has ensured the addition of out-of-hours MRI without any incremental cost to existing out-of-hours CT services.[21]

Poor compliance with the SBNS/BASS guidelines on managing patients with suspected CES appear to be driven by a lack of out of hours radiographer cover. Our recommendations are designed to encourage trusts to deliver timely access to MRI locally, removing the need for costly, and potentially risky, referrals between trusts.

Recommendation	Actions	Timescale
3. Trusts to follow SBNS and BASS guidance on the management of patients with suspected cauda equina syndrome, including urgent referral by a senior decision-maker to a 24-hour MRI scanning service performed locally in the hospital of presentation, ensuring no delay. Radiologists must prioritise these patients in light of the syndrome's severity and the time-critical nature of effective treatment.	• Trusts to review local policies related to out of hours on-call arrangements for radiography to ensure alignment with SBNS/BASS guidance.	For immediate action
	• Where individual trusts cannot resource out of hours MRI, GIRFT Hubs to work with Trusts, local infrastructure and networks to provide interim solutions.	For immediate action
	• GIRFT to work with NHS partners to ensure the Long Term Plan makes provision for the resources necessary to deliver this recommendation. This will include understanding the potential resource impacts of implementing on-call cover arrangements to support access to 24 hour local MRI scanning.	Work to be conducted immediately, with the expectation that implementation will be a long-term exercise

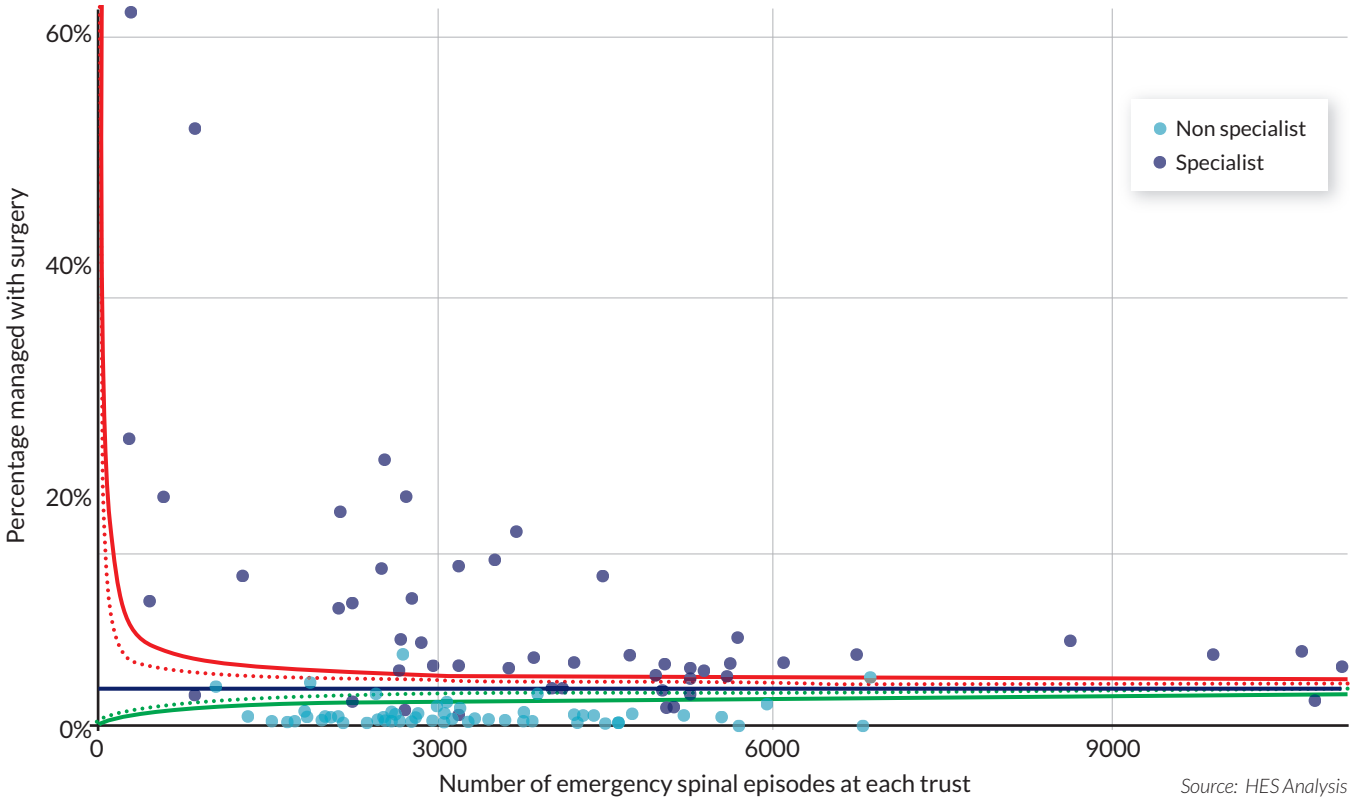
3.2 Inappropriate Emergency Admissions

Only 7% of patients who are admitted as inpatients (total admissions) with an emergency spinal condition go on to have a surgical intervention. Many of these interventions will require specialist intervention and should be managed at specialist centres.

As expected, a high proportion of emergency admissions at specialist centres do go on to receive surgery (Figure 11). Whilst there are a number of non-specialist trusts also undertaking surgery on emergency spinal admissions, many of these interventions will be non-specialist.

[21] *Hauptfleisch J, Meagher TM, King D, Lopez de Heredia L and Hughes RJ, Out-of-hours MRI provision in the UK and models of service delivery, Clinical Radiology 68 (2013) e245ee248*

Figure 11: Percentage of emergency admissions with a spinal condition managed surgically, by trust (designated specialist trust vs. other trusts) – April 2016-March 2018



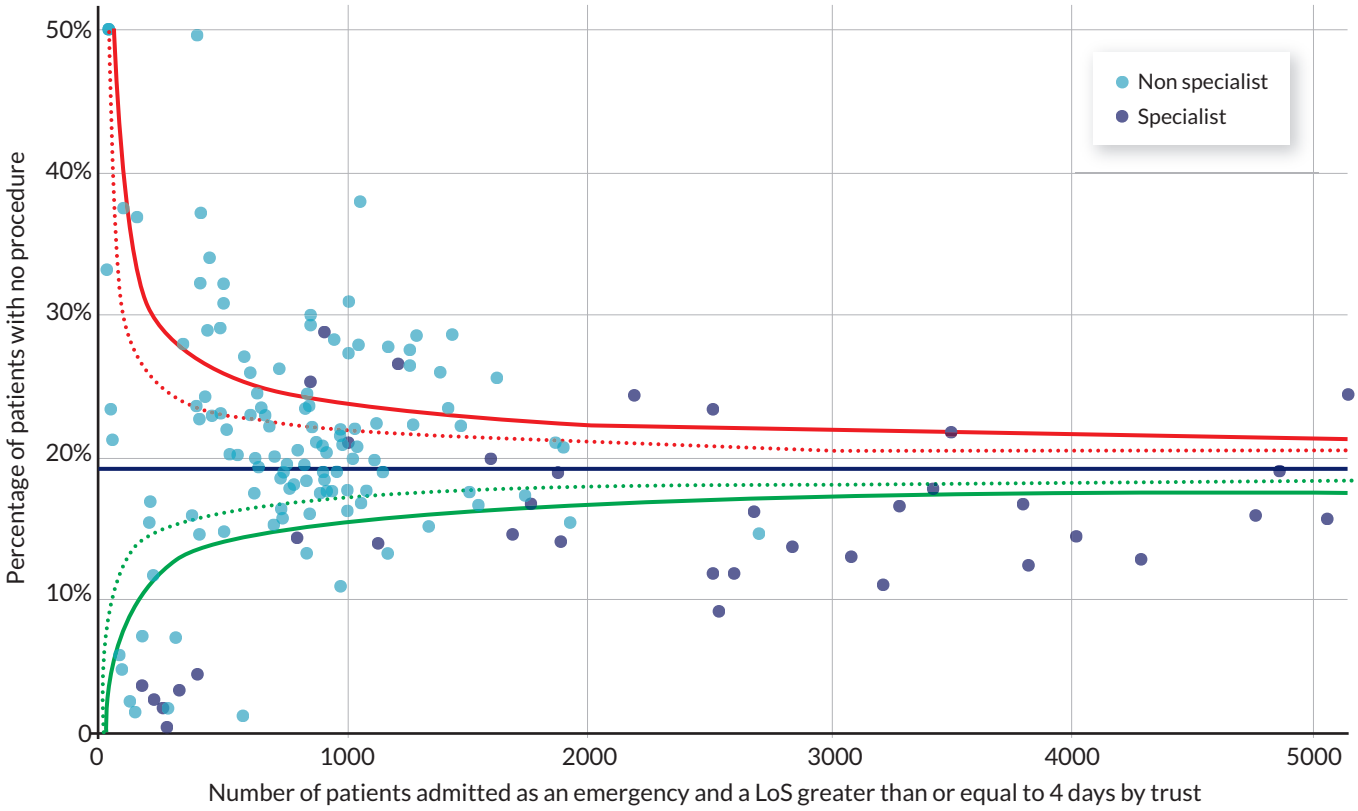
Source: HES Analysis

Figure 11 also shows that are a large proportion of emergency admissions for spinal conditions that do not require surgery. In most cases, patients who do not require surgery can be managed at home once a sinister cause for their presentation has been ruled out.

Figure 12 presents data on the number of patients (spells) admitted as an emergency with a spinal condition that do not receive surgery, but that stay for four days or more across all trusts. The designated specialist trusts are highlighted. The data highlights three principal issues:

- there are large volumes of patients admitted as emergencies, particularly to specialist trusts, that do not require a procedure;
- a high proportion of patients in non-specialist trusts are not being discharged in a timely fashion, even though they do not require a procedure; and
- the total number of episodes for emergency spinal admissions that stay as inpatients 4 days or longer and receive no surgery is 34,744. The number of bed days beyond the 4th day is 243,611 in aggregate.

Figure 12: Proportion and volume of patients, by trust, admitted as an emergency with a spinal condition that are discharged in four or more days with no procedures undertaken (April 2016-March 2018)



Source: HES Analysis

During our visits, we saw examples of good practice where trusts have worked actively to address these issues. For example, Salford Royal NHS Foundation Trust has put in place a programme that uses local outreach services to speed up discharge and reduce the volume of non-surgical patients occupying acute beds (see Box 1).

Box 1: Salford Royal – Physiotherapy-led Spinal Care in the Emergency Village[22]

Back and radicular (sciatica) pain are common presentations to emergency departments (EDs). Management ranges from simple analgesia and mobilisation to urgent imaging and surgery. Often these patients are not managed appropriately, because they lack the indications for emergency care and present a dilemma as it is not obvious under which team they should be admitted. Neither emergency medicine or general medicine can provide surgical input, and other services are not expert in providing care for non-surgical patients. Hospital-based teams have generally not been good at providing ongoing input in the community or out-patient review.

In 2012, Salford Royal NHS Foundation Trust experienced around 270 ED visits per month for lower back/radicular pain. The trust saw the direct pressures this had on the ED, and also how the lack of clear clinical ownership was leading to consequential impacts on admissions, even though 95% of the cases did not require surgery.

To address this, Salford developed a new model of care for patients presenting with lower back pain. There are clear protocols about how patients are streamed in ED (e.g. to exclude Cauda Equina Syndrome and other conditions requiring emergency intervention), with early assessment by a consultant physiotherapist. The consultant physiotherapist assesses the patient and provides evidence-based treatment including optimisation of medicines, exercise, advice, and ensuring patients have the right onward support in place. A core goal was to promote early supported discharge, with access to a range of onward services.

The results from Salford's evaluation of this model found that: (i) it reduced admissions for patients with lower back/radicular pain by about one third; (ii) it has reduced length of stay; and (iii) the 30-day readmission rate has also fallen. There was an overall net cost saving and feedback from clinicians and patients had been very positive – including an overall reduction of complaints (to zero) over the three years of the pilot.

Giving clinical teams access to specialist support, particularly for non-specialist providers, so that decisions can be taken rapidly and with confidence, helps to support appropriate onward referral and discharge. Examples of good practice observed during our visits included the provision of local out of hours diagnostic cover, which helps avoid unnecessary referrals for diagnosis, and the use of electronic emergency referral systems, which allows two-way communication between specialist and non-specialist trusts. Box 2 provides an example from one trust. The goal is to allow providers to discharge patients locally, but with confidence that they have access to early specialist follow up.

[22] *Personal communication between the Trust and the GIRFT Spinal Services Clinical Lead*

Box 2: Northern General Hospital On-Call Clinic

The seven spinal consultants do a week of on-call at a time with hand-over on a Wednesday as part of the MDT. During the week, the on-call consultant has no elective activity and a large proportion of Supporting Professional Activities are built into this week. In addition, the consultant delivers:

- Ward rounds every morning to optimise in-patient management and ensure timely and best management.
- Emergency lists on Monday and Wednesday pm and Friday 10-5pm to ensure that elective lists are disrupted as little as possible. If there are no emergency spinal cases, there is a short notice pooled list of patients already consented for injections, lumbar decompressions or cervical decompression for myelopathy. This ensures the emergency lists are fully utilised.
- Spinal On-Call Clinic on Tuesday and Thursday for two hours each day.

The aims of the spinal on-call clinic are:

- Ensure the on-call consultant is delivering some clinical activity during the on-call week.
- Give a place for urgent new referral to be seen in a timely manner.
- Follow-up for emergency patients admitted to the ward who may already have been under the care of more than one consultant.

The clinic runs for two hours, twice a week and new patients are given 30-minute consultations and follow-up consultations are 15 minutes. If there is a gap in the clinic then this is filled on the Friday before the week of the clinic with "soon" new elective patients. This has reduced the need to over-book elective clinics when urgent referrals are received. The clinic could be lengthened depending in demand. Patients seen in the clinic can be booked for a further follow-up in the clinic within six weeks or with the consultant running the clinic if a follow-up beyond six weeks is required.

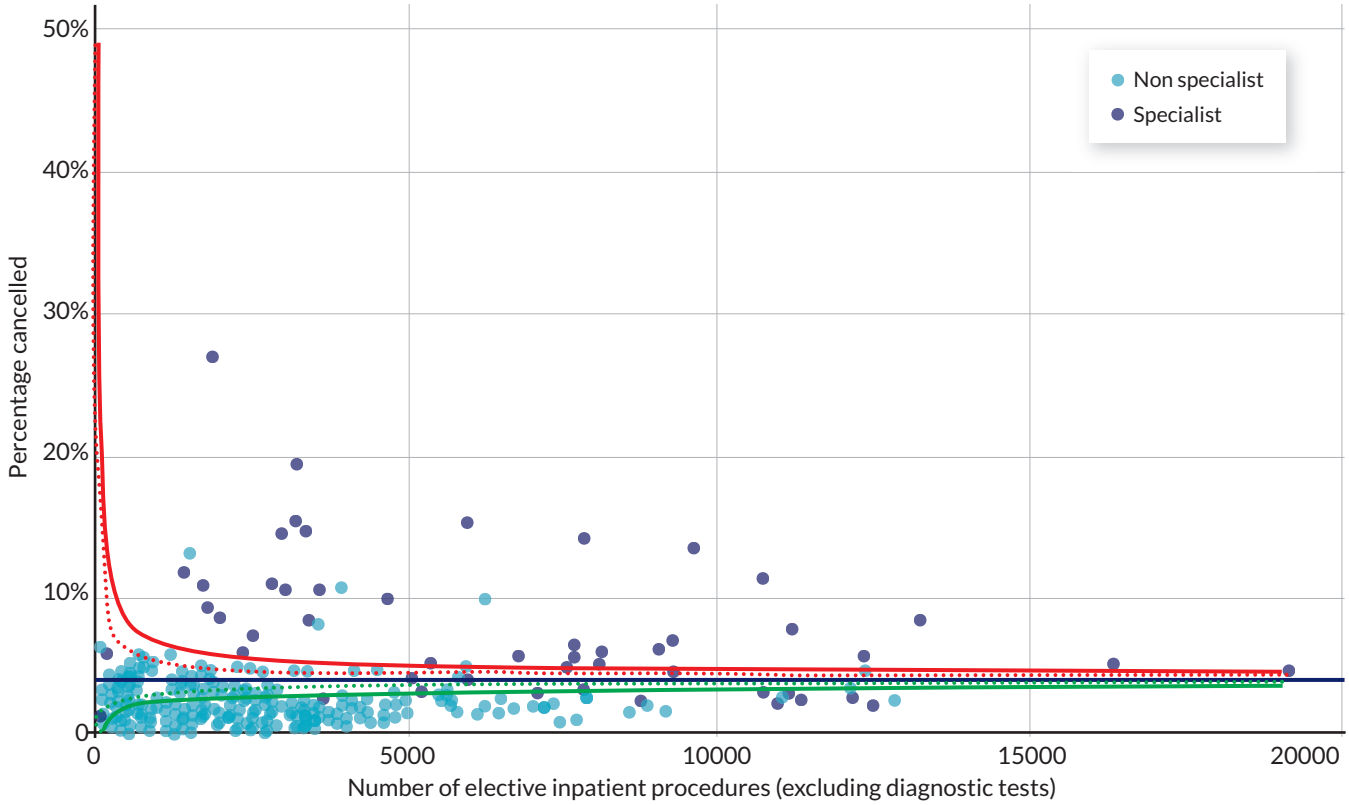
In 2017/18, the clinic had 586 attendances, but only 67 cases that were subsequently referred on and admitted or added to waiting lists.

Models like these can deliver operational benefits by improving bed availability in specialist trusts.

Figure 13 shows cancellation rates for patients admitted as an elective inpatient or day case procedure for a spinal condition.[23] Specialist centres are much more likely to cancel operations than non-specialist centres. Whilst there will be several reasons for this, a lack of available beds is a common reason for cancellation, yet the data suggest that a large volume of bed days at specialist centres are taken up by emergency patients that do not require their expertise.

[23] *Defined as elective inpatient or day case procedures, admitted with a spinal condition or for surgery, who are subsequently discharged with no procedures.*

Figure 13: On the day cancellation rates for spinal surgical admissions (injections excluded) April 2016-March 2018



Source: HES Analysis. Facet joint and radicular pain injections excluded.

We are therefore recommending measures to help manage the flow of emergency cases into specialist centres so that admissions are appropriate and proportionate. This needs to be supported by appropriate referral systems and communications between non-specialist and specialist trusts. In addition, there are measures that can be taken to support earlier discharge of patients.

Recommendation	Actions	Timescale
4. Spinal hubs (a spinal hospital with 24/7 spinal consultant on-call) to implement electronic emergency referral systems, that allow effective two-way communication between and within trusts	• Trusts in local spinal networks to review their systems and processes for managing emergency referral protocols and ensure they are fit for purpose (auditable, time-stamped and allow effective two-way communication)	For immediate action
	• Local spinal networks to act on outputs of this review, taking action as necessary	By March 2019

3.3 Spinal cord injury/Spinal Trauma

Traumatic spinal cord injury (SCI) is a complex condition that can result in the permanent loss or impairment of motor function, sensory deprivation and autonomic function. It is a potentially devastating condition requiring specialist spinal surgical assessment in the initial stages. There must also be early involvement of a regional SCI Centre. The evidence suggests that:[24]

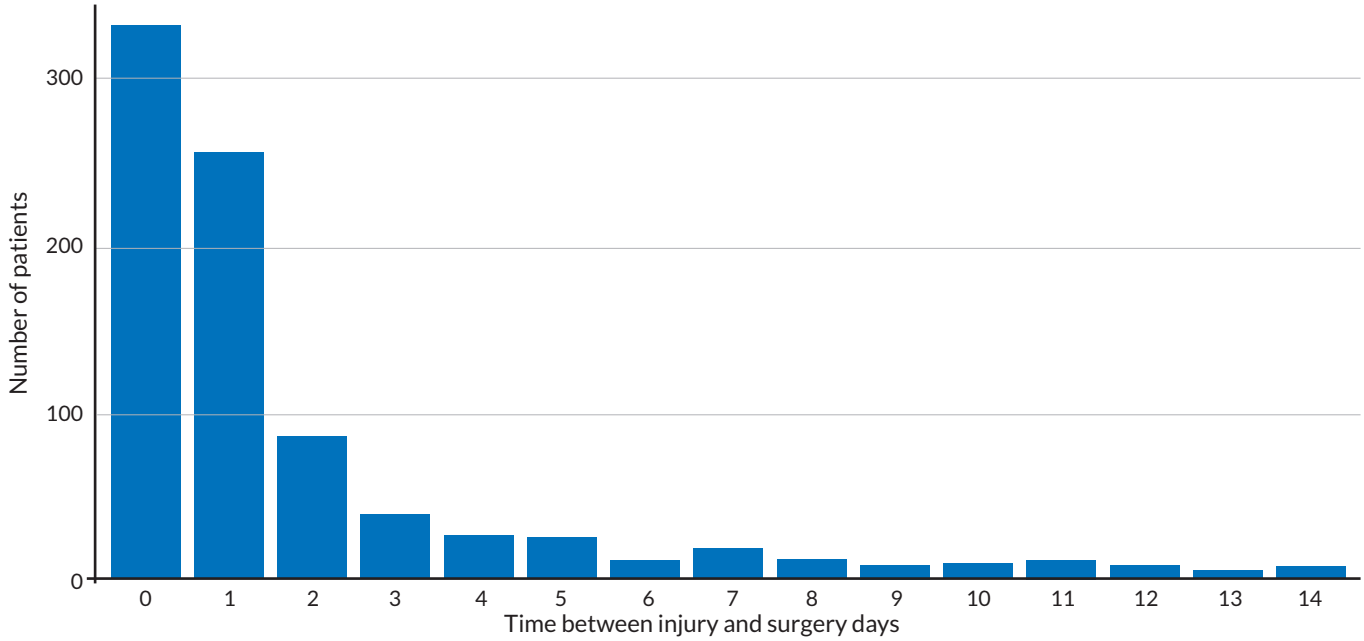
- initial management of new traumatic spinal cord injuries is critical and must focus on swift diagnosis and stabilisation, as required, to prevent further disability. Early surgery in the form of decompression and stabilisation (within 24 hours) may have a significant effect on neurological and functional outcome.[25, 26, 27] Subsequently, actions from the point of diagnosis have a significant effect on outcomes for individuals; and
- delayed admission to a specialised SCI Centre has a strong correlation with complications associated with SCI such as pressure ulcers.

To facilitate delivery of best practice treatment, SCI Centres must be a formal part of all major trauma networks, with locally agreed protocols relating to the transfer and treatment of patients. Ideally, transfer should occur within 24 hours of a patient being fit for transfer to a SCI centre. Major trauma centres should have 24/7 cover in place so that patients admitted with a fracture and or dislocation of the spine with spinal cord injury have access to specialist care, and can be stabilised and then transferred with minimal delay. Major trauma centres should have the expertise and supporting equipment to instrument the whole of the spine from the occipital bone to the sacrum, at any time.

Figure 14 uses data from the National Spinal Cord Injuries Database (NCSID) and shows the variation in time between admission for the initial SCI and surgery for decompression and stabilisation. Ideally this should happen as soon as it is safe to do so. Spinal surgery in this scenario generally happens quickly. The median time from injury to surgery is 1 day.

For 33% of patients, however, waits can be 2 or more days for surgery. Whilst many factors may influence this variation, such a high variance will not be solely due to variations in patient complexity. Evidence from site visits suggests not all centres operate emergency rotas that ensure a consultant with the ability to instrument the spine is always available.

Figure 14: Histogram of time between admission with traumatic spinal cord injury and surgery for decompression and stabilisation (April 2015 – March 2017)



Source: National Spinal Cord Injuries Database. Excludes admissions where time between injury and surgery exceeded 14 days

[24] *Advice from the National Spinal Cord Injury Strategy Board (2011) Management of People with Spinal Cord Injury, NHS Clinical Advisory Groups Report*

[25] *El Tecle NE, Dahdaleh NS and Hitchon PW, Timing of Surgery in Spinal Cord Injury, SPINE, Volume 41, Number 16, pp E995–E1004*

[26] *Furlan JC, Noonan V, Cadotte DW Fehlings MG, Timing of Decompressive Surgery of Spinal Cord after Traumatic Spinal Cord Injury: An Evidence-Based Examination of Pre-Clinical and Clinical Studies, Journal of Neurotrauma 28:1371–1399 (August 2011)*

[27] *Gatehouse S., Lutchman L., Steel M, Goss B., and Williams R., The influence of the timing of surgical intervention on neurological outcome in cervical spine injuries, Orthopaedic Proceedings, 2005 87-B:SUPP_III, 402-402*

During our site visits, we saw trusts with more than one speciality providing emergency rotas causing confusion as to which service emergency referrals should be made. We saw rotas within rotas for spines that needed instrumentation. In some cases, these 'complex spine rotas' did not run outside office hours. Many centres reported great difficulty gaining access to emergency theatre space for time dependent conditions competing with other traumatic cases such as head injuries.

We are therefore recommending that major trauma centres review their out-of-hours rotas to ensure the requisite expertise to stabilise and decompress the spine is always available and appropriate access to emergency theatre space is allocated.

Recommendation	Actions	Timescale
5. All major trauma centres to have 24/7 ability to stabilise and decompress patients with fractured and/or dislocated spines	• Major trauma centres to review out of hours cover and rotas to ensure compliance with this recommendation	April 2019

Traumatic spinal cord injuries as above are in the order of 50% of SCI admissions to SCI Centres. The other 50% are non-traumatic (e.g. disc prolapse, vascular accident, infection, iatrogenic etc.). Many of these may require spinal surgery for various indications and access to facilities for the same.

Referring cases of spinal cord injury to a SCI Centre is mandatory and the management of the spine must follow agreed protocols with the linked SCI centre. Referral should occur on the NSCID within 24 hours of injury as defined by the Clinical Reference Group in the specialist commissioning guidance for spinal surgery.[28] The NCSID dataset records the time and date of initial injury, time and date of referral to the SCI centre, and the level of neurological impairment using the American Spinal Injuries Association (ASIA) score. It also records the time between initial injury and surgery (when required), the time between initial referral and admission to a SCI Centre, the time from injury to mobilisation following spinal cord injury, and the time when deemed fit for discharge and time of discharge from SCI centre.

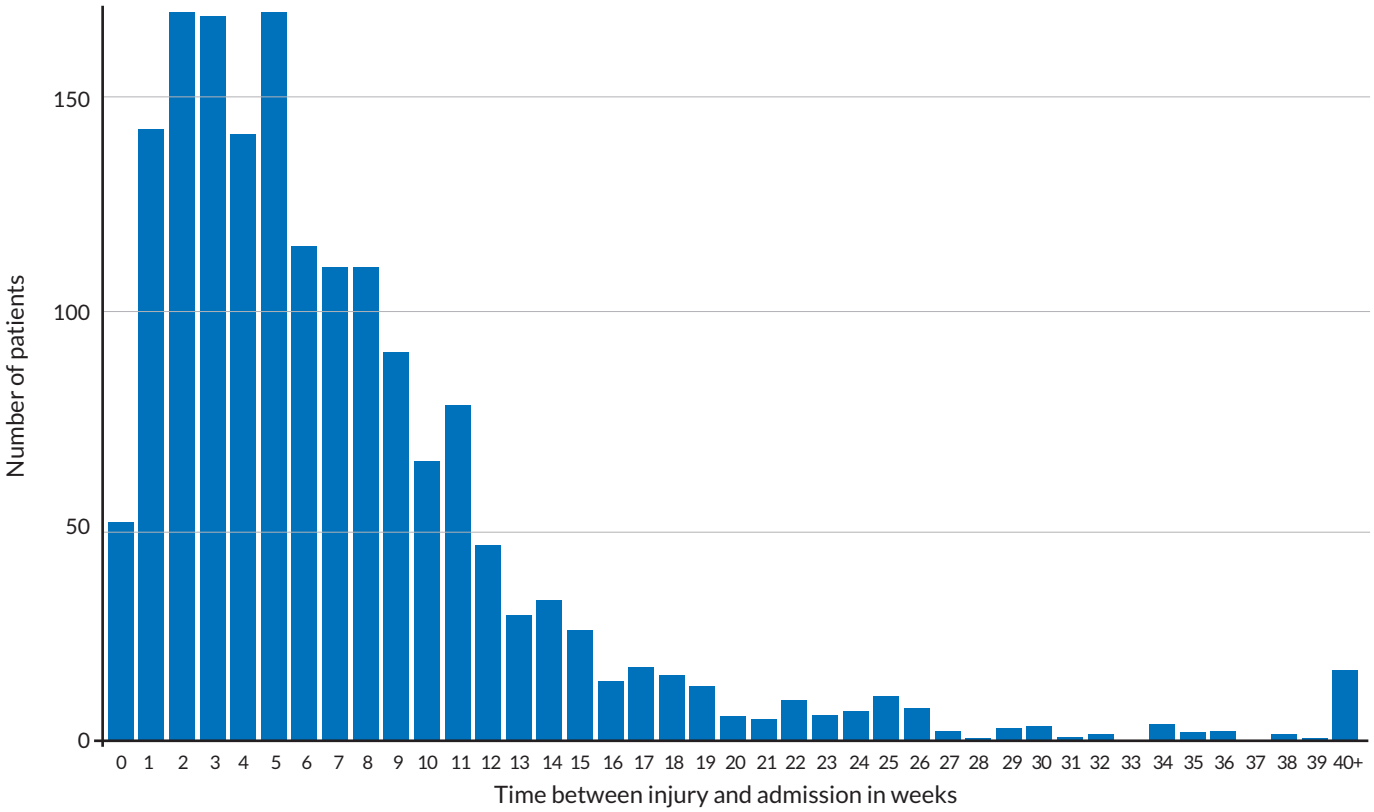
Clinicians are not good at completing the (ASIA) impairment score when referring to NSCID - only 40% of referrals were made with an ASIA score recorded. It is also imperative at this stage that an assessment of the injury includes recording of sacral sparing and whether a patient is in spinal shock (e.g. bulbocavernosus reflex). The consequence is that SCI centres often will not have a full picture of the referrals being made to them and have difficulty judging eventual outcome.

The NSCID database has the facility to track ASIA scores with time and scores recorded at admission, 28 days, 6 months, 1 year and 2 years post injury. 60% of these data points are recorded. With a small improvement in this and the recording of the initial score by referring trusts, the relative effectiveness of approaches to treating patients' SCIs could be established.

The latest data suggest this referral takes on average 6 days (median), whilst the actual time taken for admission to the SCI is far longer (see Figure 15). The median time from referral to admission to the SCI is 5-6 weeks and shows wide variation.

[28] *See, for example: NHS Commissioning Board, NHS Standard Contract for Complex Spinal Surgery, 2013*

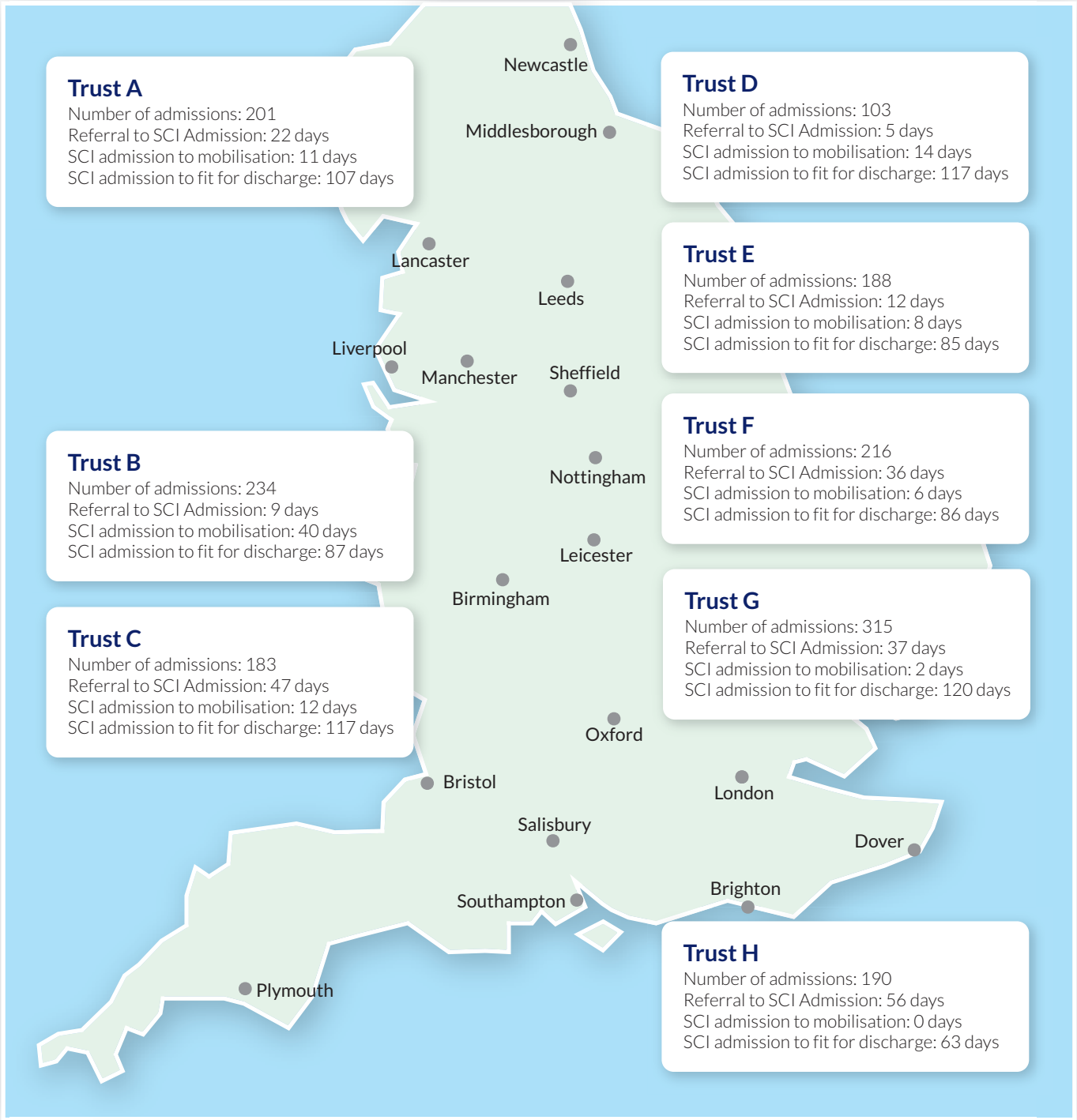
Figure 15: Histogram of the time between injury and admission to Spinal Cord Injury Unit for patients with spinal cord injury (April 2015-March 2017)



Source: National Spinal Cord Injuries Database

In addition to these delays, it was clear from the site visits that there were conflicting opinions being given to trusts from SCI centres regarding mobilisation of patients following stabilisation/decompression of the spine. Figure 16 shows variation in the median time from admission and mobilisation by SCI centre, and also variation in the median time from admission to when patients are fit for discharge. There are large differences between centres, which reflects different management protocols though there may also be other factors such as case mix.

Figure 16: Variations Across SCI Centres in England – Number of admissions; Time from Referral to Admission; Time from Admission to Mobilisation; Time from Admission to Fit For Discharge; and Volumes (April 2015-March 2017)

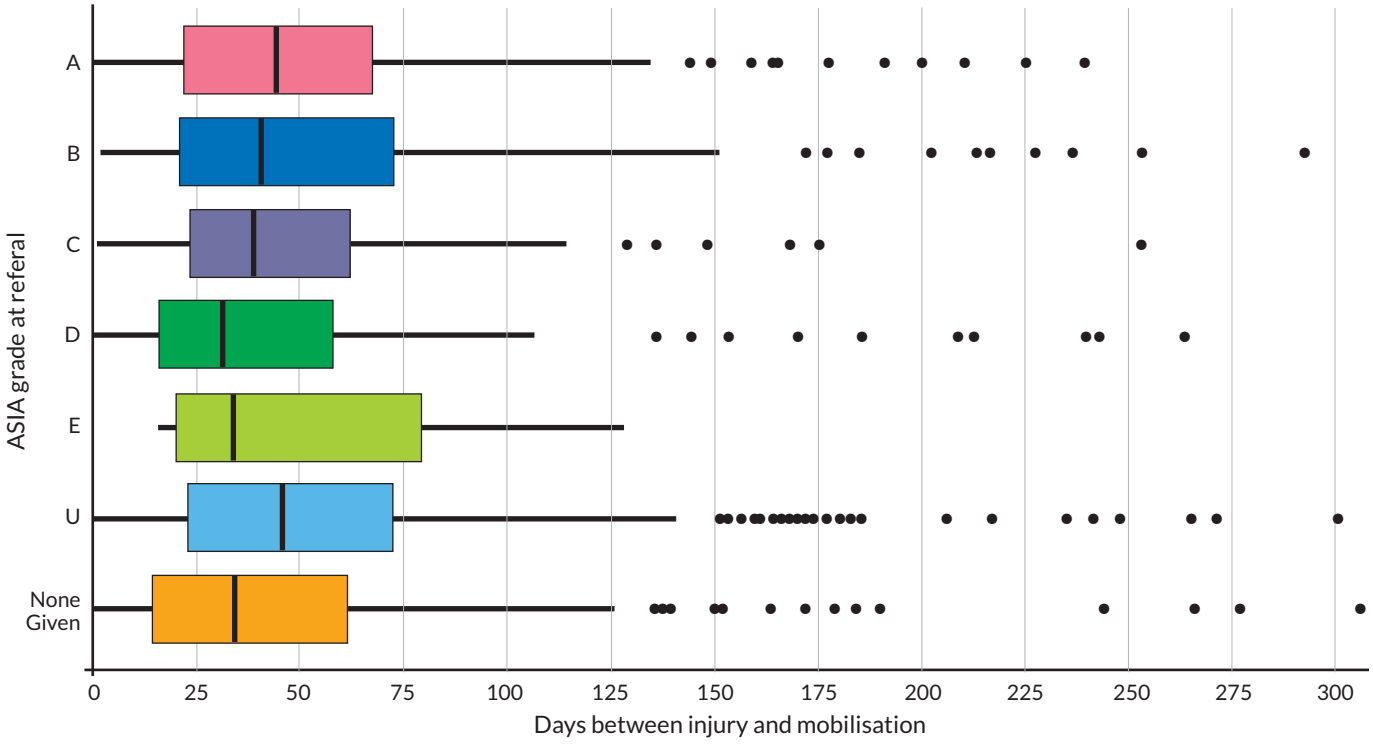


Source: National Spinal Cord Injuries Database

Some SCI centres favoured recumbent nursing care for a period of 12 weeks expressing concerns about recovery to the injured spinal cord in the upright position. Others were happy for mobilisation as able/stable. This variation in practice is out of keeping with North America, Australia and New Zealand, each of which have a mobilise as able/stable policy.[29] Given the limited access to SCI centre rehabilitation beds and with little evidence to support recumbent care following spinal cord injury, we recommend an urgent review and standardisation of rehabilitation of patients with spinal cord injury with an emphasis on mobilise as able/stable.

Figure 17 and Figure 18 shows how the average time from admission to mobilisation and then to discharge varies across patients. The data is grouped by the America Spinal Injuries Association impairment scale (ASIA) – ASIA A have the most severe neurological impairment with the poorest prognosis and ASIA E have normal function.

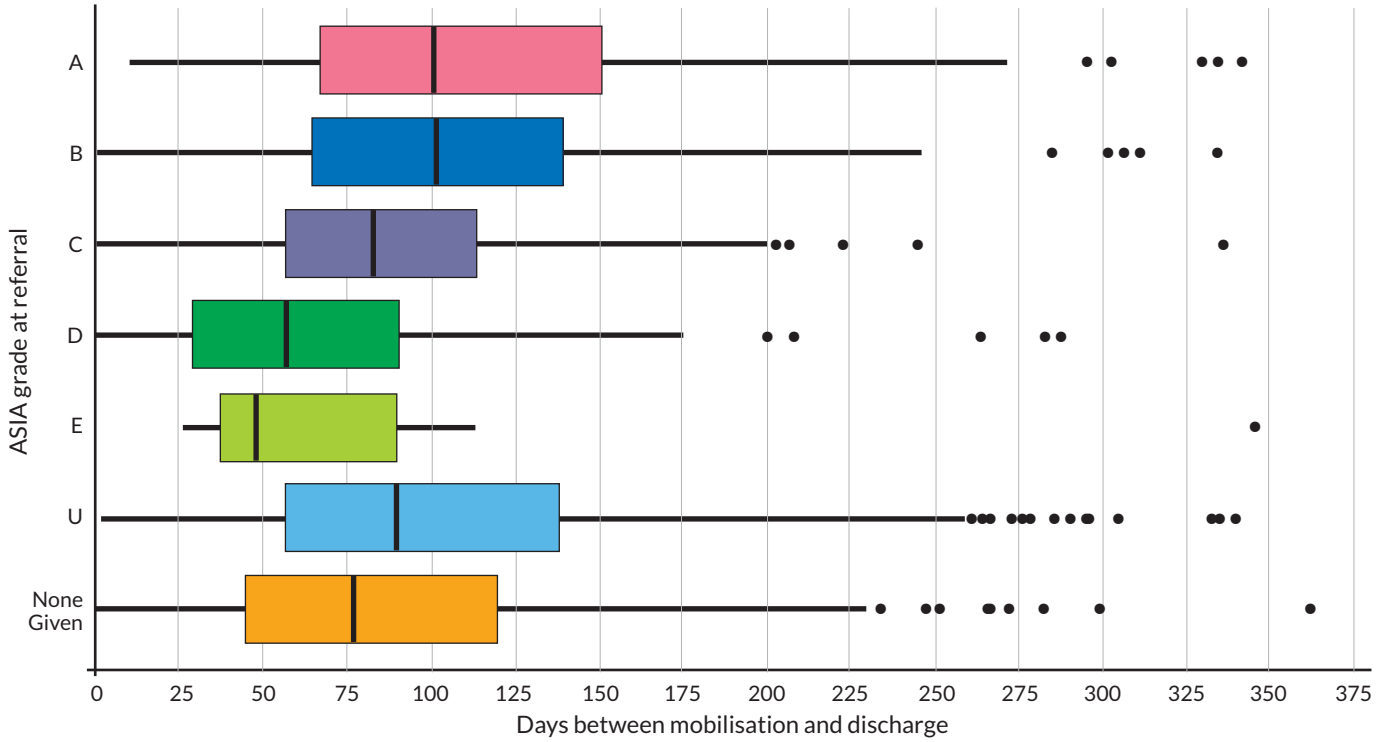
Figure 17: Time from injury to mobilisation by ASIA grade for patients with spinal cord injury (April 2015-March 2017)



Source: National Spinal Cord Injuries Database. Grade A - Complete lack of motor and sensory function below the level of injury (including the anal area), Grade B - Some sensation below the level of the injury (including anal sensation), Grade C - Some muscle movement is spared below the level of injury, but 50 percent of the muscles below the level of injury cannot move against gravity. Grade D - Most (more than 50 percent) of the muscles that are spared below the level of injury are strong enough to move against gravity. Grade E - All neurologic function has returned. Grade U - Undefined.

[29] *Czaplicka L., Clarke A., Ahuja S., Chopra I., Davies P. Rhys, Howes J., James S., and Jones A., Mobilisation of traumatic spinal cord injury patients following surgical stabilisation: A comparative audit of United Kingdom and North American practice, Orthopaedic Proceedings,2012, 94-B:SUPP_X, 027-027*

Figure 18: Time from mobilisation to discharge by ASIA grade for patients with spinal cord injury (April 2015-March 2017)



Source: National Spinal Cord Injuries Database. Grade A - Complete lack of motor and sensory function below the level of injury (including the anal area), Grade B - Some sensation below the level of the injury (including anal sensation), Grade C - Some muscle movement is spared below the level of injury, but 50 percent of the muscles below the level of injury cannot move against gravity. Grade D - Most (more than 50 percent) of the muscles that are spared below the level of injury are strong enough to move against gravity. Grade E - All neurologic function has returned. Grade U - Undefined.

Discussions with SCI centres have identified that even when patients have rehabilitated from their injury and are fit to return to the community with adjustments, many of them are not able to do so (e.g. due to a lack of wheelchair access at home). Our recommendations are designed to improve the rehabilitation of patients following a SCI by aligning protocols with best practice, and enhancing the monitoring of outcomes to inform future treatment. They are also aimed at improving flow through the SCI centre such that patients get to a SCI centre in a far more time efficient manner by improving when they are referred, providing more capacity and ensuring patients who are fit for discharge are not blocking beds with scarce resource.

Whilst these measures will improve the care of these patients, there is an obvious lack of capacity for these patients. If the time from referral to admission to an SCI could be reduced to a maximum of two weeks, we estimate it would save over 13,000 bed days. This saving would be in trusts where patients are admitted after injury, but prior to rehabilitation at SCI units. We recommend a further 45 to 55 SCI beds (including some ventilation beds) are funded in the system.

Recommendation	Actions	Timescale
6. Additional SCI beds, including ventilation beds, to be funded in the system	• Commissioners to identify potential funding and location of capacity for additional beds	April 2019
7. Develop a standardised mobilisation protocol for patients with a SCI, based on international recognised practice, and improve recording and monitoring of outcomes through the National Spinal Cord Injuries Database.	• The British Association of Spinal Cord Injury Specialists is asked to develop a standardised rehabilitation protocol for patients, seeking advice from NICE during development.	For immediate action
	• Guidance reviewed by the Clinical Reference Group for Specialist Spinal Services and adherence made mandatory as part of the Specialised Commissioning Contract for Spinal Services	From 2020
	• BASCIS & CRG to make recording of ASIA scores a mandatory field within the National Spinal Cord Injuries Database on admission, at 6, 12, 18 and 24 months following an SCI.	For immediate action
	• Trusts and NHSE to ensure compliance, providing appropriate administrative support.	Ongoing
	• Comparative data published and used by the Centres to understand variation and take appropriate action. Data to be discussed during GIRFT visits to Centres.	From April 2019

4. Strengthening the Network Model

The issues described above relate principally to patients' location of care and the coordination of care between providers. There are examples where patients are either being managed in the wrong place or the transfer of care between providers is not happening in a way that makes effective use of scarce resources and support quality.

These issues are relatively well-known and has led the Spinal Services Clinical Reference Group, with the support of the Spinal Societies, to champion the establishment of Regional Spinal Networks (RSNs). There is also significant support amongst clinicians for the creation of RSNs to coordinate the planning and delivery of spinal services across geographies.

The goal is to establish 14 RSNs. Under the network model, some providers would be the Spinal Hubs(providing 24/7 emergency services) and others would act as Partners (some with spinal surgeons and some without). Independent Sector providers should be part of the RSNs. Amongst the Hub and Partners, there are clear rules regarding how cases are managed. Specialised cases go to the Centres that have the facilities and teams capable of delivering the best outcomes. Non-specialised care is allocated across providers within the network, matching cases to each provider's capabilities and ensuring capacity is used appropriately across the network. Importantly, clinical teams across the network work together to support one-another, with multi-disciplinary meetings and review to ensure surgery is being provided in the right locations.

The RSNs would have defined operating principles and responsibilities. Importantly, as well as being responsible for guiding how spinal services are organised within a region, the RSNs would also have responsibilities for reviewing and tracking success. Their responsibilities would include:

- implementing Regional Pathways, Guidelines and Policies for elective and emergency spinal surgery;
- confirming that all Spinal Consultants are entering all cases on the British Spine Registry, with sufficient administrative support for clinicians;
- collating and analysing monitoring data;
- reviewing clinical governance issues, including deaths, serious untoward incidents, never events, duties of candour, root cause analyses and risk management issues;
- identifying areas for service improvement and ensuring spread of good practice throughout the Network;
- reviewing activity data and targets, working with Commissioners to ensure equality of access across a region; and
- co-ordinating the Spinal workforce and services in the region. These will include Triage Services, availability of MRI imaging and Spinal Consultants.

The Network approach is an opportunity to: (i) optimise how capacity is used across a region; (ii) strengthen clinical governance; and (iii) improve patient outcomes and experience. Our recommendation is therefore that NHSE should move ahead with plans to implement the RSNs, with trusts required to support their development, allowing clinical teams to actively engage in their implementation and operation.

There are two models for RSN implementation:

1. East Midlands Spinal Network, which is managed by the Operational Delivery Network team responsible for the Trauma and Critical Care Networks; and
2. South East London and Kent Network, which involved a complete re-organisation of spinal services from GP referral to tertiary care. This has involved a Project Manager co-ordinating the implementation of the National Back and Radicular Pain Pathway across all the CCGs in the region and establishment of the Regional Spinal Network.

Both models require long term funding for Management support and the Network Clinical Lead. Baseline measures to determine success should include waiting lists across the Region, referral to treatment times, activity levels and litigation costs.

Recommendation	Actions	Timescale
8. All providers, including Independent Sector Providers, to be part of a Regional Spinal Network. Clinicians including allied healthcare practitioners to actively engage in their Regional Spinal Networks.	• NHSE to oversee the development and implementation of RSNs	April 2019
	• Failure of an Independent Sector provider to actively participate reported by the RSN Network Board to the local CCG, to take appropriate action	Ongoing
	• RSNs to develop recommendations on local models for participation and engagement by clinicians in RSNs.	April 2019
	• Provision by trusts in job planning for all clinicians and allied health care practitioners to attend RSN meetings unless on annual/study leave. RSN leads to report attendance to trusts and NHSE.	Ongoing

5. Specialist Spinal Services

5.1 The provision of specialist spinal services

From evidence collected during our visits, it is apparent that the expertise and resources available to manage patients with spinal conditions are not being targeted appropriately. This is supported by the underlying data. Specialist trusts are undertaking non-specialist activity, whilst non-specialist providers are undertaking large volumes of activity that have been designated as specialist and should only be provided by specialist trusts.

The Spinal Services Clinical Reference Group (CRG) has established clear standards of care that are expected from organisations providing specialised spinal care. These standards include definitions of activity that are considered to be specialist and should only be undertaken by designated specialist centres.

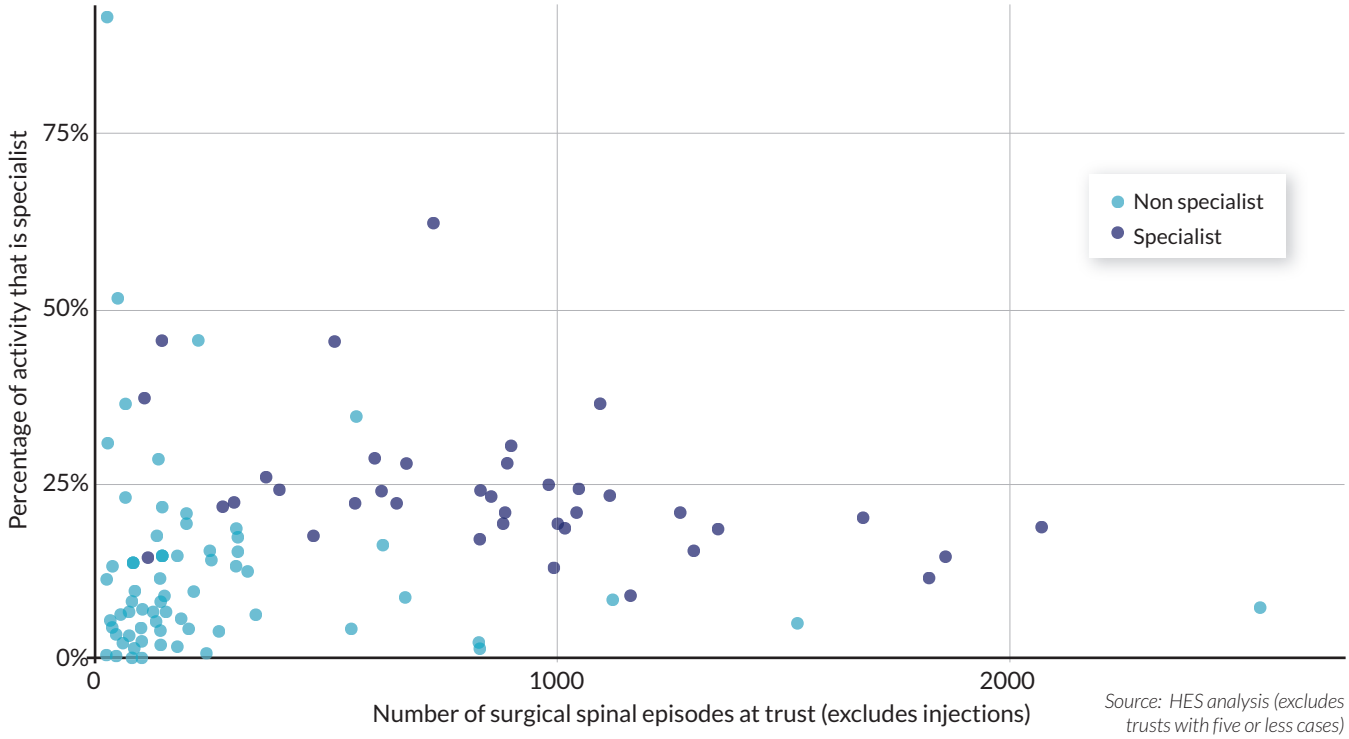
Procedures defined as specialist spinal procedures include:[30]

- any cervical spine procedure involving implants, except those for anterior cervical discectomy and fusion;
- all thoracic spinal surgery;
- all anterior lumbar spine surgery;
- paediatric, adult and degenerative spinal deformity surgery;
- posterior instrumented spinal fusion / stabilisation more than 2 levels;
- all surgical procedures except biopsy for patients with a diagnosis of spinal Infection / palliative metastatic tumour / trauma; and
- all spinal surgery for potentially curative spinal tumour including biopsy.

Only providers that are equipped with the appropriate skills and expertise (as set out by the CRG) should be delivering the specialist surgical services described above. Appendix C lists the NHS trusts that are currently designated as specialist providers of spinal surgery.

For trusts that perform spinal surgery, Figure 19 shows the proportion of their activity that is specialist, based on the procedures defined by the CRG. The chart also highlights trusts that are designated as specialist (in receipt of the specialist top-up for spinal surgery). The clear message is that there is a large amount of activity that is designated as specialist that is being undertaken outside trusts that are designated as specialist.

Figure 19: Proportion of spinal surgery caseload defined as specialist, by trust



Source: HES analysis (excludes trusts with five or less cases)

[30] *NHS England, NHS Standard Contract for Complex Spinal Surgery (All Ages)*

Table 1 quantifies the extent to which activities that are designated as specialist are being undertaken outside trusts that are designated as specialist. For the main procedure groups, it shows the number of episodes in 2017/18, the number of these that were coded as being specialist (according to the CRG definition), and the number that were performed at non-specialist trusts (based on which trusts receive specialist top-ups for spinal surgery). The difference means that approximately 1,700 specialist spinal procedures per year are being undertaken outside specialist spinal surgery centres.

Table 1: Specialist procedures undertaken by providers that are not designated as specialist providers of spinal surgery (2017/18)

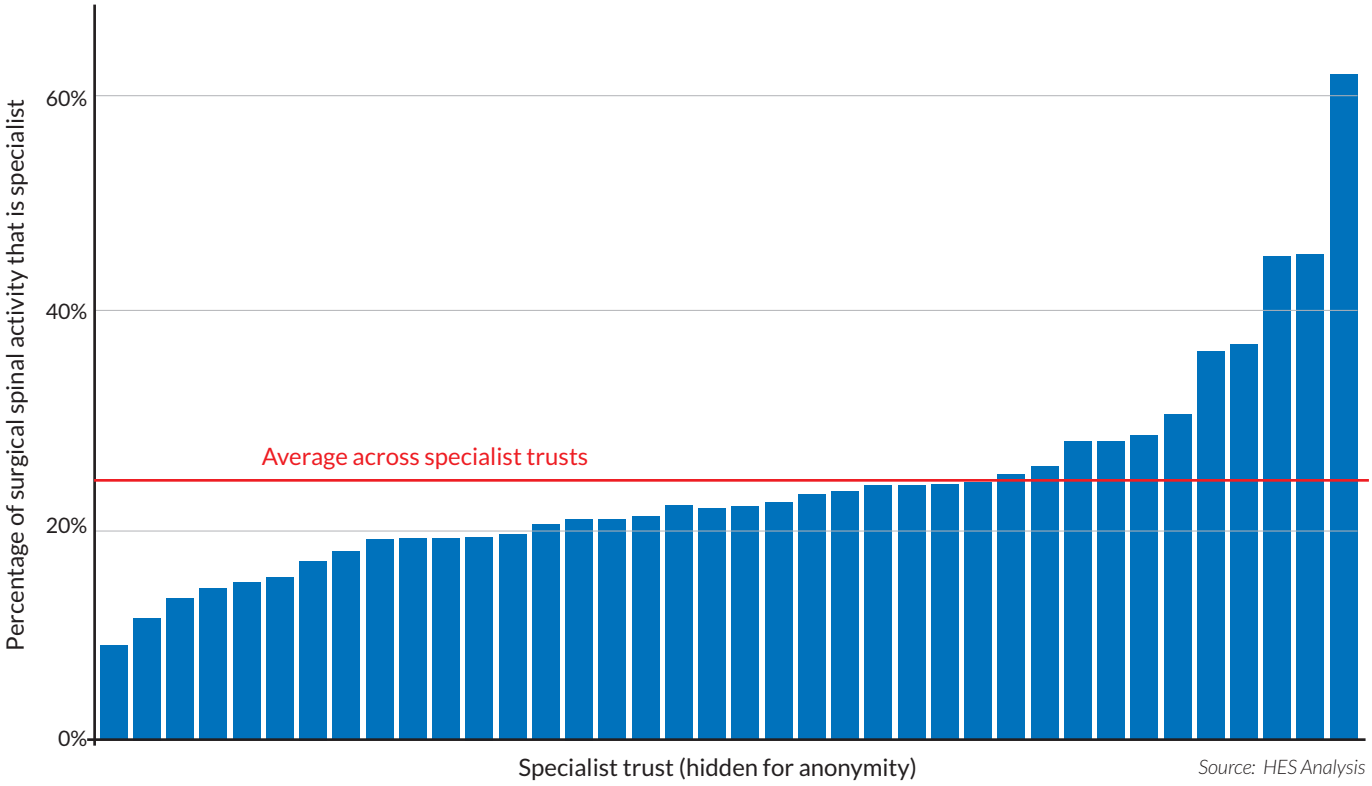
		Non-specialist providers	
Specialist Procedure	**Total no. of procedures**	**Number of procedures**	**% of total**
Prosthetic replacement of cervical intervertebral disc V361	367	147	40%
Excision of lesion of lumbar vertebra V433	345	119	34%
Primary anterior corpectomy of cervical spinal with reconstruction V224	349	95	27%
Other specified operations on spine V548	204	88	43%
Primary anterior excision of lumbar intervertebral disc and interbody fusion of joint of lumbar spine V333	248	81	33%
Primary anterior excision of lumbar intervertebral disc V334	102	64	63%
Posterior instrumented fusion of cervical V402	354	63	18%
Primary anterior excision of lumbar intervertebral disc and posterior instrumentation of lumbar spine V336	132	59	45%
Posterior instrumented fusion of thoracic spine (Level 3+) V403+V553	476	46	10%
Posterior instrumented fusion of cervical (Level 3+) V402+V553	344	41	12%
Other specialist procedures	**6,075**	**891**	**15%**
Total	**8,996**	**1,694**	**19%**

This difference is too material and concentrated to be explained by poor coding practices. The principal reason, supported with evidence seen during the GIRFT team's visits, is that the designation of specialist trusts (those that receive specialist top-up funding for spinal surgery) is not the same as trusts that are equipped and capable of undertaking specialist spinal activity. Many trusts are equipped to undertake specialist surgery but are not being funded for it in the same way as the designated specialist trusts.

This does not necessarily mean that patients receiving specialist procedures at non-specialist trusts are receiving poor quality. Rather, it demonstrates that the designation of trusts as specialist (for funding purposes) is not a good fit with what is currently taking place within trusts. We are therefore recommending that the designation of trusts as specialist providers of spinal surgery is reviewed, and once complete that non-specialist trusts are prohibited from undertaking activity designated as specialist.

In addition, specialist centres are not necessarily focusing their limited clinical resources on specialist care. We estimate that during the April 2017 to March 2018 period, 47,077 non-specialist inpatient procedures were undertaken by designated specialist spinal surgery centres.

Figure 20: Percentage of activity that is specialist spinal activity, by specialist trust (2017/18)



Source: HES Analysis

The overall picture suggests that the distribution of activity across providers is suboptimal. Specialised procedures are being undertaken by providers that are not designated and specialised, whilst many specialised trusts are undertaking non-specialised activity. Whilst this is required for training and to support the local community, we note that specialised centres are much more likely to cancel elective surgery cases, presumably, in many cases, due to a lack of capacity.

Based on the evidence described above, we are recommending that steps are taken to ensure that trusts are collectively focused on delivering the services that best match their skills and competence.

Recommendation	Actions	Timescale
9. Review the list of trusts that are designated specialist spinal surgery centres and that non-specialist trusts are not remunerated for undertaking specialist work. Specialist top-ups phased out and tariff restructured so that specialist centres are appropriately remunerated for the specialist activity they undertake and are not incentivised to perform non-specialist work	• Spinal Services CRG asked to review criteria for specialist designation	January 2019
	• NHSE Specialist Commissioning team to revisit designation of specialist trusts, based on the CRG's criteria	April 2019
	• Updated designation of providers of specialist spinal surgery becomes operational	April 2020
	• CCGs to not remunerate non-specialist trusts for performing specialist activity, in line with the CRG's updated designation	April 2020
	• NHSE, GIRFT and NHSI to work on developing proposals for reimbursing specialised spinal services	April 2019

5.2 Surgical volumes and the provision of specialist surgery

There is a growing body of evidence across many surgical specialties, including spinal surgery, that patient outcomes are improved where certain procedures are consolidated into specialist centres, and only undertaken by surgeons meeting volume thresholds. A full review is beyond the scope of this report, but as an example:

- Schoenfeld AJ *et al* (2018) found that surgeons with higher volumes of common lumbar spine surgical procedures including decompression, discectomy, and fusion-based procedures had reduced complication rates;[31]
- Malik AT *et al* (2018) undertook a systemic review of the literature related to spine surgery and found that higher surgeon volume was associated with a significantly lower risk of postoperative complications, a lower length of stay (LOS), lower cost of hospital stay and a lower risk of readmissions and reoperations/revisions;[32] and
- Paul JC *et al* found that the perioperative complication rate associated with revision adult spinal deformity surgery RASDS was lower when patients were treated by high-volume surgeons at high-volume centres.[33]

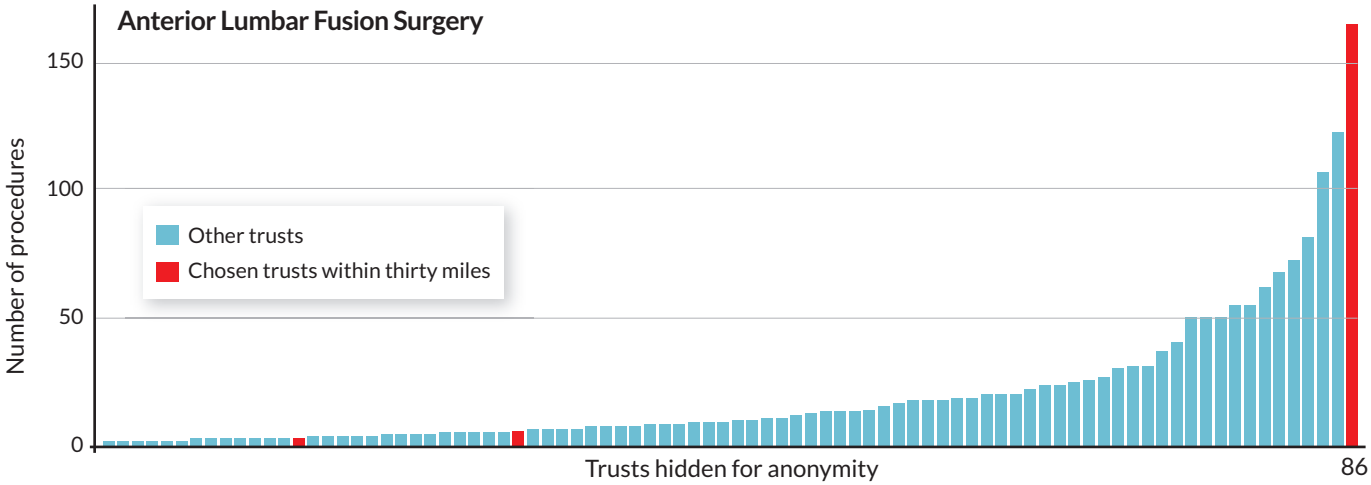
The data show that there is wide variation across units and surgeons in the volume of spinal procedures being undertaken. As an illustration, Figure 21 shows the variation in volume by trust for three procedures that are complex and with a high risk of complication: anterior lumbar interbody fusion surgery, anterior thoracic spine surgery, and intradural intramedullary spinal tumours. As an illustration (and not shown for all trusts) the graphs highlight trusts in one region of the country where there are 2 to 3 providers of these specialist and complex surgeries within close proximity (30 miles).

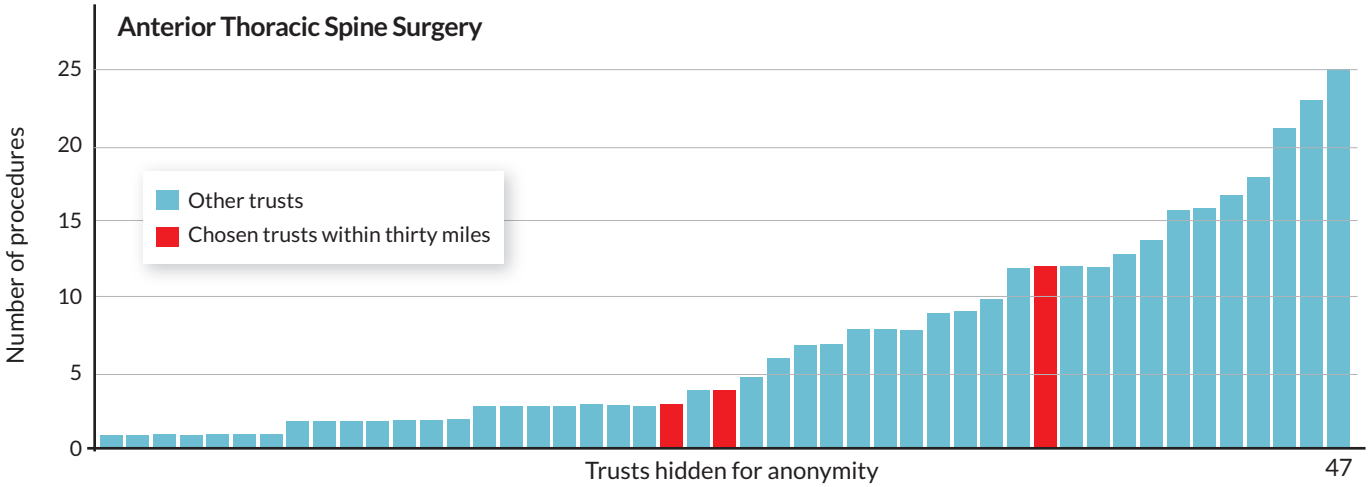
[31] *Schoenfeld AJ, Sturgeon DJ, Burns CB, Hunt TJ, & Bono CM, Establishing benchmarks for the volume-outcome relationship for common lumbar spine surgical procedures, Spine J. 2018 Jan;18(1):22-28*

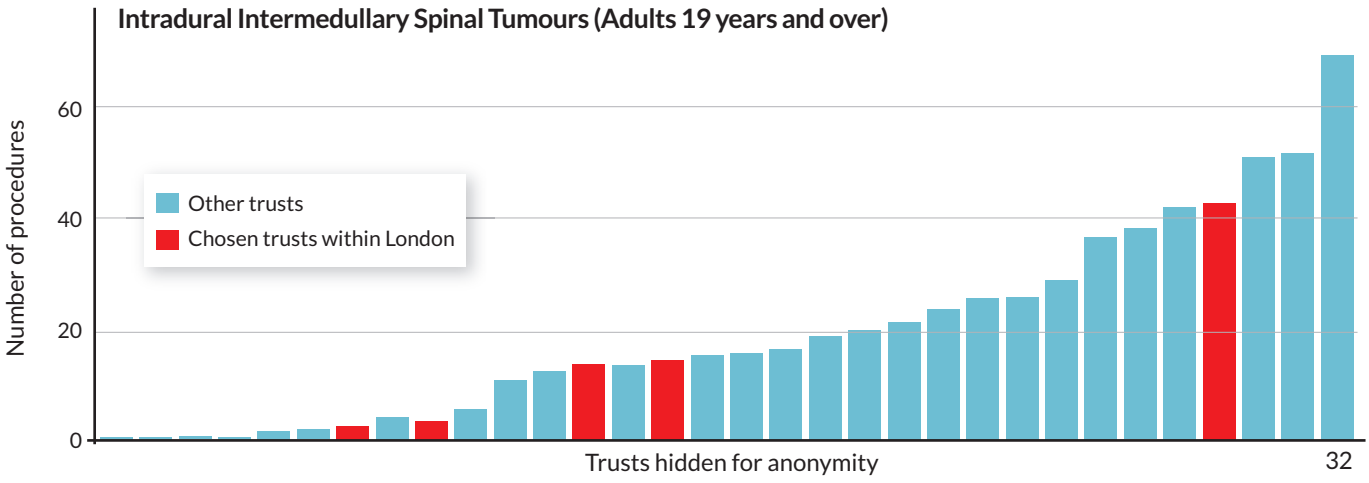
[32] *Malik AT, Panni UY, Mirza MU, Tetlay M, & Noordin S, The impact of surgeon volume on patient outcome in spine surgery: a systematic review, Eur Spine J. 2018 Mar;27(3):530-542*

[33] *Paul JC, Lonner BS, Goz V, Weinreb J, Karia R, Toombs CS, and Errico TJ, Complication rates are reduced for revision adult spine deformity surgery among high-volume hospitals and surgeons, Spine J. 2015 Sep 1;15(9):1963-72*

Figure 21: Number of operations by trust across three rare and highly specialised procedures (2015/16-2017/18)







Source: HES analysis

The data show wide variation in the volume of procedures being performed across trusts. We are not able to show a definitive link between volumes and outcomes for these procedures, principally because compliance with recording data associated with specialist activity on the BSR is poor. Nonetheless, given the complex nature of certain procedures, and the associated risks, we are recommending that the professional bodies (such as the British Association of Spine Surgeons, the British Scoliosis Society and the Society of British Neurological Surgeons) are asked to prepare guidance for the sector on minimum activity levels for specialist spinal procedures at a surgeon level. This guidance should inform decisions about the provision of highly specialist procedures and the case for limiting certain activities to a small number of supra-regional centres.

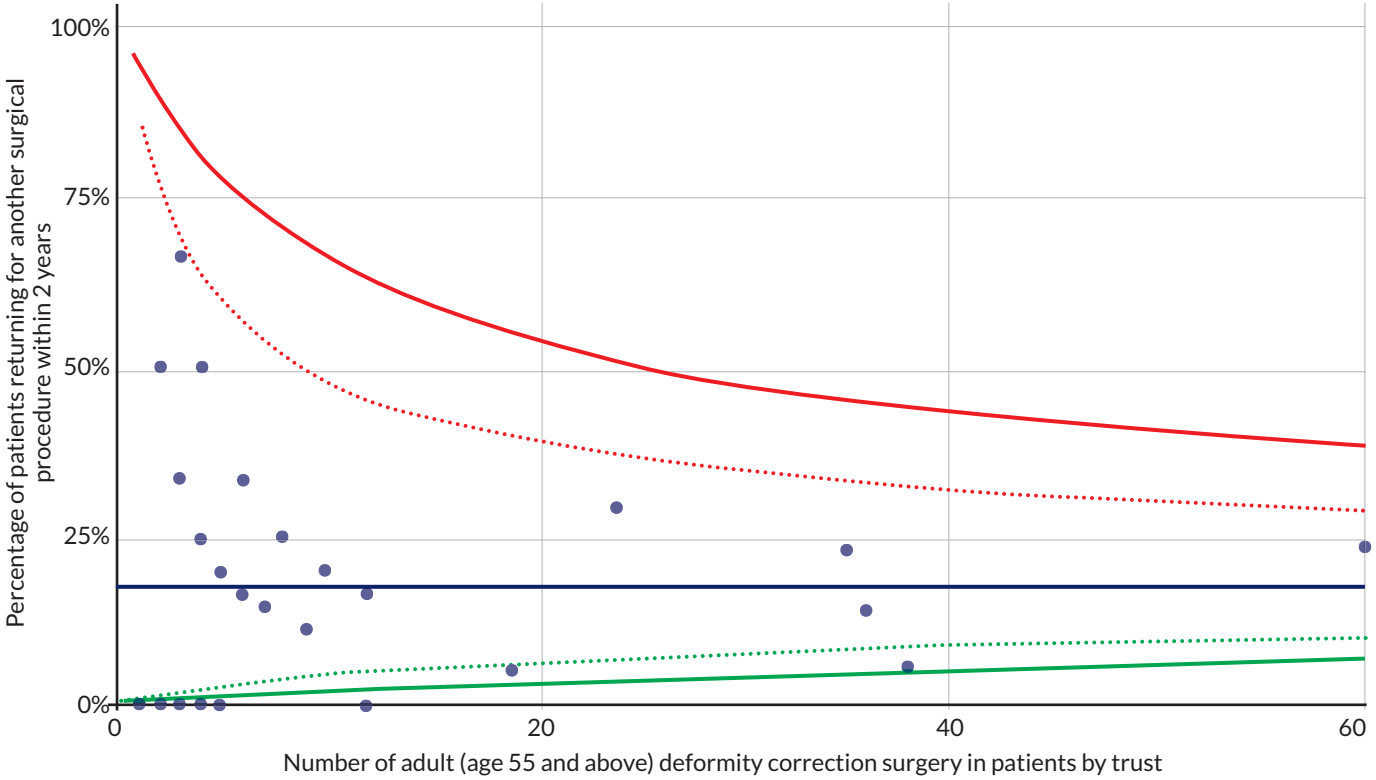
5.3 Adult Spinal Deformity Correction

Adult spinal deformity correction is considered to have one of the highest complication rates of all spinal operations currently performed, and should therefore be considered cautiously. Reported rates in the literature of degenerative scoliosis correction patients having a complication related to their surgery is about 7 out of 10 cases, of which 3 out of 10 cases are considered major complications seriously impacting future health. Revision rates for surgery are reported as around 13% at one year and 25% at three years post operatively due to complications.

Figure 22 demonstrates the number of centres performing this type of surgery within England and the return to operating theatre rate at 2 years. The English average of 21% fits with the published literature. There are currently 24 units undertaking this type of surgery. The resource associated with both primary and revision surgery is large with estimates in a USA study demonstrating average primary costs of surgery of $103,143 and readmission costs averaging $67,262 per readmission.[34]

The number of units performing less than 10 of these operations per year is 18. If surgery of this type was restricted to 10 centres in England whose funding for such procedures was predicated on accurate reporting of complication rates and outcomes then in 5 years the NHS in England would have a far better opportunity to accurately assess the cost benefit to our healthcare system and make the difficult decision as to whether we continue to commission it.

Figure 22: Adult deformity surgery (aged 55+) - % of patients returning to theatre for another surgical spinal procedure within 2 years (initial surgery 2015-16)



Source: HES Analysis

[34] *McCarthy I, Hostin R, O'Brien M, Fleming N, Ogola G, Kudyakov R, Richter K, Saigal R, Berven S, Deviren V & Ames C. Cost-Effectiveness of Surgical Treatment for Adult Spinal Deformity: A Comparison of Dollars per Quality of Life Improvement Across Health Domains, Spine Deform. 1, 293–298 (2013)*

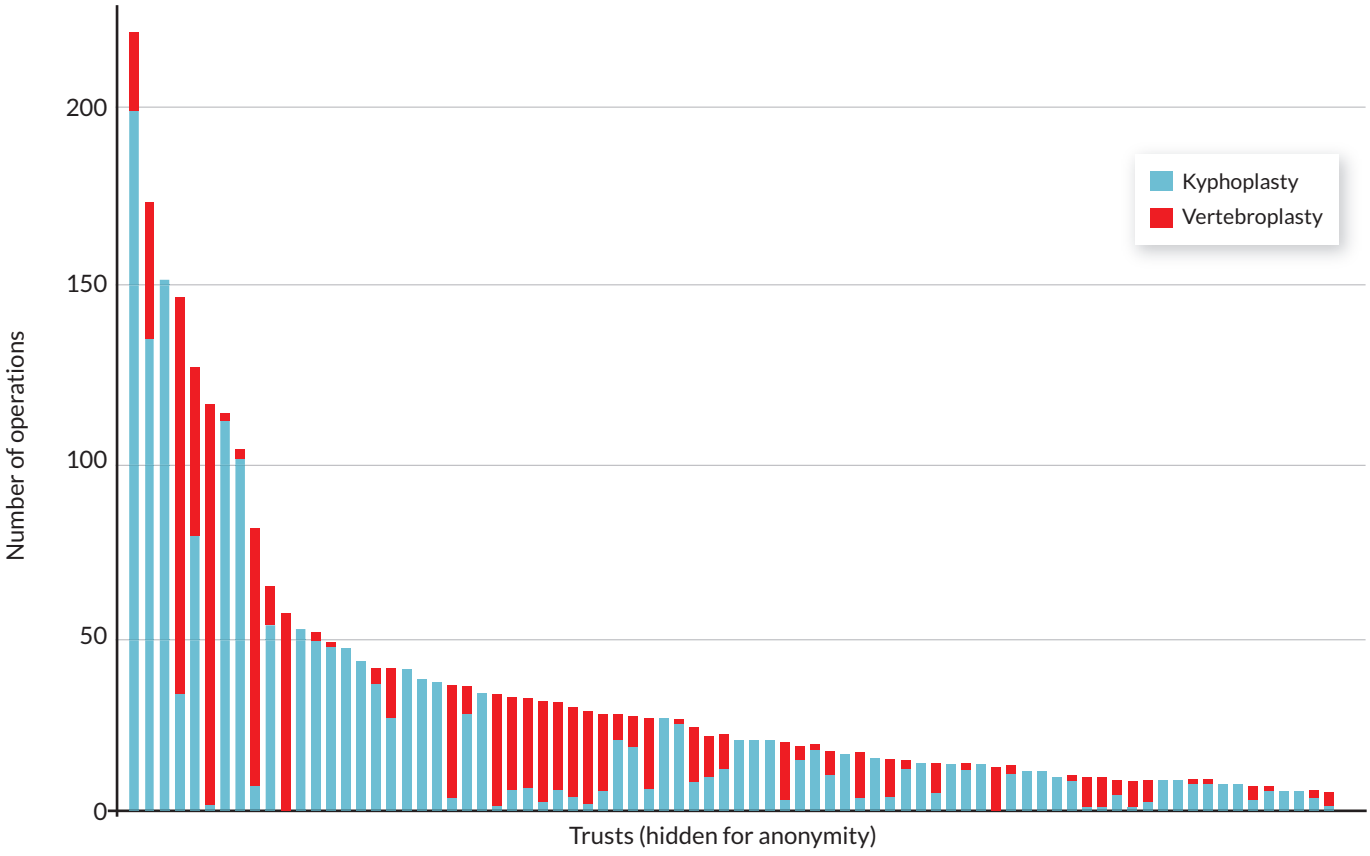
Recommendation	Actions	Timescale
10. Review of minimum surgeon and provider volumes for a range of rare spinal conditions and complex spinal surgeries, including adult spinal thoracolumbar degenerative deformity surgery and paediatric spinal deformity surgery. Spinal societies asked to make recommendations.	• GIRFT, BASS, BSS and SBNS asked to consider evidence for and develop recommendations on minimum volumes.	For immediate action
	• CRG for spinal surgery to consider recommendations and make appropriate changes to specialist commissioning guidance	For implementation from April 2020

6. Management of Osteoporotic Fractures

The natural history of benign osteoporotic fractures is, on the whole, one of improvement without intervention. Kyphoplasty and vertebroplasty are interventions aiming to improve symptoms of pain associated with these fractures. Both procedures involve the injection of cement into an osteoporotic fracture, but kyphoplasty uses a balloon to create a cavity, which allows the cement to be injected in a contained manner.

Whilst the use of these cement augmentation procedures in spinal malignancy, such as myeloma, for pain relief has a good evidence base, their use in the management of osteoporotic fractures is controversial with a recent Cochrane review and double blind randomised sham study suggesting no difference in outcome.[35, 36] NICE recommends both procedures as appropriate treatment for osteoporotic vertebral compression fractures but does not specify particular circumstances where one may be preferred over the other.[37] The data suggest that there is wide variation in the use of the two procedures across the NHS. Figure 23 shows the variation in the use of the two procedures by Trust.

Figure 23: Number of Kyphoplasty and Vertebroplasty operations done by trust (April 2016 to March 2018)



Source: HES analysis.
Procedures defined using OPCS codes (Kyphoplasty - V445 and Vertebroplasty - V444) Excludes all trusts with five or less cases.

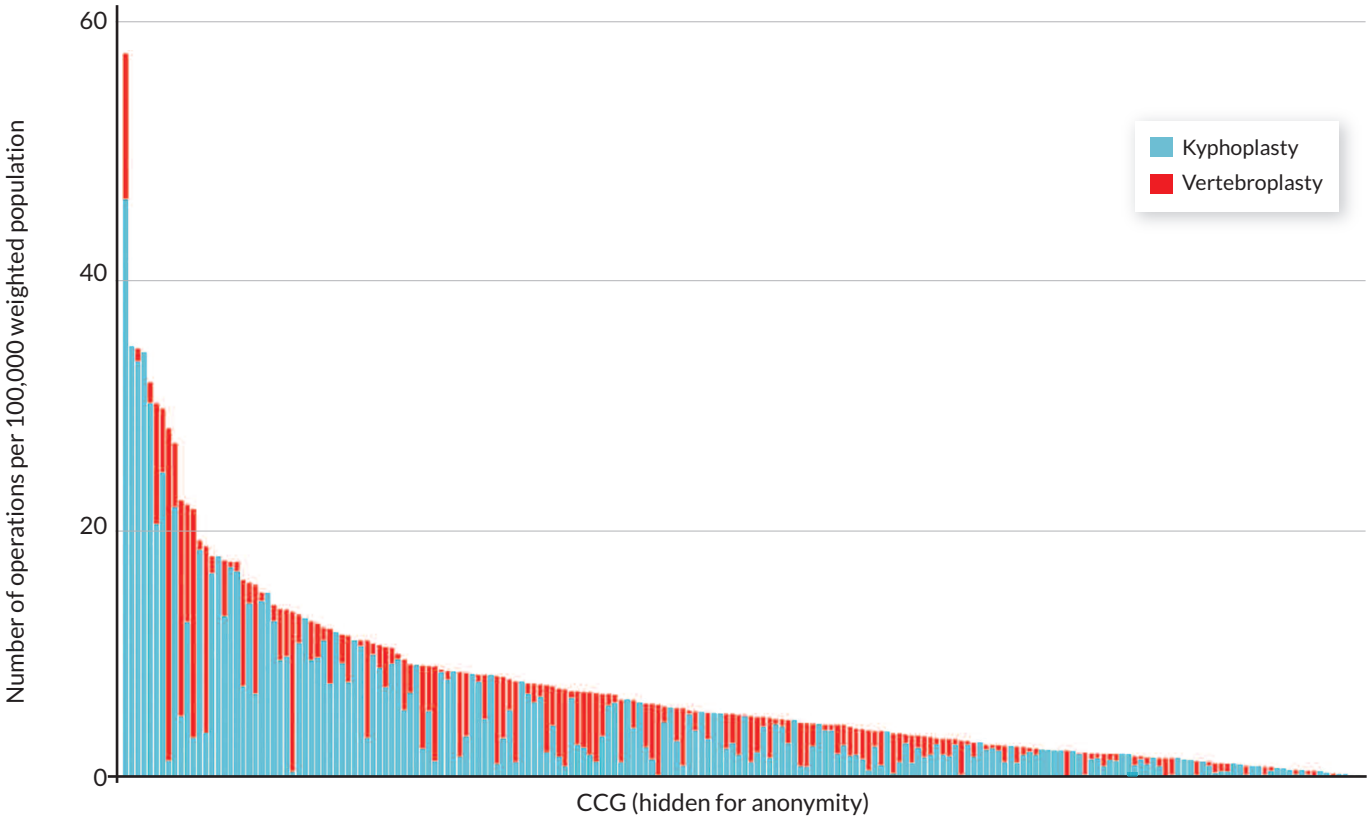
[35] *Firanescu CE, de Vries J, Lodder P et al, Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures (VERTOS IV): randomised sham controlled clinical trial, BMJ, 2018 May 9;361*

[36] *Buchbinder R, Johnston RV, Rischin KJ, Homik J, Jones CA, Golmohammadi K, Kallmes DF. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. Cochrane Database of Systematic Reviews 2018, Issue 4*

[37] *NICE (2013) Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures, Technology appraisal guidance [TA279]*

During our visits, the clinicians we met suggested this variation could be due to casemix. For example, kyphoplasty might be favoured in patients when correcting vertebral collapse and wedging. The hypothesis that casemix is driving the observed variation, is not supported by the data. Figure 24 shows variation in the use of vertebroplasty and kyphoplasty by CCG. Taking a CCG population-based view helps, at least in part, to control for the casemix differences that affect trust-level comparisons. The evidence shows that there is still wide variation in the relative use of the two procedures, which is not being driven by casemix difference. This variation will have a significant impact on costs, with little supporting evidence that, for most patients, the higher cost is justified by improved outcomes for patients.

Figure 24: Number of Kyphoplasty and Vertebroplasty operations done by CCG (per 100,000 weighted population, April 2016 to March 2018)



Source: HES analysis. Procedures defined using OPCS codes (Kyphoplasty - V445 and Vertebroplasty - V444)

Our recommendation is that further work is required to develop guidance on the use of kyphoplasty and vertebroplasty so that there is greater standardisation in the use of the two procedures and more consistency in decisions about when one is preferred over the other.

Recommendation	Actions	Timescale
11. BASS to review NICE guidance and recommendations on the appropriate use of vertebroplasty and kyphoplasty and timing of intervention	• BASS asked to review latest evidence on the use of vertebroplasty and kyphoplasty	For immediate action
	• Recommendation from BASS on whether NICE should be asked to update their guidance on when intervention should occur in osteoporotic fractures	For immediate action

7. Paediatric Spinal Surgery

7.1 The Distribution of Spinal Deformity Surgery

Across England, there are 26 specialist spinal centres that are commissioned to undertake spinal surgery on paediatrics. By far the most common operation is adolescent idiopathic scoliosis (AIS) – spinal deformity - in children aged 10-18. AIS patients are generally fit and well.

The Spinal Services Clinical Reference Group (CRG) divides paediatric spinal deformity surgery into two types:[38]

- **Type I:** Instrumented spinal deformity correction in ambulant, otherwise healthy children aged 10-18 years.
- **Type II:** All other spinal deformity surgery including surgery on non-ambulant children, those with associated medical problems and younger children with congenital deformity.

The CRG sets a clear specification that centres must meet in order to deliver Type 1 surgery. These are wide ranging and cover areas such as access to supporting paediatric specialists, specialist paediatric anaesthetists, guidance on staffing levels and a requirement to perform regular surgery to maintain skills. Centres providing Type II procedures must also provide on-site paediatric intensive care (PICU) and have the ability to provide short-term post-operative ventilation.[39]

Our visits identified that, in general, these service designations were being followed but that there was confusion and variation in what factors define whether a patient should be treated as a paediatric case in the transition age 16 to 18. We are recommending that the British Scoliosis Society and CRG work together to define the criteria about when a patient in the 16-18 age group should be treated as a paediatric case.

We also identified that, in some circumstances, centres that were not designated to perform paediatric spinal surgery were undertaking this surgery in low volumes in the young adult idiopathic scoliosis age group over 18. The clinical decisions and service requirements for this type of patient are similar to that in the paediatric population. Performing surgery in low volumes is likely to be associated with less favourable outcomes and higher complication rates.

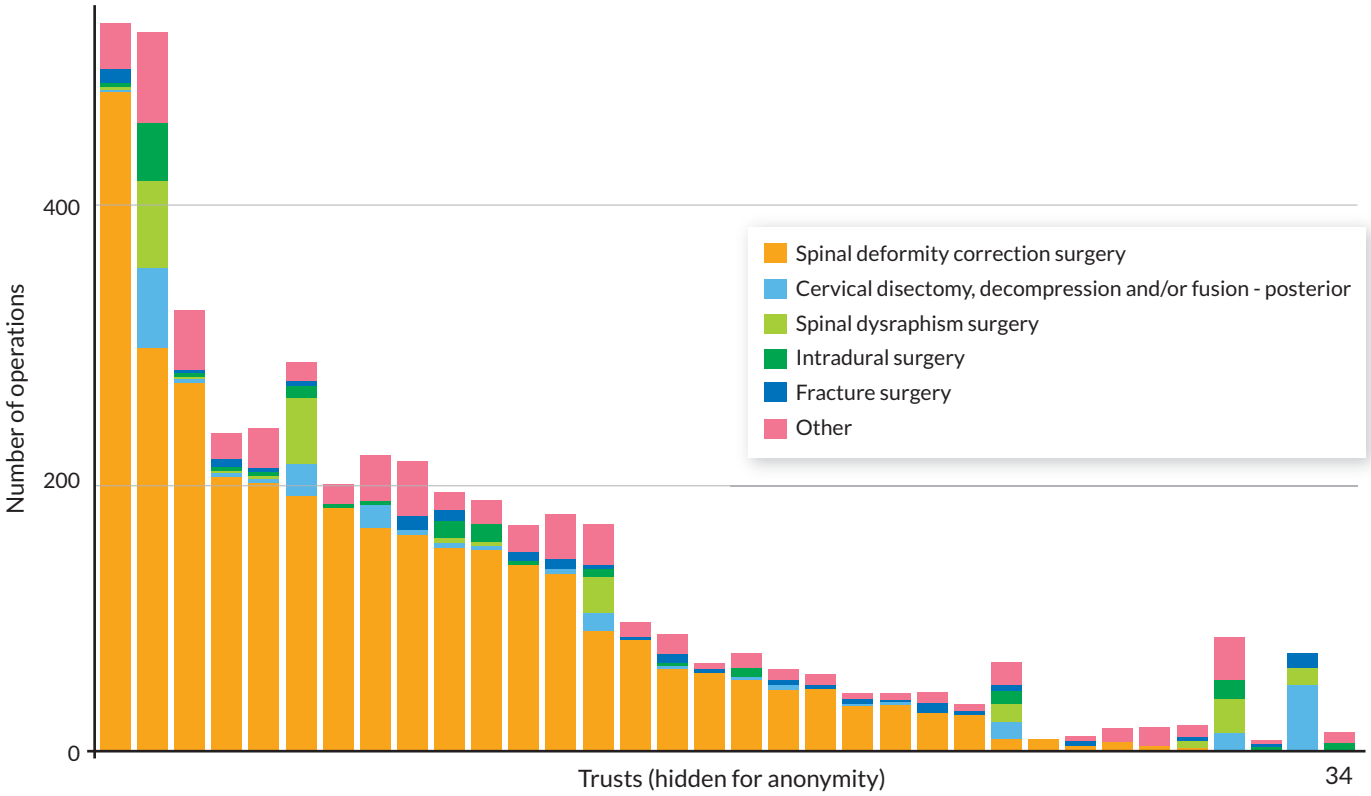
To address this, as part of Recommendation 10, we are proposing that the CRG defines centres that are capable of performing spinal deformity surgery in the young adult population, including ensuring a smooth transition from paediatric to adult centres.

The data, and feedback during our visits to paediatric centres, indicate that the allocation of paediatric spinal surgery volumes across providers is not optimal. Figure 25 shows the total number of spinal operations performed in paediatrics between April 2017 and March 2018, by trust. There is wide variation in the volumes being performed – including some paediatric spinal surgery being undertaken in trusts that are not designated specialist paediatric trusts. Overall, the majority of paediatric spinal surgery is highly concentrated in a small number of centres, despite a larger number being equipped to undertake this type of work. These centres are potentially under-utilised and a number of centres are undertaking very low volumes.

[38] *NHS Commissioning Board, NHS Standard Contract for Complex Spinal Surgery, 2013*

[39] *NHS Commissioning Board, NHS Standard Contract for Complex Spinal Surgery, 2013, pp. 16-17*

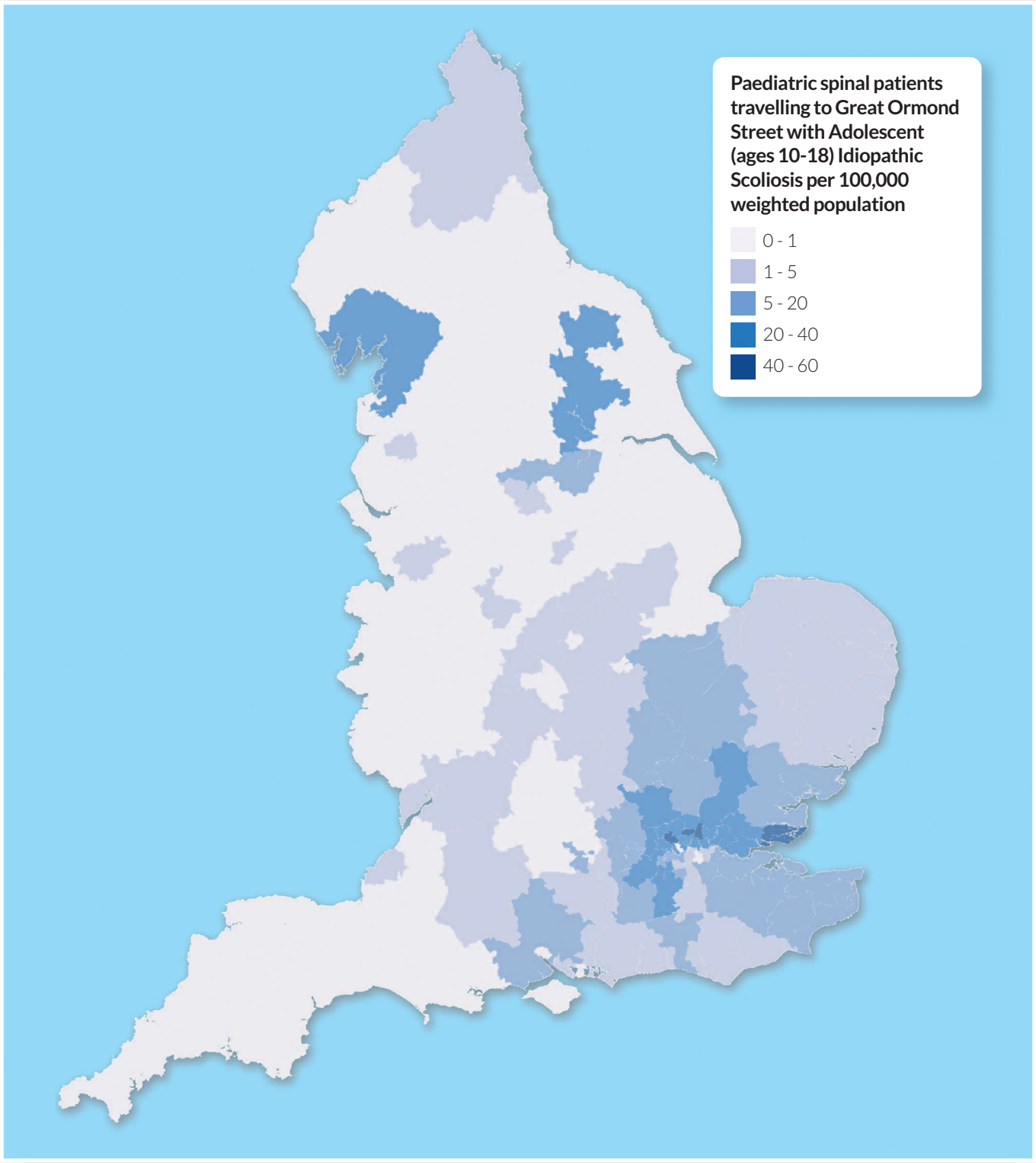
Figure 25: Total number of paediatric (age under 19) surgical operations by trust (April 2017-March 2018)



Source: HES Analysis (excludes trusts with less than 5 cases)

On the whole the delivery of spinal services to our paediatric population should occur as close to home as is safe as possible. We found in some instances patients not being referred to their local specialist paediatric deformity unit and being sent further afield to super specialist units, which are coping with very high demand. As an example, Figure 26 shows the geographical distribution of patients travelling to Great Ormond Street for Adolescent Idiopathic Scoliosis surgery. Many patients are not going to their local paediatric spinal deformity centre.

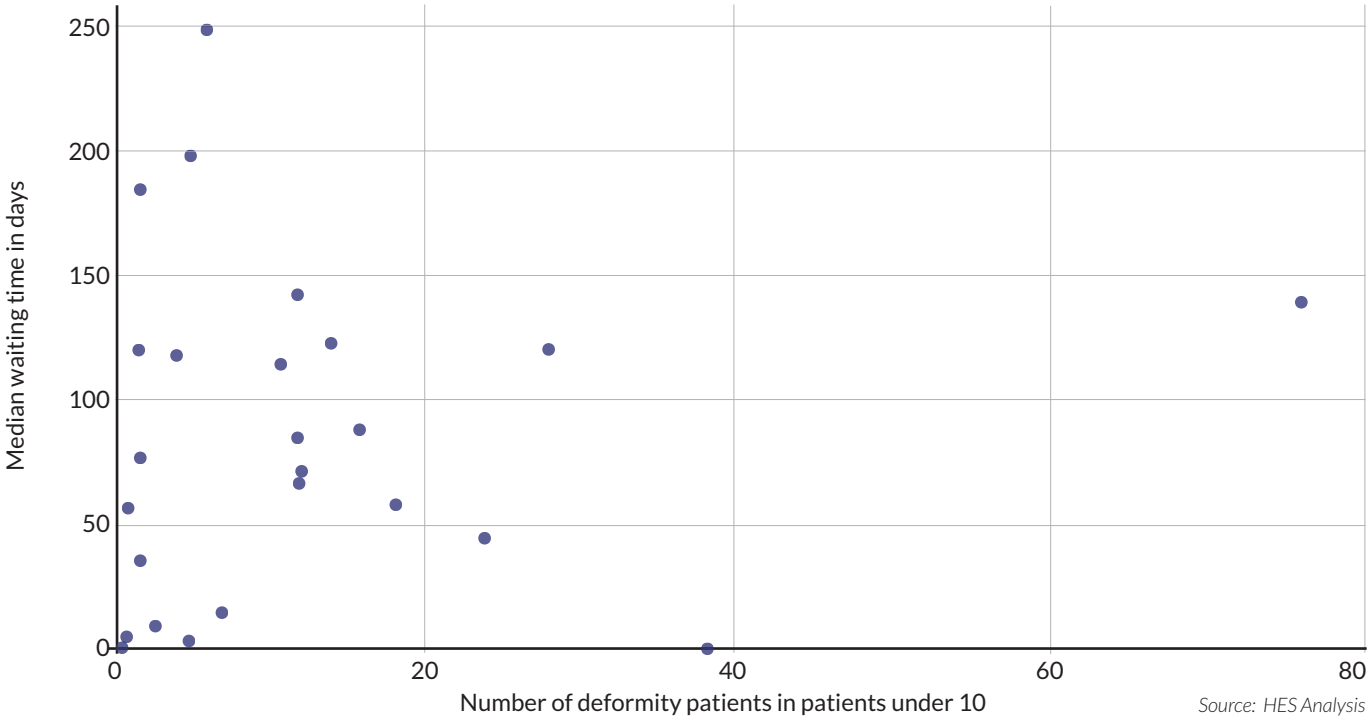
Figure 26: Geographic distribution of patients receiving surgery for adolescent idiopathic scoliosis (Aged 10-18) being treated by Great Ormond Street Hospital for Children NHS Foundation Trust (April 2017-March 2018)



Source: HES Analysis

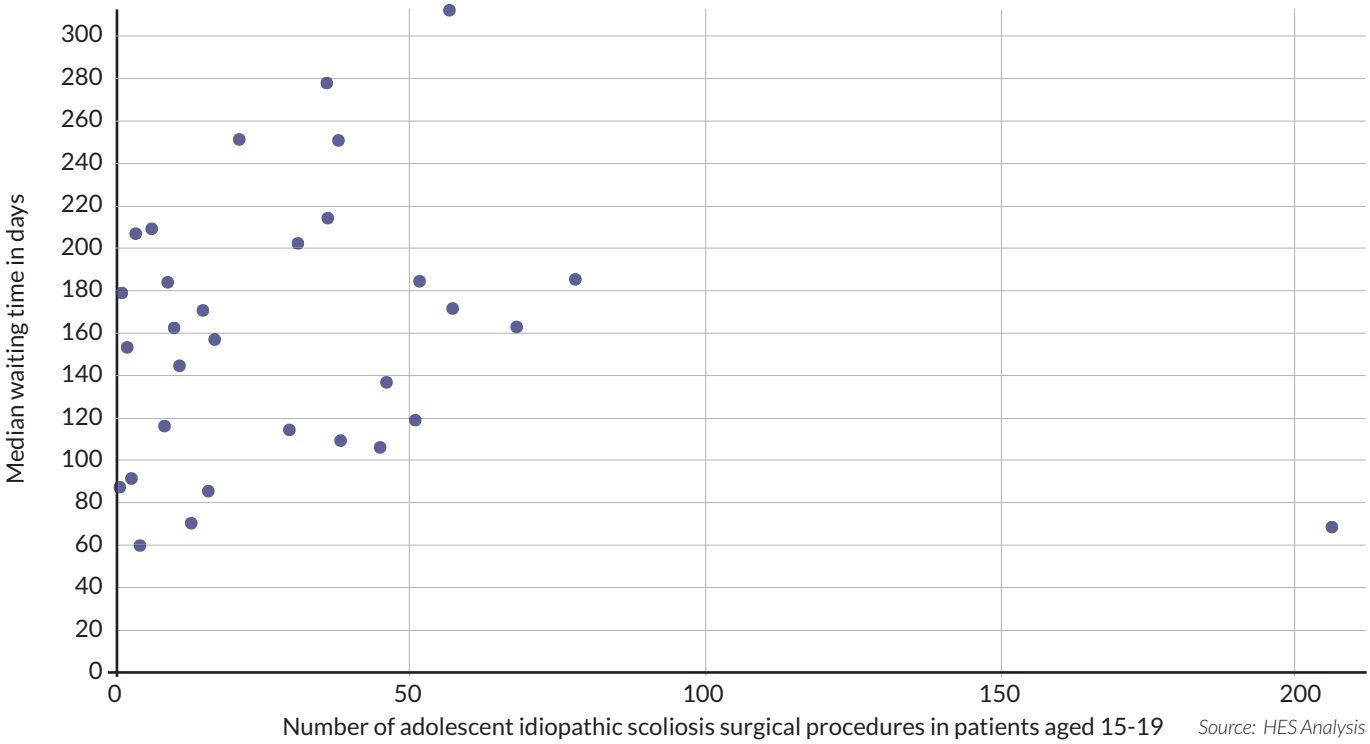
There is also wide variation in the waiting times for spinal deformity surgery (see Figure 27 and Figure 28). Delays in surgery can be particularly detrimental to the under 10s and young teens because their bodies are growing rapidly.

Figure 27: Median waiting times – spinal deformity surgery, aged under 10 (April 2016-March 2018)



Source: HES Analysis

Figure 28: Median waiting times - patients receive adolescent idiopathicscoliosis surgery, aged 15-19 years, (April 2016-March 2018)



Source: HES Analysis

The evidence suggests that there is a clear opportunity to look at how the volume of paediatric deformity surgery is spread across providers. A reallocation of activity across specialist paediatric deformity units could potentially reduce waiting times by easing pressure on centres with high waits. We are therefore recommending that CCGs take action to review their referral arrangements for patients requiring paediatric deformity surgery. In some cases, this may mean patients are given choices that are not their closest units. Development of a central paediatric deformity digital management tool with waiting time to first appointment and waiting time from decision to operate to operation for the centres involved in providing this surgery would help clinicians to direct referrals appropriately.

Recommendation	Actions	Timescale
12. The BSS and the Spinal Services CRG asked to define criteria in the 16-18 age group that should be treated as a paediatric case	• BSS and Spinal Services CRG to make a recommendation	To begin immediately
13. CCGs to ensure that all primary care referrals for paediatric deformity surgery go through their local paediatric deformity unit. A central paediatric deformity referral management tool is used to ensure that cases go to the correct geographical centre with appropriate skill sets and shorter waiting times	• CCGs to review their referral management arrangements for paediatric spinal deformity	April 2019
	• NHS England to develop a central paediatric deformity referral management tool	

7.2 Type I & Type II Surgery

Clinicians from our visits expressed concerns that the 'line in the sand' approach, where a patient's age and ambulatory status determine whether a case should only be undertaken in centres with a PICU, was too simplistic. There was a view that suitability of a centre to undertake surgery should be on a case by case basis. We saw numerous examples where trusts undertake their own risk assessment based on the specifics of each case. For example:

- **Royal Devon & Exeter Hospital Paediatric Deformity Unit MDT:** Since 2011, all patients with paediatric spinal deformity that are considered or listed for surgery at the trust attend a MDT meeting, with input from a consultant paediatrician, a consultant specialist spinal paediatric anaesthetist and paediatric nursing staff. The decision about whether a patient undergoes surgery at the trust or whether higher level paediatric intensive care facilities are required rests with the MDT. Ten MDTs are held per year. From April 2011 to April 2018, 264 patients were referred by the surgeons as candidates for surgery at the trust to the MDT. Of these, 60 were non-ambulatory and hence Type II designation. Thirty patients were referred to centres with a higher level of paediatric postoperative intensive care. There were no recorded cases of prolonged postoperative ventilation at the trust in any of the cases.
- **Royal National Orthopaedic Hospital (RNOH):** The RNOH hospital is the largest provider of paediatric spinal deformity surgery in England. It has a paediatric High Dependency Unit (HDU) only (no paediatric intensive care unit - PICU). Between January 2008 and January 2018, 2,833 HDU episodes for paediatric spine deformity unit occurred. Of these cases, 106 (3.7%) were below 9 years old, 195 (6.9%) were for congenital deformity. Overall, 214 cases stayed beyond 48 hours in HDU, whilst 11 (0.4%) were transferred to other hospitals for interim management (none under the age of 9). There was one perioperative death from cardiac arrest secondary to blood loss.

In summary, both "Type I" and "Type II" scoliosis patients were treated safely with a low hospital transfer rate and low mortality, in a hospital without PICU on-site. Stand-alone elective hospitals may not have all medical specialties or PICU on-site, but they have the advantage of less emergency HDU bed pressures. Service planning should also take into considerations the robustness of the MDT approach to patient care. With a robust multidisciplinary approach, and close links with specialist paediatric units, patient safety can be maintained even in hospitals without PICU on-site.

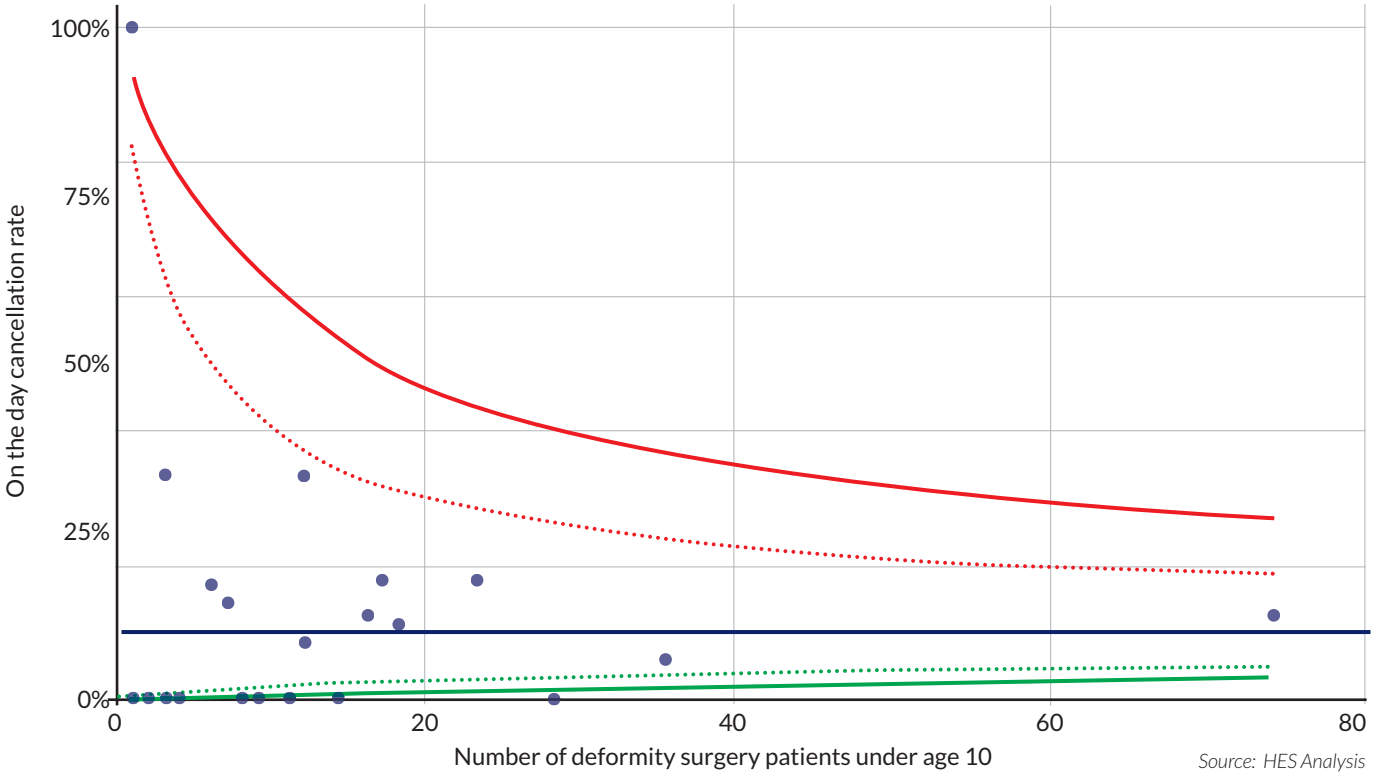
Recommendation	Actions	Timescale
14. Spinal Services CRG (NHSE) asked to review service specification for Type I and Type II Paediatric Scoliosis Surgery	• Spinal Services CRG (NHSE) to review evidence on the indicators for high risk patients and make recommendations on approaches for identifying and managing high risk paediatric scoliosis patients.	To begin immediately

7.3 Theatre Efficiency and Cost

Whilst the absolute numbers of paediatric deformity surgery are low in comparison to other types of spinal surgery, the resources involved in undertaking this type of surgery are very high. Surgery is time consuming and usually involves 1 or 2 operative cases on an all-day operating list. The operating list involves theatre staff, a neurophysiology team (monitoring spinal cord function), an anaesthetist and, in many cases, two consultant spine surgeons.

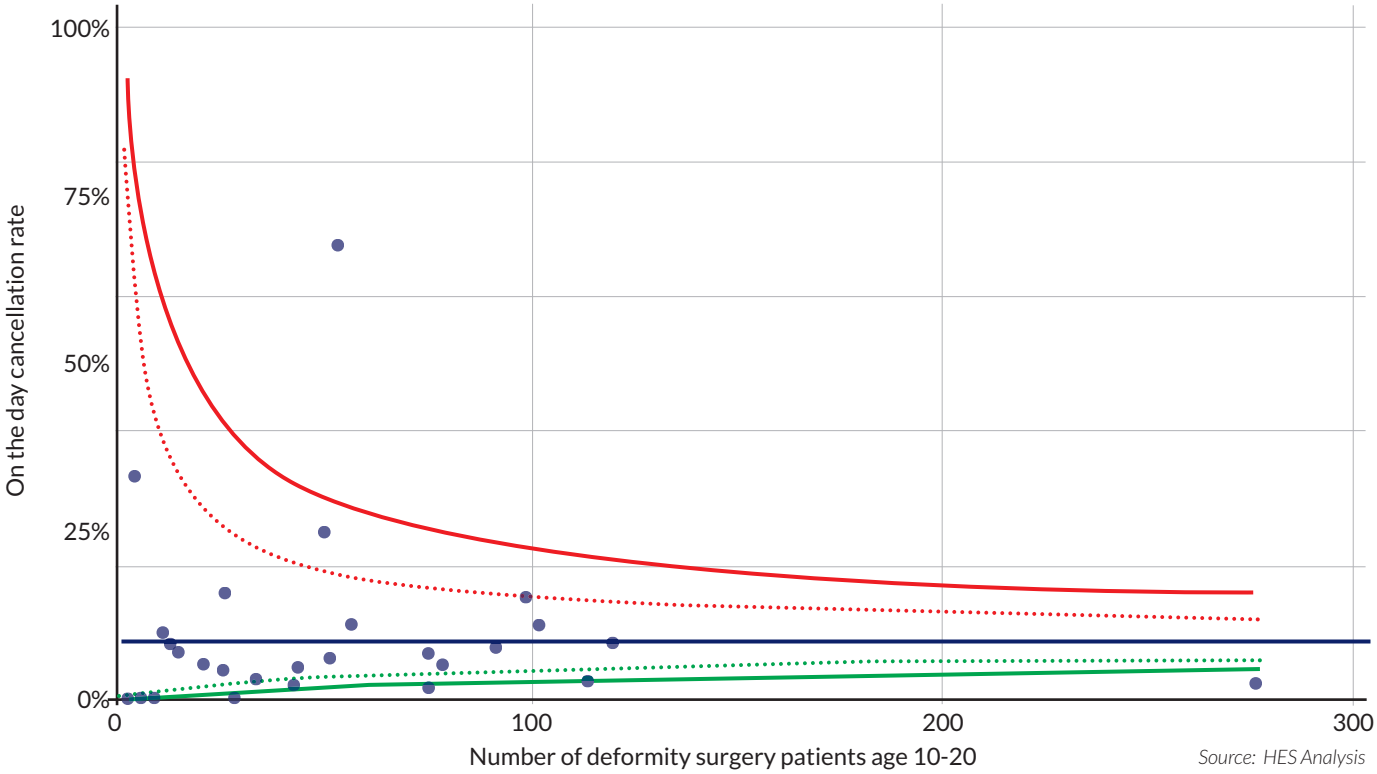
The majority of units undertaking this surgery reported delayed start times to their operating lists and high on the day cancellation rates (see Figure 29 and Figure 30). The primary reason for this, based on feedback during our visits, is a lack of HDU beds or delay in confirming HDU bed availability. Many units reported that they would be able to perform two rather than one case on an all-day operating list if they were able to start on time with a ring-fenced HDU bed.

Figure 29: On the day cancellation rates – deformity surgery procedures in patients aged under 10 years, April 2016-March 2018



Source: HES Analysis

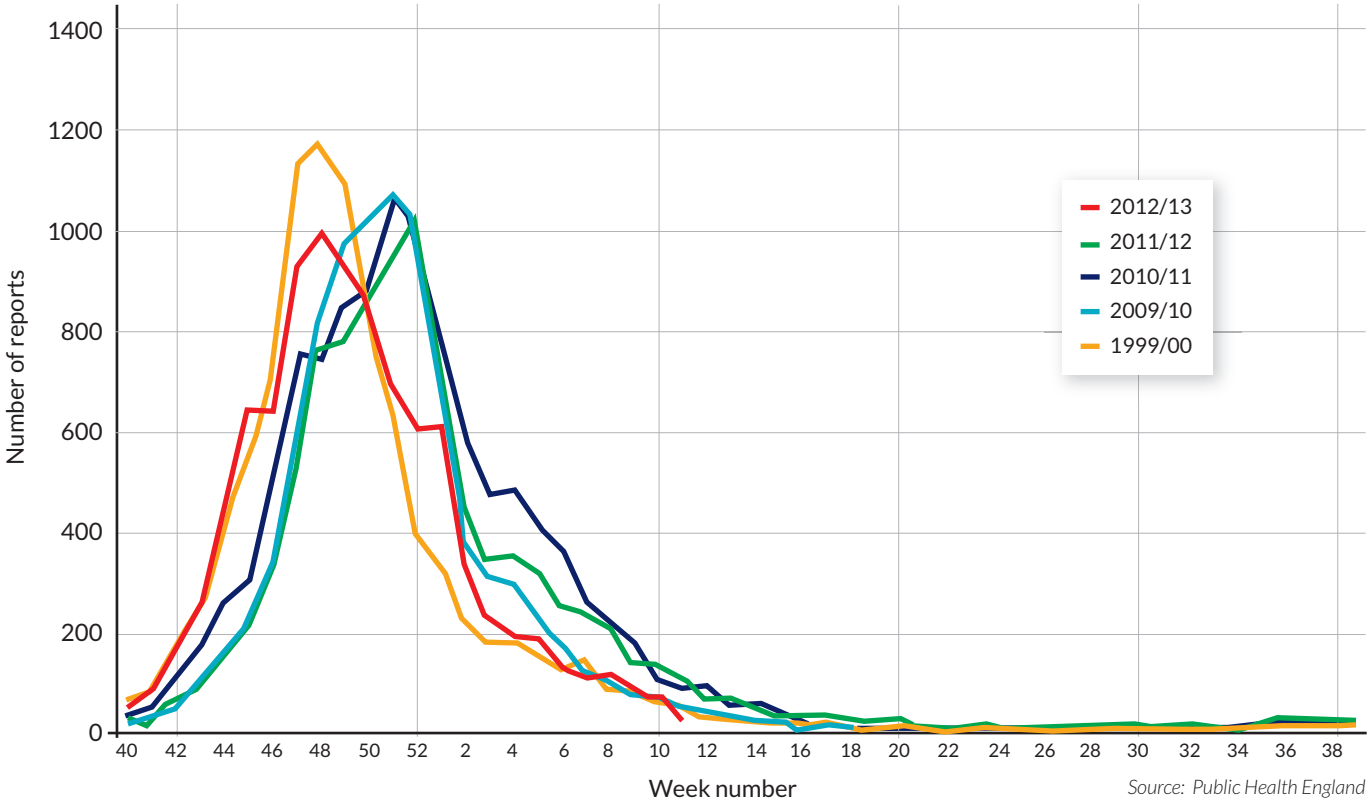
Figure 30: On the day cancellation rates – deformity surgery procedures in patients aged 10 -19 years, April 2016-March 2018



Source: HES Analysis

This problem was particularly worse during winter months, most noticeable during Respiratory Syncytial Virus (RSV) season. RSV is a major cause of respiratory illness in children. In severe cases, children require treatment in hospital and may need to be cared for in intensive care and high dependency beds, where they can be helped with their breathing. The RSV season runs every year from November until March (see Figure 31, which shows reports of RSV in England in recent years).

Figure 31: Laboratory reports of RSV received by HPA Colindale from NHS and Health Protection Agency microbiology laboratories by date of specimen, 2012/13 and recent years



Source: Public Health England

RSV is a particular issue for paediatric providers of spinal surgery because high volumes of urgent cases interrupt the flow of elective cases that also require high dependency care. Evidence from our visits suggested that many trusts are cancelling elective cases to deal with urgent admissions for RSV and other pressures during winter. However, we also saw examples of trusts where the predictable rise in urgent admissions during winter was built into winter planning and elective scheduling, to reduce cancellations for elective care (see Box 3).

Box 3: Norfolk and Norwich University Hospitals NHS Foundation Trust – Super Scoliosis Week

Due to the increased pressures of winter, Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUHFT) was cancelling almost 70% of its routine scoliosis work due to bed issues. This was having a profound effect on their young adolescent scoliosis patients and their families.

As a consequence, the trust started to question why it offers adolescent scoliosis operations in term time, which affects schooling, the need for parents to take significant time off work and, over winter, the added anxiety of cancelled operations.

NNUHFT's solution was a programme – super scoliosis week – where high volumes of scoliosis procedures are undertaken in a 5-day period, at times that are generally more convenient to adolescent patients. Appropriate patients were selected, seen collectively in pre-operative assessment and shown around the hospital.

During the week, NNUHFT's team were able to operate on 8-10 patients with no over-runs, equivalent to 10 weeks work completed in 5 days. Working in small skilled teams, the trust was able to dramatically improve efficiency, with no adverse impact on outcomes.

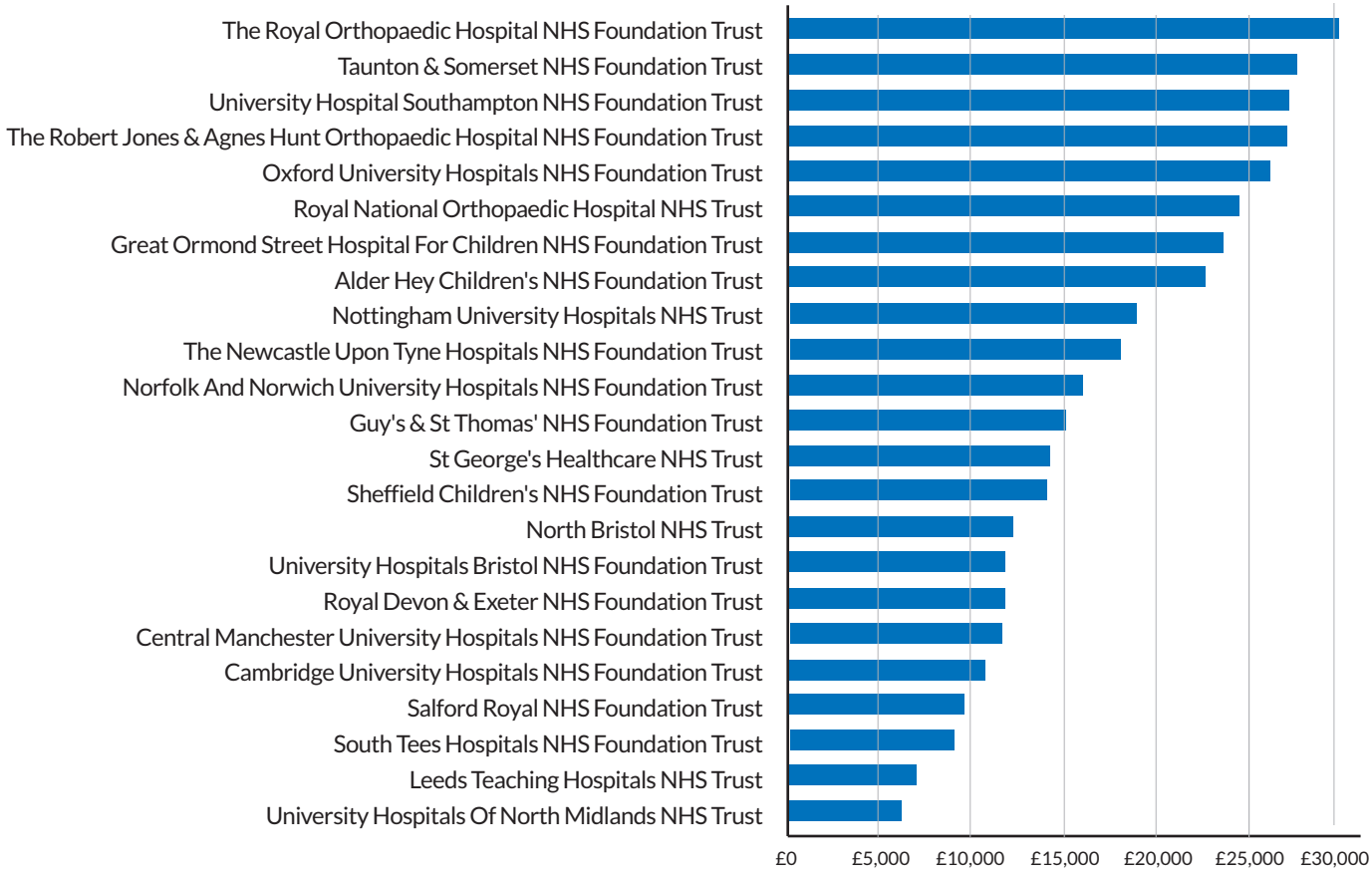
Previous GIRFT reports have emphasised the clinical advantages of having dedicated (ring-fenced) cold site elective hospital beds. In orthopaedics, they have been shown to reduce infection, shorten length of stay and reduce cancellations. Similar principles applied to paediatric spinal deformity surgery could support trusts in reducing their on-the-day cancellation rates for children undergoing this complex surgery.

We also established that there were varying practices regarding the use of HDU and length of stay on HDU following surgery for adolescent idiopathic scoliosis. We saw examples of trusts that had reduced their on the day cancellation rate for AIS by providing appropriate levels of nursing care in a non-HDU environment.

7.4 The Cost of Delivering Spinal Deformity Surgery

In many cases, different spinal procedures map to the same HRG chapter. This makes establishing the true cost of a particular procedure very difficult. Adolescent Idiopathic Scoliosis is an exception to this as it maps to one HRG (HC51E: Complex instrumented correction of spinal deformity, 18 years and under with a CC score 0-2). The cost of performing this procedure varies 4-fold across trusts (see Figure 32).

Figure 32: Variation in Reference Costs by NHS Trust for Adolescent Idiopathic Scoliosis (2016/17)

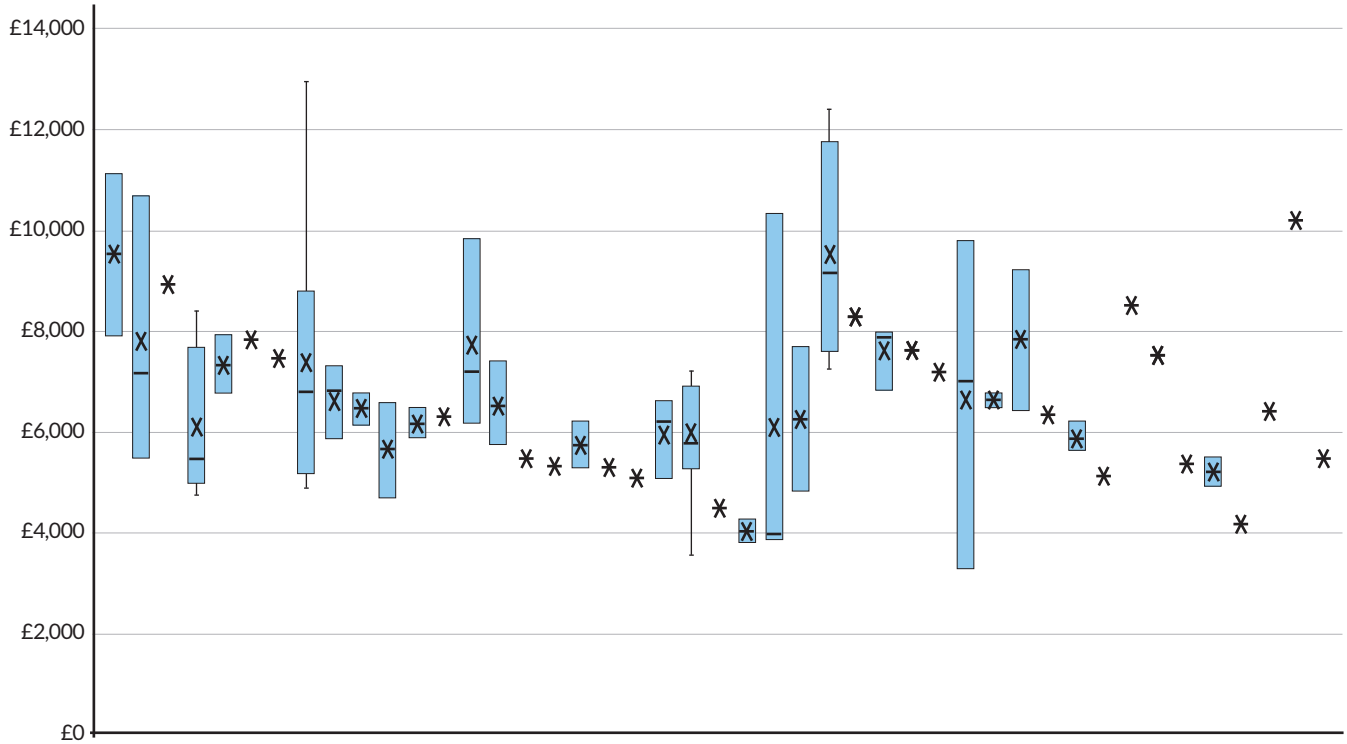


Source: Reference Cost Data Files published by NHS Improvement. Data shown is limited to elective cases for HRG HC51E (Complex instrumented correction of spinal deformity, 18 years and under with a CC score 0-2), for trusts performing more than 5 cases a year. Excludes excess bedday costs. Costs have not been adjusted to account for the Market Forces Factor.

This variation in cost will be driven by many factors, not least inaccurate coding and different approaches to cost allocation by trusts. But other factors have a direct and significant impact on costs, including length of stay in a critical care environment, length of stay in general, staffing costs, trust overhead costs and implant costs.

Implant costs are driven by the number of anchor points a surgeon wishes to use in a spine correction (implant density) and the cost of a construct. Most surgeons currently use pedicle screws as their implant of choice. Our visits to paediatric deformity units found significant variation in attitudes towards implant density and wide variation in implant costs both within and between trusts. In one trust we visited, four deformity surgeons were using four different brands of implants with significant variation in cost to the trust per case. Figure 33 shows the variation in implant costs within each trust for a standardised scoliosis construct. There is a three-fold variation in the price being paid across trusts.

Figure 33: Variation in costs, by trust, for a standardised scoliosis construct (16 screws, 2 rods and a crosslink)



Source: PPIB Tool

Later in this report we make a series of recommendations about procurement processes to ensure that trusts get better value from suppliers. These recommendations apply equally to the procurement paediatric implants.

8. New Models of Care

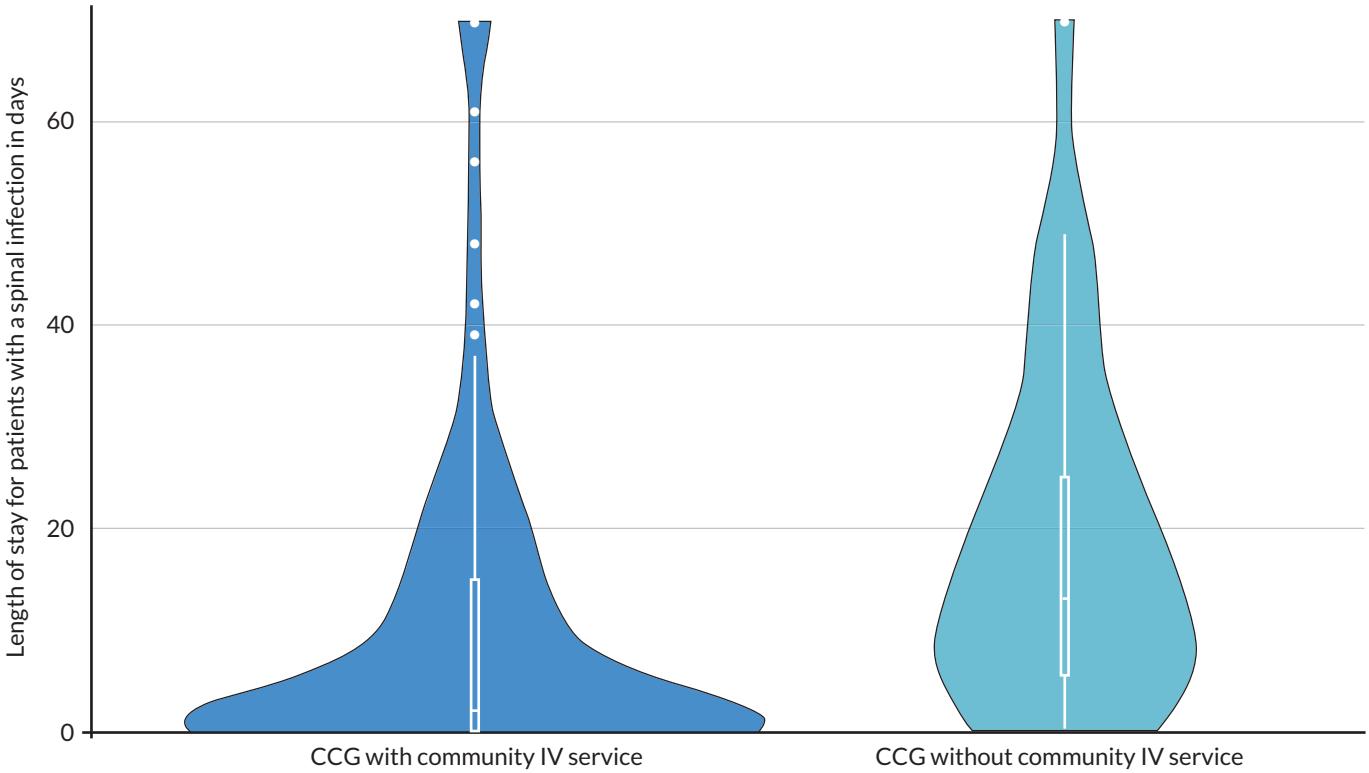
8.1 Vertebral Osteomyelitis/Infective Discitis

Most patients presenting with a case of spinal infection (osteomyelitis/infective discitis) will be treated non-operatively using intravenous (IV) antibiotics. Typically, antibiotics will be delivered over a long period of time – for 6 to 12 weeks.

In our visits, we found very different approaches to managing patients with non-iatrogenic spinal infection. In many parts of the NHS, individuals are managed in an acute hospital bed for the entire time they are receiving IV antibiotics. As well as taking up a significant number of acute bed days, it is well-recognised that prolonged hospital stays expose patients to other risks, such as hospital-acquired infections.

In some trusts, individuals are initially treated in an acute setting and then discharged to the care of a community IV team. These alternative models of care have a dramatic impact on length of stay. This has significant benefits to patients and is financially advantageous to the NHS. Figure 34 takes an example of patients treated at one trust with a catchment that principally covers two CCGs. One of the CCGs has a community IV service in place whilst the other does not. Figure 34 shows the distribution of inpatient length of stay for patients with spinal infection in the trust, split according to the patient's CCG of residence.

Figure 34: Case study of the distribution of inpatient length of stay for spinal infection, by CCG of residence (April 2016 to March 2018)

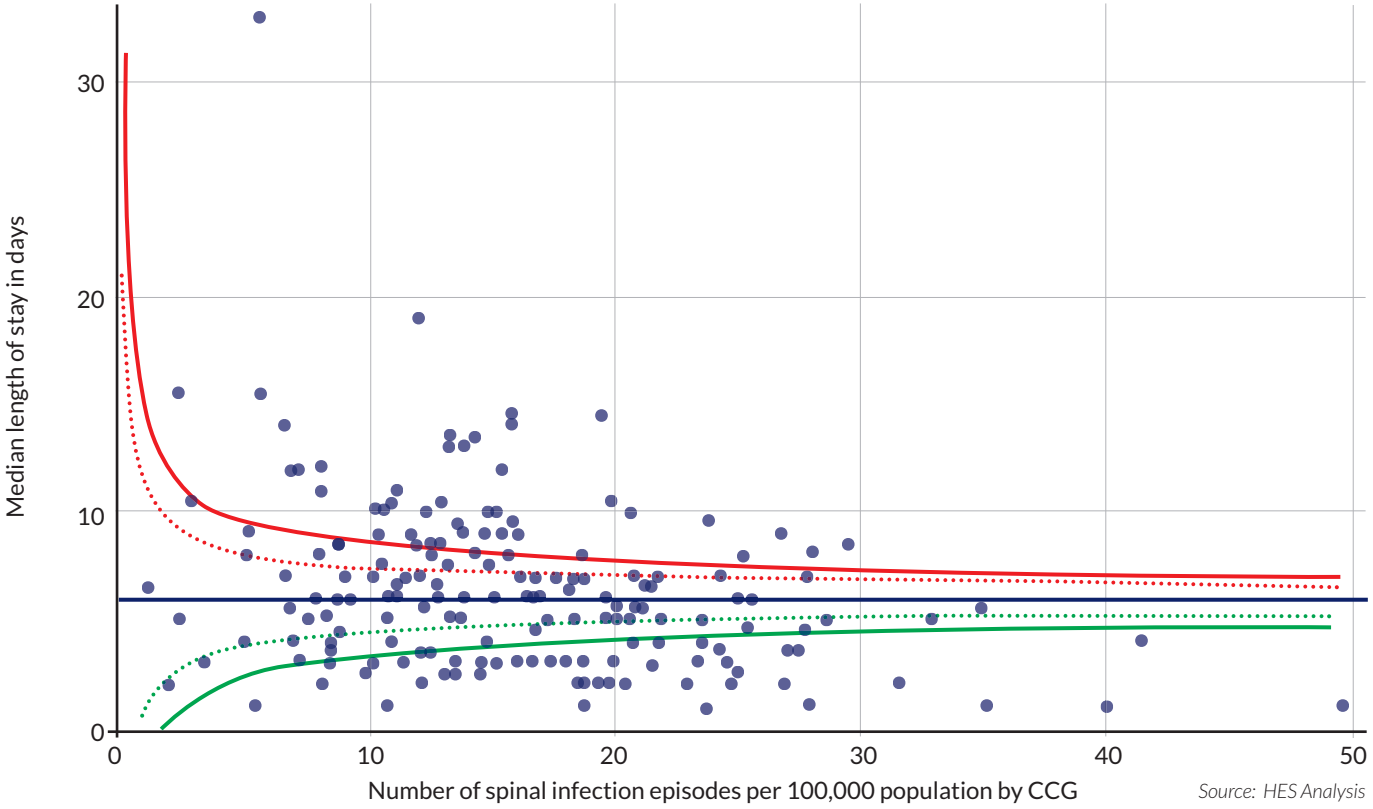


Source: HES Analysis

The median length of stay for patients is 2 days in the CCG with a community IV service, versus 13 in the CCG without the service. Looking nationally, there is wide variation in the median inpatient length of stay for patients with spinal infection.

Taking a national view, Figure 35 looks at the variation across all CCGs in the median length of stay for patients with a diagnosis of spinal infection. It shows wide variation. If trusts achieved the mean length of stay or better in 2017-18 (which is possible through the use of community IV services), it would have saved over 20,000 bed days, with a potential saving to the acute sector of £7.8m.

Figure 35: Variation in length of stay, by CCG, for patients with a diagnosis of spinal infection (April 2016 to March 2018)



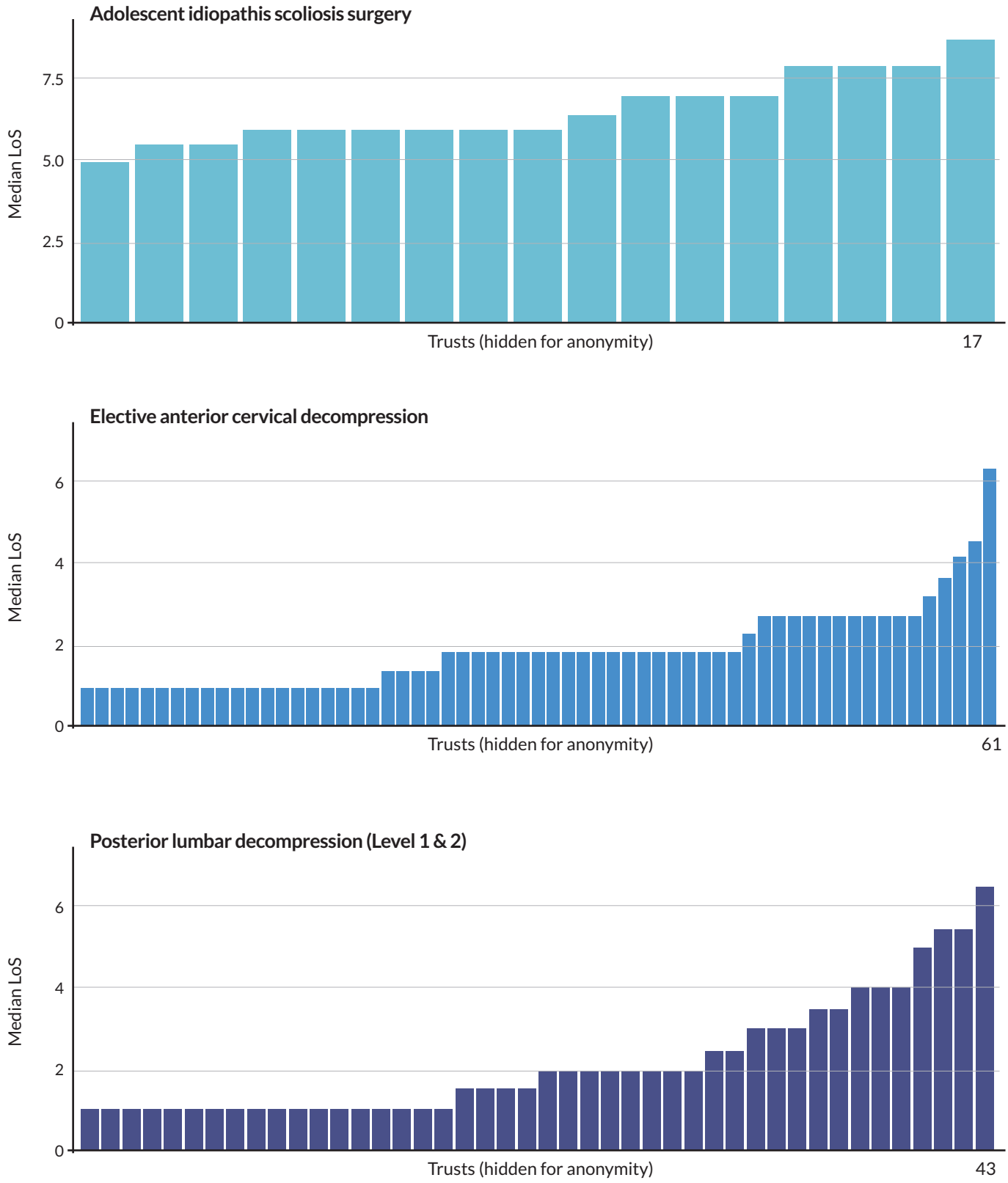
8.2 Supporting early discharge from elective spine surgery

This example of community intravenous antibiotic therapy for infection is typical of a range of measures that trusts across the country are taking to support early discharge from hospital and the management of patients in community settings.

The safe and expeditious return to home after spinal surgery is usually preferred by patients, generally improves outcomes (by getting patients mobile earlier) and makes the best use of scarce hospital resources. Data collected during our visits show wide variation in post-operative length of stay, suggesting some hospitals are more successful at supporting early discharge than others.

Figure 36 shows the variation nationally in the median length of stay by trust, for 3 surgical procedures – elective anterior cervical decompression and fusion, posterior lumbar decompression/discectomy (1 or 2 level), and adolescent idiopathic scoliosis.

Figure 36: Variation in median length of stay by trust for 3 specialist procedures (April 2016 - March 2018)



Source: HES analysis (excludes trusts with five or less cases and procedures with zero length of stay; one private provider excluded due to coding discrepancies)

Based on the variation described above, the inpatient bed day saving would be over 5,000 days per year if all trusts were able to bring their length of stay down to at least the mean average for the 3 procedures described, with a notional saving of £1.9m per year.

During our visits we met with several trusts that had made significant progress in reducing length of stay and implementing early discharge programmes. Box 4 summarises some recent changes at Taunton and Somerset NHS Foundation Trust, focused on the pathway for patients receiving single level lumbar spinal decompressions and discectomies. Their experience is that length of stay can be reduced through appropriate use of day case procedures, supporting early discharge and providing specific information to patients to help them plan for and manage their recovery out of hospital.

Box 4: Taunton and Somerset Day Case Discectomy Programme

Single level lumbar spinal decompressions and discectomies are regularly performed as day case procedures in Musgrove Park Hospital, Taunton. The procedures take place either in spinal theatres or in our day surgery unit and all patients follow the same pathway.

From the time that they are listed for these procedures, patients are constantly prepared and reminded at every contact by every team member they see that they will be mobile within 2-3 hours of surgery and will be encouraged and expected to go home in a further 3 hours as it is very safe. Patients are asked to identify at the time of the consent, their method of transport to and from hospital and post-operative care arrangements which are documented in their EPRs. They are given a Patient Passport that contains information that they might find relevant.

There is a standardised process for how patients are managed on the day of surgery:

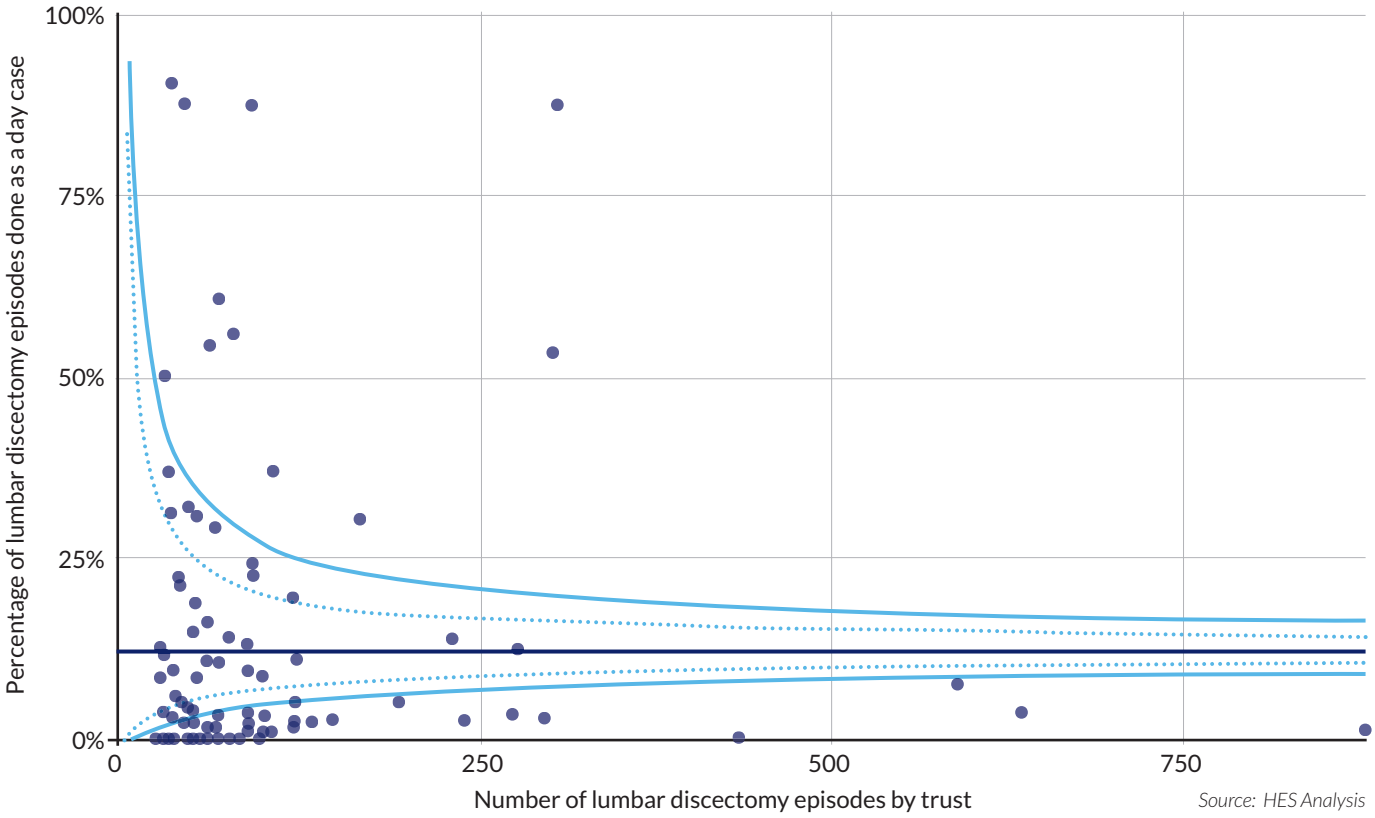
- Patients arrive at the Surgical Admissions Lounge (SAL) at 7:30am on the day of surgery and are reviewed by a member of the anesthetic and surgical teams. They will have previously signed a consent form during their last clinic visit.
- Anesthetic technique has been standardised.
- After surgery, patients return to the SAL and are discharged once they have passed urine and are mobilised with the help of the nursing staff or physiotherapists.
- A post-operative analgesia recipe designed by the anesthetists is used routinely for all patients.
- Discharge summaries are written by the operating surgeon immediately post-surgery and patients are followed up at 3 weeks in the post-operative physiotherapy clinic.

The Day Case Discectomy programme started in Dec 2013 as an Improvement Project and has had a dramatic impact on efficiency and patient satisfaction. Complication rates including recurrence, infection and readmission show no change when compared to rates pre-2013. Patient satisfaction rose almost immediately (from 75% to >95% by 2014) and has been sustained. The pathway is routinely followed by consultants.

The pathway is updated periodically. Since the last update (July 2016), 93% of patients were discharged within 23 hours of surgery.

A national view shows that there is significant scope for models similar to those described above to be applied more widely. As an example, Figure 37 looks at day case rates for lumbar discectomy across trusts, suggesting wide variation in their use across trusts.

Figure 37: Variation in day case rates across trusts, lumbar discectomy (April 2016 - March 2018)



Source: HES Analysis

Our recommendation is that the Society of British Neurological Surgeons (SBNS), the British Association of Spine Surgeons (BASS) and the British Scoliosis Society (BSS) be asked to develop guidance for trusts on best practice on the use of day case surgery and on developing and implementing early discharge programmes. As well as the broader benefits to patients, improvements in discharge planning have the potential to have significant NHS resource savings. For example, in the example of lumbar discectomy, we estimate that if trusts were able to meet the national average daycase rate, it could lead to an annual saving of £110,000. The principles discussed in the case studies have broader application beyond the procedures discussed in this report.

Recommendation	Actions	Timescale
15. SBNS, BASS and BSS asked to collate and disseminate evidence on best practice in reducing hospital length of stay and supporting early discharge	• SBNS, BASS and BSS asked to prepare guidance	For immediate action
	• Recommendations shared with providers and CCGs for implementation	September 2019

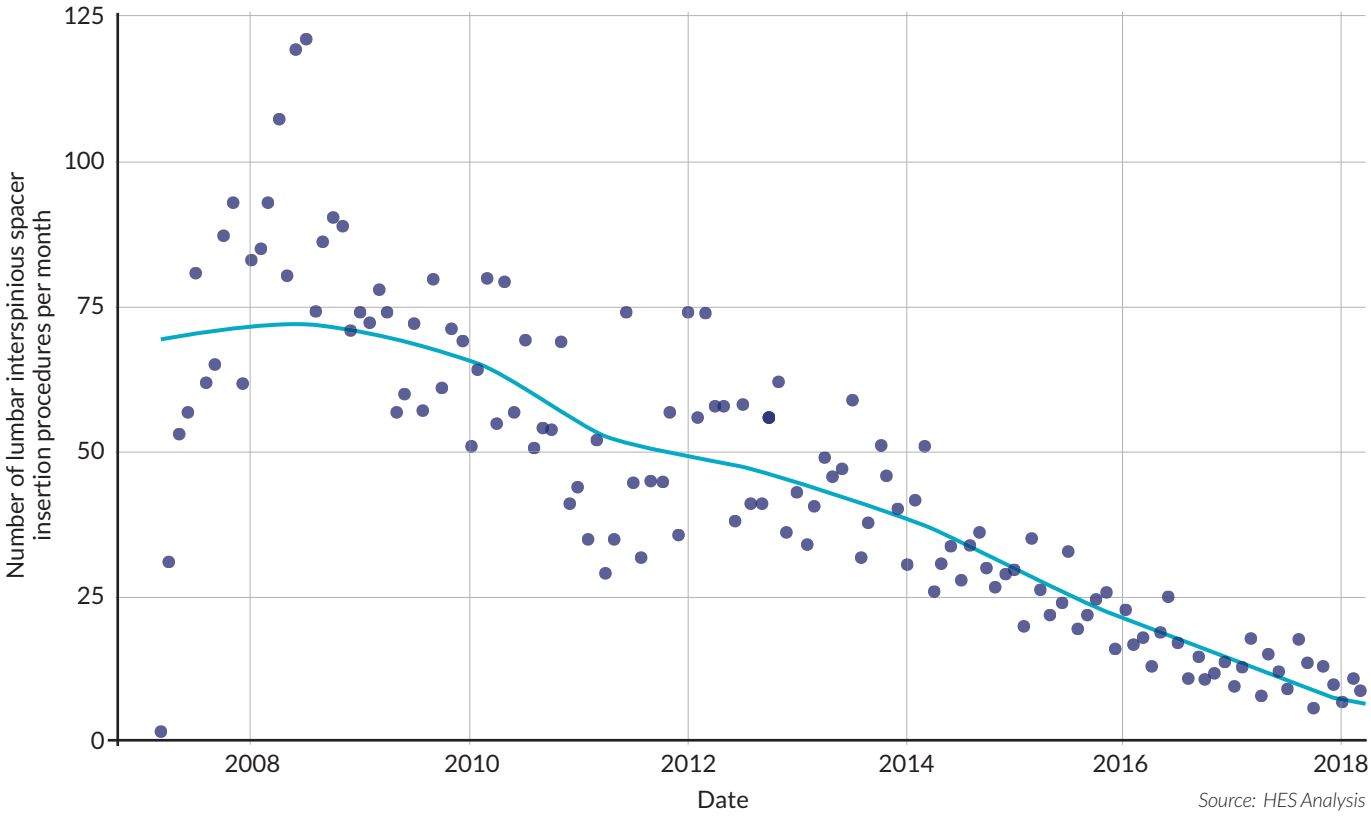
9. Spotting Failure Earlier

9.1 The use of new technologies

Spinal surgery in England is littered historically with enthusiastic use of new technology where emerging new evidence takes too long to feed through to changes in clinical practice because clinicians are not routinely recording and tracking activity and outcomes.

As an example, symptomatic lumbar canal stenosis is traditionally treated by making more room for the nerves without implants (a decompression). Lumbar interspinous spacers implants were introduced initially around 2005 as an alternative or adjunct to lumbar decompression and saw enthusiastic uptake in their use. Whilst the use of interspinous devices is still debated, current evidence indicates no superiority for mid- to long-term patient-reported outcomes for interspinous devices compared with traditional bony decompression. Reports of significantly higher reoperation rates and unfavourable cost-effectiveness compared to traditional decompression techniques have resulted in a decline in their use.[40, 41] Figure 38 demonstrates the volumes of insertion over time since 2007 in England in the NHS.

Figure 38: Lumbar Interspinous Spacer Insertions (per month, 2007-18)



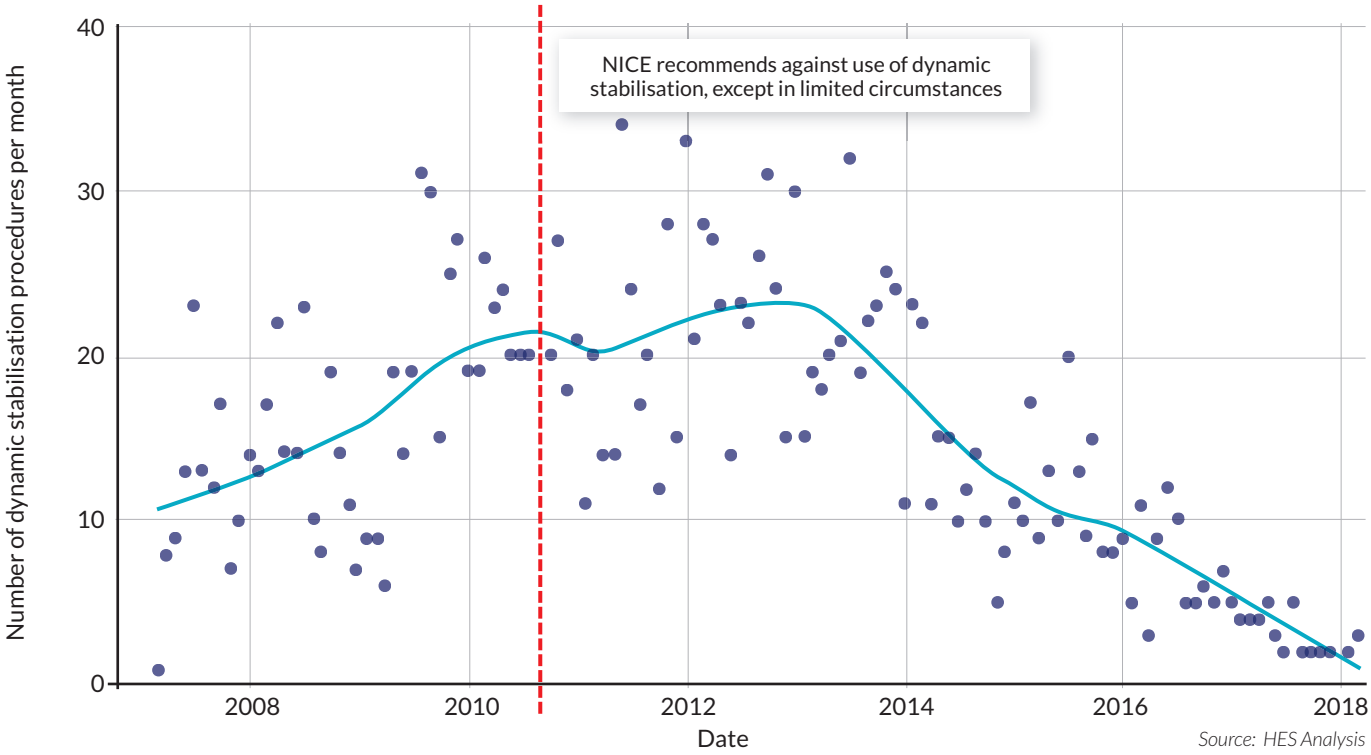
Source: HES Analysis

[40] *Phan K, Rao PJ, Ball JR, Mobbs RJ. Interspinous process spacers versus traditional decompression for lumbar spinal stenosis: systematic review and meta-analysis. Journal of Spine Surgery. 2016;2(1):31-40.*

[41] *Strömqvist BH, Berg S, Gerdhem P, Johnsson R, Möller A, Sahlstrand T, Soliman A, Tullberg T, X-stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year follow-up, Spine , 2013 Aug 1; 38(17):1436-42.*

Dynamic stabilisation of the spine is a procedure that provides support to the spine, whilst retaining some of the mobility of the spine. It was first used in the NHS around 2005 but NICE recommended against its use by the NHS, except in limited circumstances in 2010. Figure 39 demonstrates how their use has changed over the last decade, suggesting the sector was slow to respond to the NICE recommendation. In the last year (April 2017-March 18), this procedure was performed 43 times.

Figure 39: Number of Procedures of Dynamic Stabilisation of the Spine (per month, 2007-18)



Source: HES Analysis

The data collected for the trust-level reports show that there is wide variation in the use of implants across trusts and across clinicians. New innovations are being taken up at different rates and clinicians are often using different approaches to meet the same clinical objective.

Whilst variation is not necessarily an indicator of poor practice and may not necessarily have a negative impact on patient outcomes, clinical practice should be based on sound evidence and experience. In the case of spinal surgery, little information is available to assess the benefits or downsides of technologies because very little data is recorded on their use and the subsequent impact on patient outcomes.

Recent experience with Magnetic Expansion Control (MAGEC) rods is another a good example of an innovation that has significant potential to have a positive impact on quality of life, patient outcomes and costs. MAGEC rods are used in the management of early-onset scoliosis. They were made available for use in the NHS in 2009 and underwent NICE guidance on their use in 2014. Traditionally, patients with early-onset scoliosis were treated with growing rods that need to be lengthened as a child grows, with repeated surgery and the associated risks of complication. MAGEC rods include a magnetically driven linear actuator, which allows the rods to be lengthened without surgery, potentially avoiding the need for repeated operations.

NICE recommended the system for NHS use, and NHS England confirmed funding for children meeting treatment criteria,[42] and it has been widely adopted. It was designated that all patients with this novel device be tracked on The British Spine Registry. Since then, evidence has emerged suggesting that there are risks with the system in some groups of patients.[43,44] The MAGEC system may still be appropriate for many patients, and some reports have been published that highlight the benefits.[45]

[42] *www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/Non-Invasively-Lengthened-Spinal-Rods-for-Scoliosis.pdf*

[43] *Rushton PRP, Siddique I, Crawford R, Birch N, Gibson MJ & Hutton MJ, Magnetically controlled growing rods in the treatment of early-onset scoliosis, Bone Joint J. 2017;99-B:708–13*

[44] *Thakar C, Kieser DC, Mardare M, Haleem S, Fairbank J, Nnadi C, Systematic review of the complications associated with magnetically controlled growing rods for the treatment of early onset scoliosis, Eur Spine J. April 2018, pp 1 – 10*

[45] *See, for example, Nnadi et al, An NIHR-approved two-year observational study on magnetically controlled growth rods in the treatment of early onset scoliosis, Bone Joint J. 2018;100-B:507–15*

Others have questioned the overall benefits of the system, with concerns expressed regarding mechanism failure, metallosis, reoperation rates and the duration the device continues to distract after insertion.[46, 47]

This example illustrates the time taken to adopt and learn about the benefits and risks of new technologies, particularly for devices that individual surgeons may use infrequently. The MAGEC system has been available to the NHS for nearly 10 years, but only now are the risks and complications beginning to be understood. NHS England made it a mandatory requirement that patients treated with the MAGEC system be entered into the British Spine Registry (BSR), meaning data on the use of the system and associated outcomes and complications would be routinely recorded. But only 28% of cases receiving the system between April 2014 and March 2016 were entered into the BSR. Had compliance been greater, the surgical community would have a far better understanding of which patients benefited from its use and the rate of complication, allowing surgeons to adapt practice accordingly more swiftly.[48] Recent data suggest the NHS currently spends around £800,000 per year on the MAGEC system.

Given the rate of innovation in spinal implants, it is critical that good information and evidence is collected and made available to inform best practice and support the appropriate diffusion of new technologies. There are numerous examples across the spinal surgery.

The British Spine Registry (BSR) already provides an infrastructure for this data to be collected. The current position, however, is that clinicians and trusts are not yet recording data consistently and comprehensively in the BSR. This is despite it being a contractual requirement of work performed under the specialised services contract and it being a condition of CQUIN payments. Table 2 shows the proportion of activity recorded in the BSR by procedure group compared to activity recorded in the Hospital Episodes Statistics (HES) database. Given that HES is a complete record of NHS-funded activity, this gives a measure of the amount of activity that is undertaken but not recoded in the BSR. Whilst reporting appears to be improving across the time periods shown, the vast majority of activity is still going unrecorded in the BSR, meaning that important information about clinical practice and outcomes is neither reported nor available to inform future provision.

Table 2: Comparison of Reporting Compliance in the British Spine Registry (activity recorded in BSR as % of activity recorded in HES, by Procedure Group)

Spinal Procedure Group	**Activity recorded in BSR as % of activity recorded in HES**	
	Apr 2013-Mar 2015	**Apr 2015-Mar 2017**
Spinal tumour surgery	6.5%	13.0%
Intradural surgery	14.9%	6.2%
Cervical-thoracic surgery	5.0%	12.4%
Lumbar surgery	22.6%	26.0%
Fracture surgery	6.9%	10.6%
Deformity correction surgery	15.7%	32.6%

Source: Analysis of HES and BSR

[46] *Joyce TJ, Smith SL, Rushton PRP, Bowey A, Gibson MJ. Analysis of explanted magnetically controlled growing rods from 7 UK spinal centers. Spine, 2017;43:E16-22*

[47] *Teoh KH, Winson DMG, James SH, Jones A, Howes J, Davies PR, Ahuja S, Do magnetic growing rods have lower complication rates compared to conventional growing rods?, The Spine Journal (2016)*

[48] *www.beyondcompliance.org.uk*

Given the rate of innovation in the sector, there are opportunities to collect and use evidence much more comprehensively and consistently so that we learn more quickly what works and identify poor innovation more easily. The BSR provides an opportunity to do this and we are recommending that clinicians be required to record data of all spinal surgical activity on the BSR so that comprehensive data are collected and outcomes can be tracked. Clinicians should be given administrative support by trusts to ensure this happens.

Alongside this, we are recommending that spine surgery should learn from experience in orthopaedics and introduce the Beyond Compliance programme. Implant manufacturers can choose to include their products in this programme, which has the following five elements:

i. **Advisory Group:** The Beyond Compliance Advisory Group provides initial advice to manufacturers on the level of risk exhibited by the device. This is used to agree the rate at which a product should be introduced to the market, which may be limited for implants that are regarded as high risk. Appendix D provides more detail on the risk assessment framework that is used. At this stage, a Rapporteur is also appointed, who acts as an independent assessor for the implant.

ii. Patient Consent: Surgeons are required to capture explicit consent from patients for whom they intend to use a product. This allows data to be captured and used by the Beyond Compliance service.

iii. **Data Collection:** Beyond Compliance builds on data collected by the National Joint Registry, using its own secure on-line surveillance system.

iv. **Reporting and Independent Scrutiny:** Data collected is analysed to assess the performance and outcomes of products. This assessment is available to the manufacture and implanting surgeons only. The nominated Rapporteur meets regularly with manufacturers to provide ongoing scrutiny of product performance and review guidance regarding the rate of introduction of a product to the market.

v. **Explants:** Where an implant has to be removed, it can be retrieved and forensically examined to give additional information about a product's performance.

The aim of the programme is to support controlled introduction of implants into the market and to strengthen post-marketing surveillance, using independent experts to provide advice on the performance of a product.

Recommendation	Actions	Timescale
16. All spinal surgical interventions to be recorded on the British Spine Registry	• NHSE to implement best practice tariff for providers that comply with this recommendation	By April 2019
	• Trusts target set at 50% for the introduction in 2019/20 Tariff. Target increased over time (to 80%).	From April 2020
	• Trusts to provide necessary administrative support and ensure compliance with this requirement	Ongoing
17. Implement a range of specific measures to ensure that spinal surgery implants are introduced and adopted in line with emerging evidence and best practice, and that comprehensive data is collected to support appropriate dissemination.	• Spinal implants to join the Beyond Compliance service already available for hip and knee implants. www.beyondcompliance.org.uk	By April 2019
	• Novel implants to be introduced in a fully audited and controlled manner by the National Institute of Health Research	By April 2020

9.2 Iatrogenic infections

Iatrogenic infections following spinal surgery are both costly and have a significant impact on patient experience and quality of life.

Public Health England is responsible for running the national surgical site infection (SSI) surveillance service. This service covers England and is used by NHS and independent sector hospitals to monitor and benchmark rates of post-surgical infection. This information is used to review or change practice as necessary with quarterly assessment and alerting of increases in rates embedded within the programme.

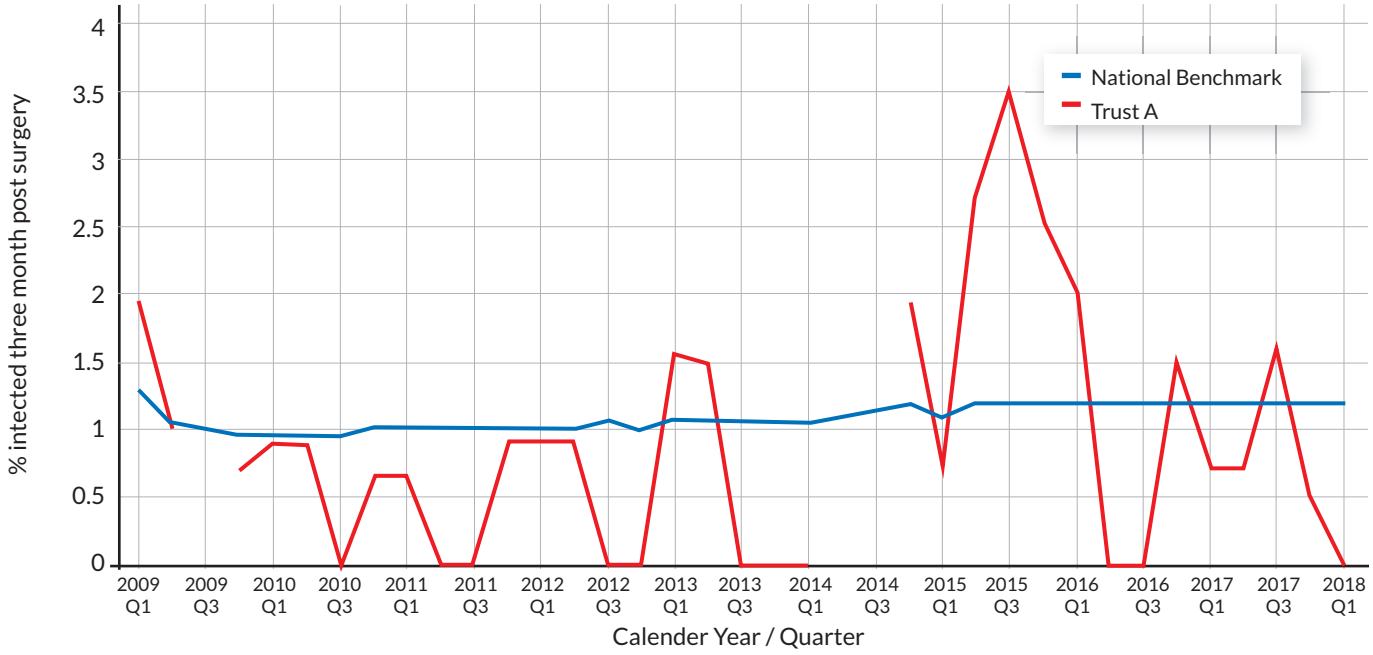
Currently, there is mandatory SSI surveillance in four surgical procedures - hip replacements, knee replacements, repair of neck of femur, and reduction of long bone fracture. SSI is voluntary for a further 13 categories of surgical procedures, including spinal surgery.

In our pre-visit questionnaires, very few trusts (20%) were able to provide data on their surgical site infection rates for spinal surgery. Data from Public Health England suggests that only 25 NHS providers that undertake spinal surgery are submitting data to the SSI surveillance service (compared to 192 providers undertaking hip prosthesis and 181 providers undertaking knee prosthesis).[49]

This suggests that the majority of trusts undertaking spinal surgery are not routinely monitoring their post-surgical infections rates and do not have a robust indication of how their rates compare to other providers. It further suggests that the majority of trusts may not be taking consistent action to deal with higher than expected infection rates.

This also poses a difficulty for trusts that do monitor their infection rates. As a result of the fact that most trusts are not submitting data to the PHE SSI surveillance service, trusts that do submit data are comparing their SSI rates against a self-selected sample who by virtue of their participation may have reduced their infection rates over time.[50] However, participation in surveillance also facilitates internal comparison and the identification of changes in SSI risk. Figure 40 gives an example from one trust we visited (Trust A), comparing their SSI rate for spinal surgery against the (limited) benchmark contained within Public Health England's data. Through participating in the PHE surveillance, Trust A saw a jump in its infection rate for one quarter (Q3 2015) and took immediate action to audit and review practice, with positive effects.

Figure 40: Example benchmark of trust surgical site surgery infection for spinal surgery rate versus peer average (spinal surgery inpatient/readmission due to SSI, % infected 3 months post-surgery)



Source: Public Health England. (Note that there are some quarters where data are missing)

[49] *Source: Public Health England, Surveillance of surgical site infections in NHS hospitals in England, April 2016 to March 2017*

[50] *Abbas M et al Impact of participation in a surgical site infection surveillance network: results from a large international cohort study, The Journal of Hospital Infection, 2018.12.003*

Whilst the trust was able to identify and address a rise in infection, the interpretation of these data would have been stronger with a more robust national benchmark because:

- the national benchmark may not be representative of all trusts because current participation rates are low;
- there is insufficient data to assess statistically significant changes in rates; and
- low participation rates make it hard to control for case mix (which is likely to be a significant driver of variations in SSIs for spinal surgery).

SSIs are a serious adverse event and there are well-established processes for monitoring rates, auditing practice and taking actions, which are being more routinely applied in other surgical specialties. Given the limited data for spinal surgery, it is hard to judge the level of variation in SSIs and the actions that should be taken, but there is a real possibility that avoidable SSI risk is going unnoticed. We are therefore recommending that it becomes mandatory for trusts to participate in the PHE surgical site infection surveillance. Our proposal, for further discussion during implementation, is that this should cover:

- single level posterior lumbar discectomy and decompression (unilateral and bilateral);
- single level posterior lumbar fusion (including interbody fusion);
- posterior correction of adolescent idiopathic scoliosis; and
- posterior cervical spine decompression with or without instrumentation.

Recommendation	Actions	Timescale
18. Mandatory requirement for trusts to participate in Public Health England's surveillance of SSI post-spinal surgery	• GIRFT and Public Health England to cost and burden-assess increase in data collection, with a view to subsequent national communication of mandatory requirement for collection. This may consider needs in other GIRFT workstreams	For immediate action
	• GIRFT to work with national bodies to consider any compliance mechanisms relevant	For completion following first action

10. Training

The GIRFT data have demonstrated significant variation in the management of patients with spinal conditions. This may well be in part due to variation in training and exposure to certain subtypes of spinal surgery. As an example, 75% of anterior cervical surgery is performed by neurosurgical units, 75% of posterior lumbar fusion is performed by orthopaedic spine surgeons, the number of posterior decompressions is split equally. Furthermore, the range of spinal interventions and the rate of innovation in this sector in managing spinal problems is such that having this sub-speciality under two generic umbrellas (Orthopaedics and Neurosurgery) has now become outdated.

There is a need for spinal surgical training to become standardised. Both specialities have much to learn of each other and exposure to both specialities' expertise in training programmes as they exist at present is limited.

The first steps in this would be standardising exposure to the management of spinal conditions around the country. The Spinal Training Interface Group (STIG) group is the first steps towards this. It has proposed spinal fellowship posts with standardised curriculum across both specialities and has the support of the professional societies. These are yet to gain funding.

Our visits also identified areas where doctors would benefit from continuous professional development activities related to spinal services. For example, trusts need to regularly educate doctors from most specialities to consider spinal infection. There are too many cases of paralysis due to delayed diagnosis of spinal infection which have enormous patient and cost implications.

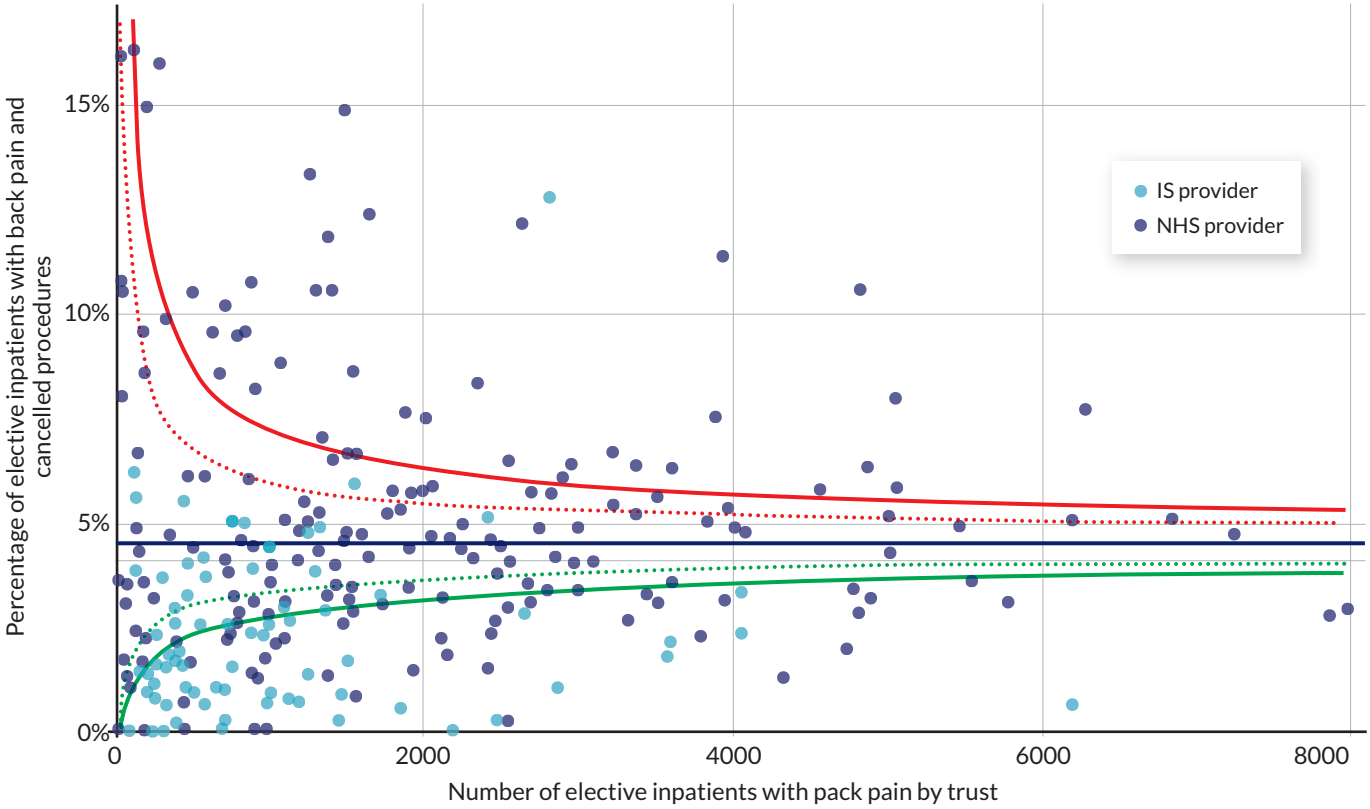
Recommendation	Actions	Timescale
19. Training across the spinal specialties and within trusts to be strengthened by funding the Spinal Training Interface Groups and reviewing the ongoing training provided by trusts in relation to spinal services	• Health Education England to implement the Spinal Training Interface Group	July 2019
	• BASS to identify core elements of spinal services and the presentation of spinal conditions that trusts need to educate doctors about on a regular basis	July 2019
	• Trusts to implement core training alongside other Continuous Professional Development activities. Recommendation also applies to non-spinal partner hospitals who also see spinal patients	Ongoing

11. Independent Sector Providers

Independent Sector (IS) providers are a significant contributor to the provision of spinal care in England. They account for 9% (by volume) of total NHS-funded spinal activity in secondary care and 16% of total spinal surgery activity.

Without IS provider capacity, the transfer of activity back to NHS providers would put additional pressures on acute trusts. Data suggest that IS provider have relatively low cancellation rates for surgery, relative to NHS providers (shown in Figure 41), which is typically thought to be because IS providers, in the majority of cases, are not involved in emergency spinal care or operations/patients requiring HDU/ICU provision alongside their elective workload.

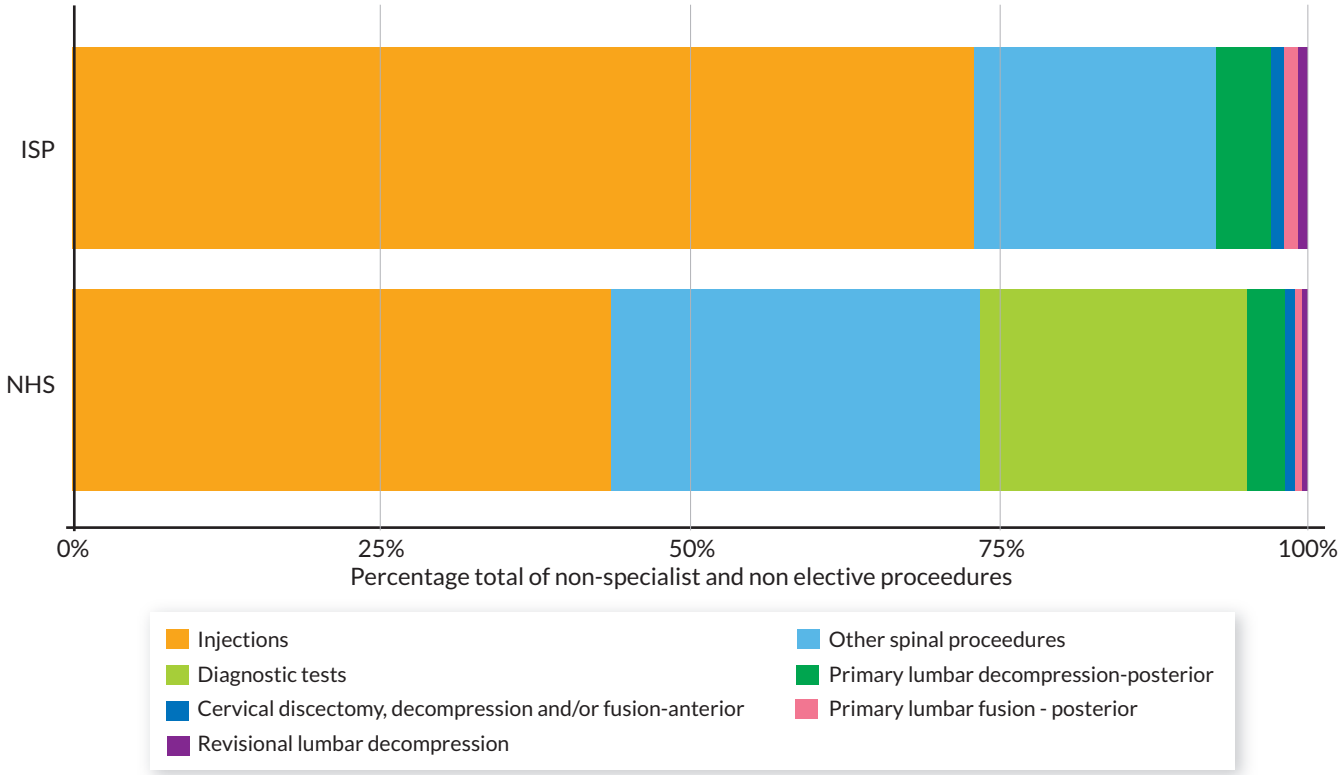
Figure 41: Cancellation rates for patients admitted as elective inpatients for back pain (April 2016-March 2018)



Source: HES analysis. Excludes all trusts with twenty or less cases

Data suggest that the mix of activity undertaken by IS providers is very different to NHS trusts. Figure 42 compares the mix of spinal procedural activity between IS providers and NHS trusts, excluding non-elective and specialist activity (which should not be undertaken by IS providers). It shows, for example, that IS providers are more likely to undertake epidural and facet joint injections than NHS trusts, despite current NICE guidance recommending against their use because of limited clinical value. A suggested explanation at deep dive visits was that patients being referred to IS providers are not placed on the same triage pathways as patients attending NHS trusts.

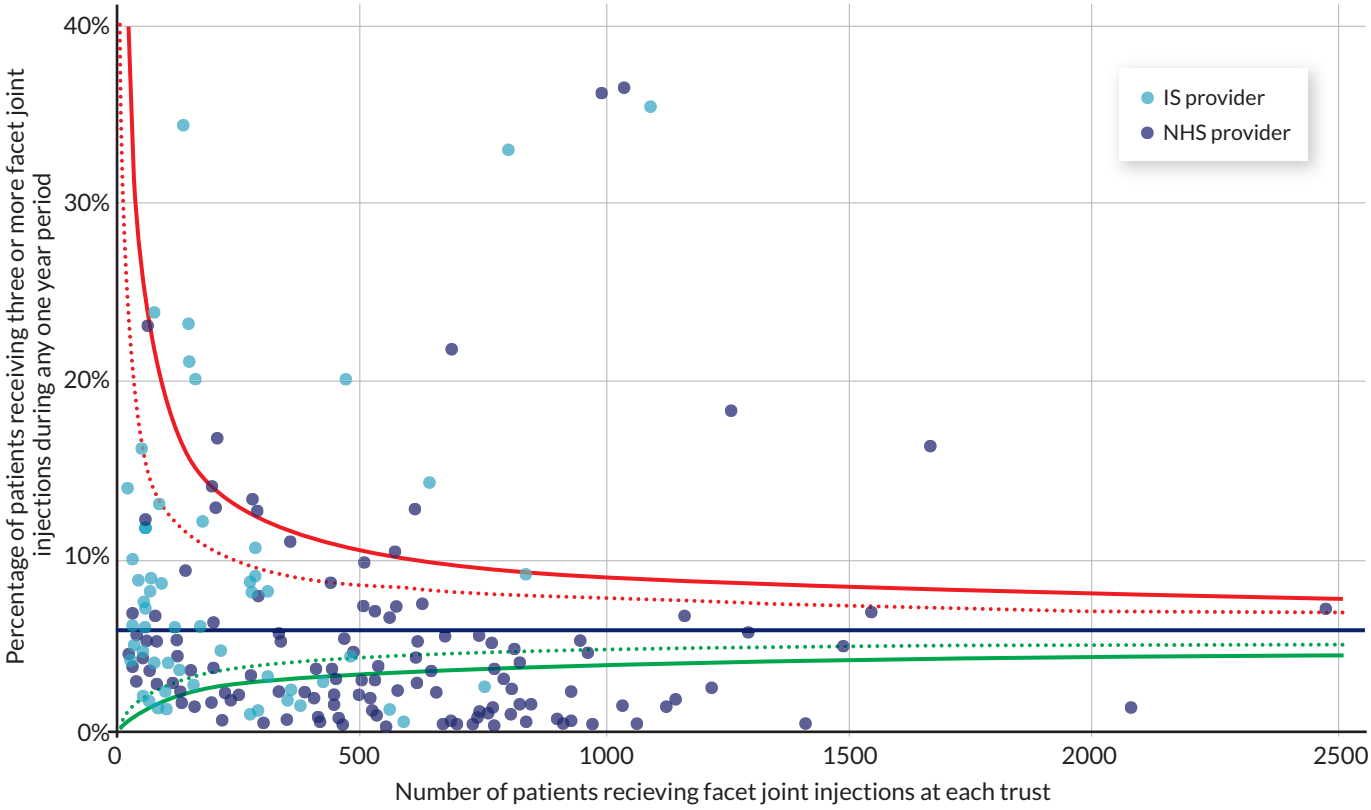
Figure 42: Comparison of activity between NHS trusts and IS providers, excluding specialist and non-elective activity (April 2016-March 2018)



Source: HES analysis. Note that "other" includes any procedures that are less than 1% of total non-specialist activity.

In addition, data suggest that IS providers are more likely, relative to NHS trusts, to be undertaking repeat facet joint injections. Figure 43 shows the number of patients receiving facet joint injections, by NHS trust and IS provider, and the proportion of those that receive three or more injections within a 12-month period. Across NHS provider, the average proportion receiving repeated injections is 4.3%, compared to 11% for IS providers. The evidence and guidance suggest this rate should be zero.

Figure 43: Number of patients with three or more facet joint injections within 12 months, by trust (April 2015 - March 2018)



Source: HES Analysis. The denominator is the number of patients receiving at least one facet joint injection in April 2015 to March 2017. The numerator allows an extra year of data to search for repeats April 2015 to March 2018. Excludes all trusts with twenty or less cases.

To address the variations in the mix of activity and differences in clinical practice between IS providers and NHS trusts, our recommendation is that IS providers should be formally brought within the governance arrangements of the Regional Spinal Networks. The aim is that this will help ensure that established best practice pathways of care are applied evenly across NHS and IS providers, and that patients receive consistent standards of care regardless of which referral route they choose.

Our early recommendation about use of the national back and radicular pain pathway applies equally to NHS and IS providers.

Recommendation	Actions	Timescale
Recommendation 8 applies: IS providers are made part of the Regional Spinal Networks	• CCGs to ensure inclusion of IS providers within their Regional Spinal Networks	April 2019
	• Failure of an IS providers to actively participate reported by the RSN Network Board to the local CCG, to take appropriate action	Ongoing

12. Litigation

The data indicate that the costs of, and risks associated with, litigation in spinal surgery are greater now than they ever have been in the past. NHS Resolution data suggests claims related to spinal surgery average over £100m per year, whilst the largest UK medical defence organisation (the Medical Defence Union) has decided to withdraw cover for spinal surgeons working in the private sector.

Following a review of recent claims, there is an emerging consensus that the number and size of claims can be reduced through a more consistent and rigorous approach to the inclusion of patients in the decision-making process about their treatment, together with adhering to best practice to obtaining consent. This has been a long-standing recommendation of the BASS, and forms the core of our recommendations, set out below. There are also opportunities to strengthen how trusts engage staff and learn from past claims.

Table 4 shows the latest data from NHS Resolution related to medical negligence claims against spinal surgery over the last 5 years. There are around 200 claims per year and in the last year for which data are available (2016/17), the estimated aggregate cost of claims was £135m (averaging almost £650,000 per claim).

Table 4: Volume and cost of medical negligence claims against spinal surgery notified to NHS Resolution 2012/13 to 2016/17 (claims identified from those coded to neurosurgery or trauma & orthopaedic surgery)

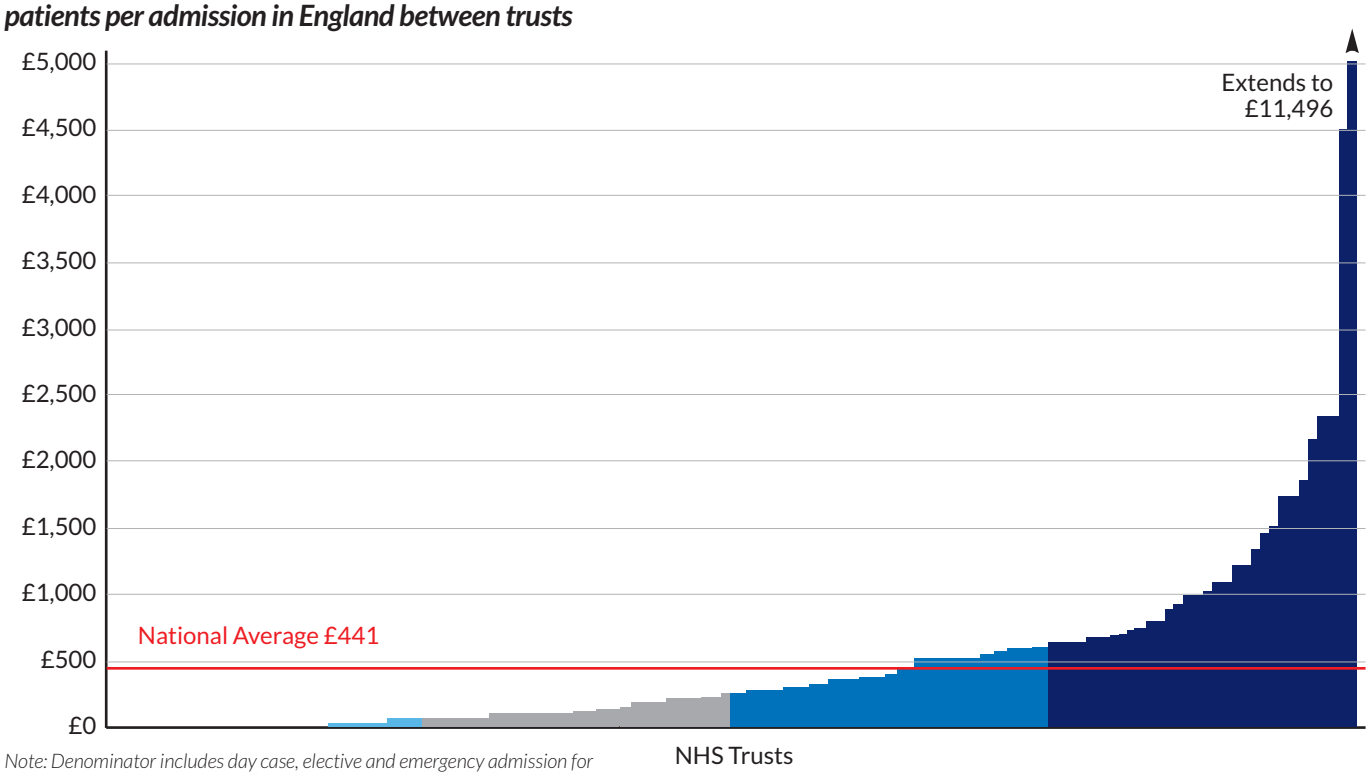
Year	No. of claims	% change in Claims No.	Total costs (£m) (including estimated and reserve values	% change in Total costs
2012/13	188	-	£112.2m	-
2013/14	196	4.3%	£95.4m	-15.0%
2014/15	190	-3.1%	£102.4m	7.4%
2015/16	195	2.6%	£90.4m	-11.8%
2016/17	209	7.2%	£135.1m	49.5%
Total (2012/13-16/17)	**978**	**-**	**£535.5m**	**-**

Source data: NHS Resolution 2012/13 to 2016/17

These aggregated data mask wide variation. The cost of claims varies depending on the procedures being performed, the age of the patient and the trust or surgeon performing the procedure. For example, the average estimated litigation cost per spinal surgery (including procedures for back and radicular pain), per admission in adults, is estimated to be £441. This increases to £1,102 in respect of claims for those aged 0-18 years. Damages awarded to younger patients tend to be higher due to the fact that the impact of the negligence has greater impact on their future life (taking into account life expectancy and the impact on the cost of care and treatment).

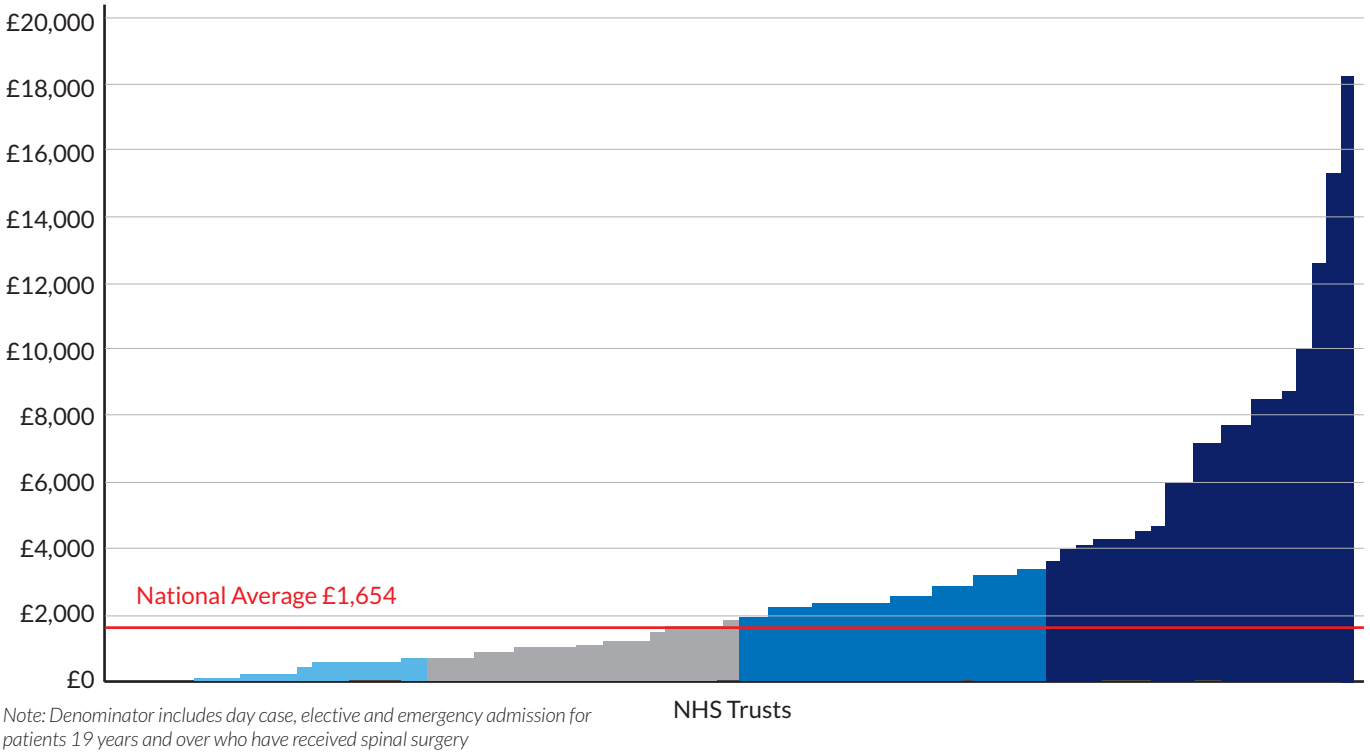
Figures 44 to Figure 47 demonstrate how the cost of claims varies across trusts and by procedure. They show the average cost of claims per admission for patients undergoing spinal surgery, with separate data for patients receiving spinal surgery or a procedure for back or radicular pain. The data are presented separately for adults and children. Many trusts have no or very low claims, but others have claims that are 5 or 10 times the mean cost per admission. For example, the average claim per admission in paediatrics for spinal surgery or a procedure for back or radicular pain ranges from £0 to £9,804 per admission, with an average of £1,102. If low risk activity such as injections are excluded (because they rarely contribute to litigation), the variation increases to £0 to £12,917.

Figure 44: Variation in estimated litigation costs for spinal surgery or procedure for back or radicular pain in adult patients per admission in England between trusts



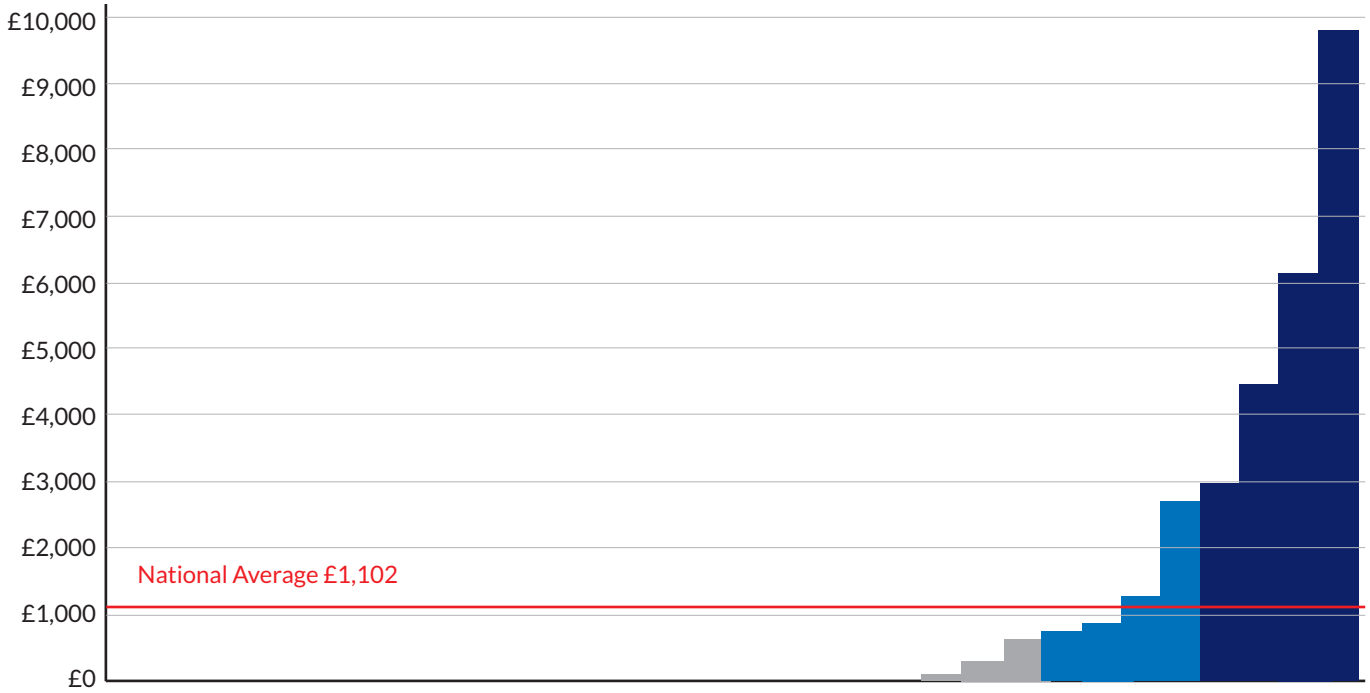
Note: Denominator includes day case, elective and emergency admission for patients 19 years and over who have received spinal surgery or a procedure for back or radicular pain

Figure 45: Variation in estimated litigation costs for spinal surgery in adult patients per admission in England between trusts



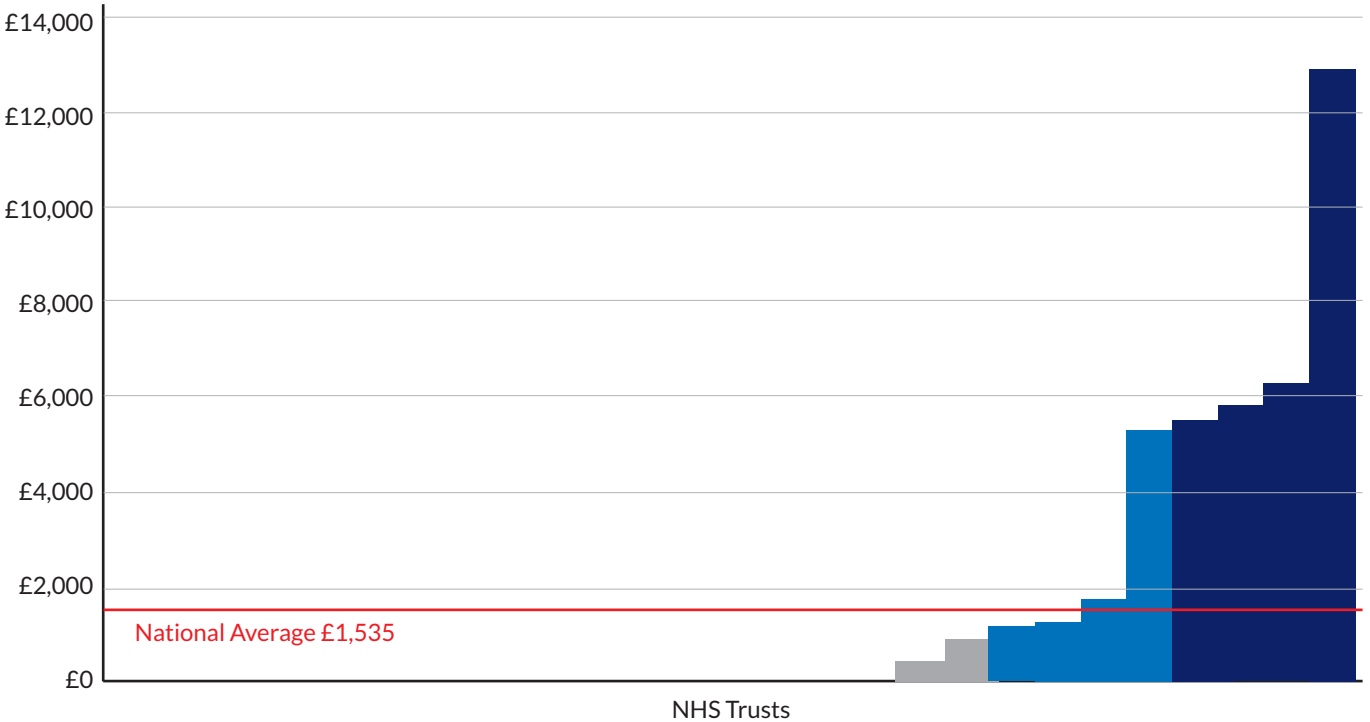
Note: Denominator includes day case, elective and emergency admission for patients 19 years and over who have received spinal surgery

Figure 46: Variation in estimated litigation costs for spinal surgery or procedure for back or radicular pain in children per admission in England between trusts



Denominator includes day case, elective and emergency admission for patients 0-18 years who have received spinal surgery or a procedure for back or radicular pain

Figure 47: Variation in estimated litigation costs for spinal surgery in children per admission in England between trusts



Notes: Denominator includes day case, elective and emergency admission for patients 0-18 years who have received spinal surgery

It was clear during GIRFT visits that many providers had little knowledge of the claims against them. Therefore, very few lessons have been learnt from the claims to inform future practice. Ensuring that clinical staff can learn from claims in conjunction with learning from complaints, severe untoward incidents (SUIs) and inquests, is likely to lead to improved patient care. It will also reduce costs, both in terms of litigation itself and the management of the resulting complications of potential incidents.

The most common causes for claims in spinal surgery between 2012/13 and 2016/17were:[51]

- 'judgement/timing' (512 claims (52.4%));
- 'interpretation of results/clinical picture' (255 claims (26.1%));
- 'unsatisfactory outcome to surgery' (192 claims (19.6%));
- 'fail to warn/informed consent' (80 claims (8.1%)); and
- 'never events' including 'wrong site surgery', or 'retained instrument post-operation' (26 claims (2.7%)).

The impact of informed consent on surgical claims is more significant than the 80 claims which were directly identified. Lack of fully informed consent has played a role in many of the claims which were attributed to 'unsatisfactory outcome of surgery'. Many of these claims are potentially avoidable through an adequate consent process in which an informed patient is involved in shared decision making.

BASS was one of the first national bodies to set out guidance as to how to achieve satisfactory consent. The "three-legged stool" model describes three components which are necessary to achieve fully informed consent. All three must be present as any in isolation are insufficient. The three components are:

- the provision of information booklets, written and illustrated at a level at which a reasonable patient can comprehend;
- patient-centered dialogue that covers the risks of the proposed treatment that a patient would need and want to know; and
- the use of a specific procedure and surgeon-guided consent form, along with the NHS or individual hospital form. The surgeon should also gain consent for surgical outcome data to be sent to the national registry.

The BASS guidance also suggests that consent should be obtained in "consent clinics", which take place 2 to 4 weeks prior to proposed surgery.

A more detailed analysis of the recent claims data (for 2014/15 -15/16) suggests that the most prevalent pathologies involved in claims were: iatrogenic nerve damage (23%), CES (23%), inadequate decompression (16%), iatrogenic cord damage (13%), and infection (9%).

CES is a significant cause for litigation in spinal surgery, both in terms of cost and claim volume. The projected value for all CES related claims is £68m for this period (24% of the total projected cost). Delay or failure of diagnosis was the most common factor cited (58 claims, 44%), followed by delay or failure in treatment (22 claims, 17%). 17 claims (13%) specifically refer to failures in obtaining a MRI scan, and 10 claims (8%) detail issues in referral or transfer. The standard of surgical procedures to treat CES was raised in 8 claims (6%). A further clinical analysis found that 57% of patients involved in litigation relating to CES had symptoms of incomplete or complete CES at first presentation. A further 39% were identified as having bilateral radiculopathy.

It is clear from the data on litigation that greater awareness of the drivers of litigation, as well as adherence to existing policies, guidance and best practice, could go a long way to improving patient care and managing litigation costs. For example:

- BASS sets out clear guidelines covering the diagnosis of CES, as well as the provision for timely MRI scan and specialist transfer for emergency decompression. The analysis summarised here, showing how delay can drive subsequent litigation, highlights the importance of local adherence to this guidance;
- 'never events', which include the retained instruments post operation and 'wrong site surgery', represent a system failure and patient safety issues. They can be eradicated by more diligent organisation and closer adherence to tools including the World Health Organisation checklist;
- improved training will help to address claims related to experience and decision-making, such as issues around judgement and timing;
- there is evidence that some claims could not be effectively defended because the provider lacked the documentary evidence to demonstrate either that the correct processes had been followed, the material risks explained, or the patient's specific interests considered in the context of the available treatment options; and
- through reviewing claims with clinicians, we have become aware of a minority of expert witnesses who have given medicolegal opinions on behalf of claimants in a particular field of spinal surgery which they are not qualified to provide such opinions (based on an assessment of their clinical practice).

[51] *Note that percentages do not sum to 100 because some claims may list more than one cause.*

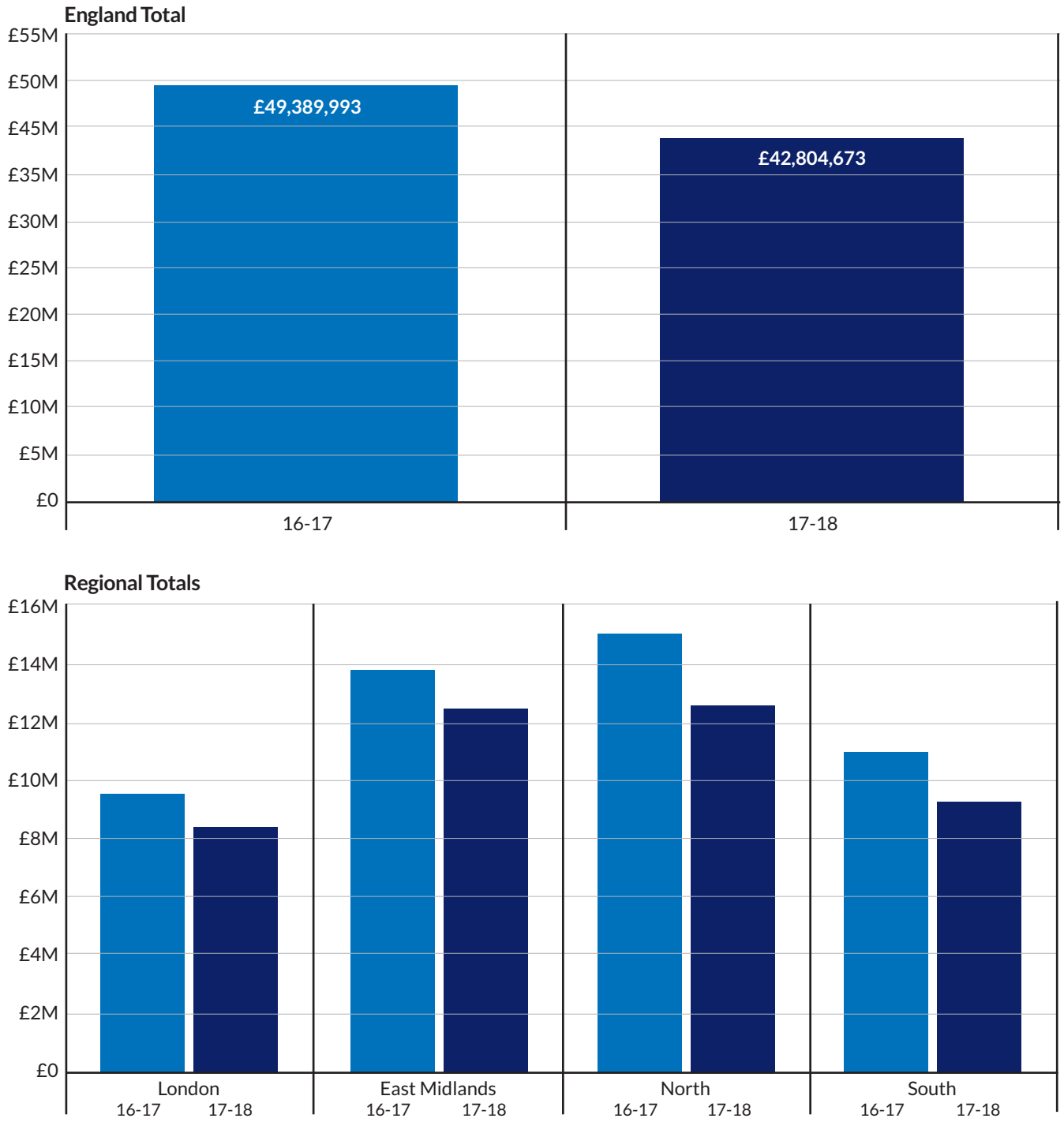
Recommendation	Actions	Timescale
20. Urgently implement measures to reduce litigation costs by applying GIRFT's five-point plan, adopting best-practice consenting processes, and adhering to guidance on the management of suspected CES	Reduce litigation costs by application of the GIRFT Programme's five-point plan.	
	• Trusts to assess their benchmarked position compared to the national average when reviewing the estimated litigation cost per activity. Trusts will have received an updated version of this for spinal surgery including variation charts for surgery and pain modulation and spinal surgery alone for both adults and children in the GIRFT 'Litigation in surgical specialties data pack', December 2017	For immediate action
	• Clinicians and trust management to discuss with the legal department or claims handler the claims submitted to NHS Resolution included in the data set to confirm correct coding to that department. Inform NHS Resolution of any claims which are not coded correctly to the appropriate specialty via CNST.Helpline@resolution.nhs.uk	Upon completion of A
	• Once claims have been verified clinicians and trust management to review claims in detail including expert witness statements, panel firm reports and counsel advice as well as medical records to determine where patient care or documentation could be improved. If the legal department or claims handler needs additional assistance with this, each trusts panel firm should be able to provide support	Upon completion of B
	• Claims should be triangulated with learning themes from complaints, inquests and serious untoward incidents (SUI) and where a claim has not already been reviewed as SUI we would recommend that this is carried out to ensure no opportunity for learning is missed	Upon completion of C
	• Where trusts are outside the top quartile of trusts for litigation costs per activity, GIRFT national clinical leads and regional hub directors will support trusts in the steps taken to learn from claims. They will also be able to share with trusts examples of good practice where it would be of benefit.	For continual action throughout GIRFT programme
	Reduce litigation claims volume and cost related to consent and dissatisfaction with surgery due to lack of informed consent.	
	• Trusts to ensure that all centres performing spinal surgery to implement the BASS 'three-legged stool' model for spinal informed consent. For elective surgery, this should occur in advance of the day of surgery to allow a 'cooling off' period	Immediate
	– The provision of information booklets, written and illustrated at a level at which a reasonable patient can comprehend.	Immediate
	– 'Patient-centered' dialogue including the risks of the proposed treatment, about which a reasonable patient, in this patient's position, would need and want to know. This should also encompass a discussion of alternative treatment options, so that there is informed and shared decision-making.	Immediate
	– Specific procedure, and surgeon-guided consent form, along with the NHS or individual hospital form. The surgeon should also gain consent for surgical outcome data to be sent to the national registry.	Immediate
	Reduce litigation claim volume and cost for CES by adherence to existing guidance.	
	• Trusts to follow the BASS/SBNS guidelines covering the diagnosis of CES, the provision for timely MRI scan and specialist transfer for emergency decompression.	Immediate
	• BASS/BSS/SBNS/GIRFT to set up a working group to provide standards expected of an expert witness	Immediate

13. Procurement

13.1 Trends in Expenditure on Spinal Implants

Implant costs are a significant part of the overall cost of spinal surgery. Data collected using the Purchase Price Index and Benchmark Tool (PPIB) suggests that in 2016-2017, NHS Trusts in England spent approximately £49m on implants for spinal surgery. Since the onset of GIRFT this has fallen to £42m in 2017-2018, with all regions in England reducing their implant budget without a reduction in surgical procedure volume (see Figure 48). Whilst progress has been made, further opportunity to improve this aspect of spinal service provision exists.

Figure 48: Total spend by NHS Trusts on implants for spinal surgery (England and by Region, 2016/17 to 2017/18)



Source: Purchase Price Index and Benchmark Tool

The evidence collected through the Spinal GIRFT programme and seen on our site visits demonstrates that most trusts unfortunately still do not fully understand the real costs of the implants they are procuring, and they are not working effectively to secure best value for the NHS. For example:

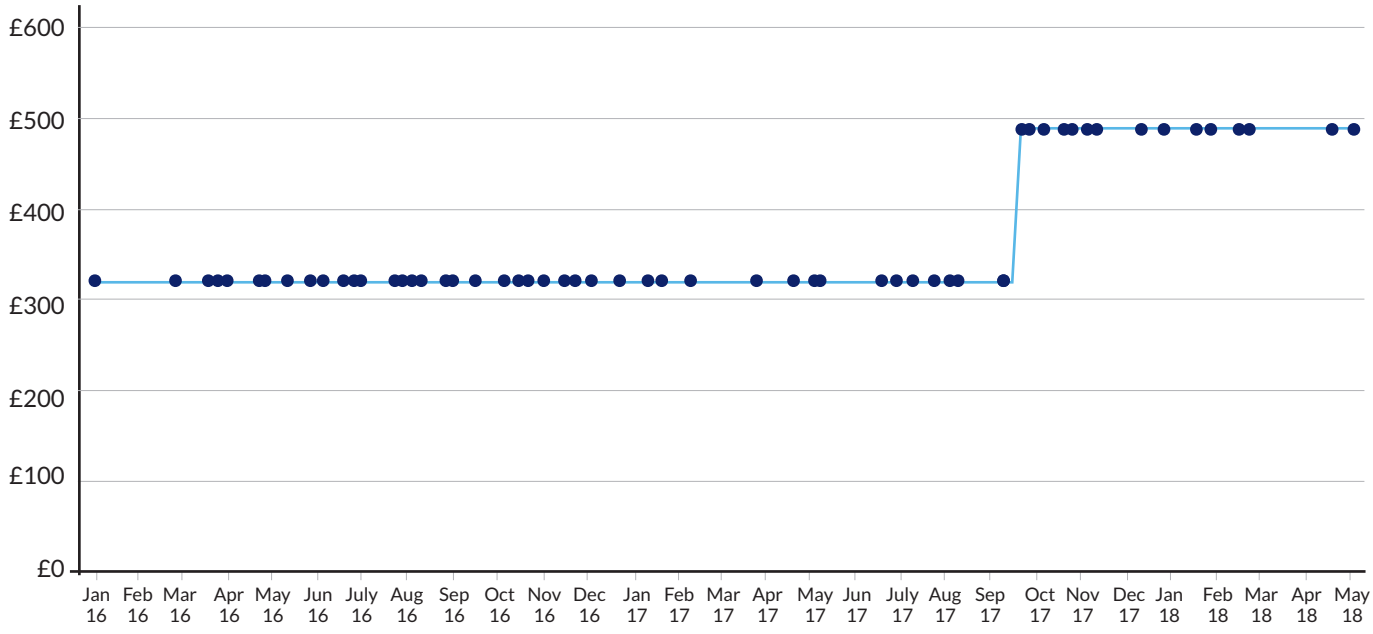
- the data show wide variation in the prices being paid by the NHS for the same implant, even when they come from the same supplier. There is no transparency about what is driving this variation;
- individual trusts are often buying the same implant from different suppliers at widely varying prices;
- trusts are generally procuring component by component rather than focusing on the overall implant and component costs of a procedure. This gives a false view of whether procurement processes are delivering value for money. Companies often charge lower prices on certain components and higher prices on other parts, potentially making the overall bundled price poor value;
- trusts are not always aware of the prices that they are paying for implants and components. In some cases, the pre-visit questionnaires on implant prices used by the GIRFT team to collect data had to be passed on to suppliers to obtain the price information; and
- clinicians invariably were unaware of what their implant costs were and, when challenged, could not demonstrate that a higher implant cost was associated with a better clinical outcome. Whilst cost has traditionally not been at the forefront of most clinicians' decisions, it should be carefully considered.

These issues persist because of poor information, insufficient clinical input into procurement decisions, and a lack of transparency. Our recommendations, described in the following sections, focus on having greater clinical involvement in procurement planning with a view to supporting better procurement practices, coupled with improved information flows.

13.2 Price Increases

Whilst some price increases are inevitable due to changes in underlying inflation, evidence collected across the GIRFT workstreams and previous work by Lord Carter[52] suggests there is much that the NHS can do to strengthen its procurement processes to help constrain prices. This includes requiring companies to publish data on prices, use of the PPIB (Purchase Price Index and Benchmark) and a more centralised and consistent approach to procurement. During our national visits we saw examples where basic procurement practices were not being followed – such as prices automatically rising following contract expiry without new arrangements being put in place. Figure 49 shows an example for one trust, illustrating the increase in price for polyaxial pedicle screws after contract expiry. This sort of pattern is repeated across a range of trusts and implants.

Figure 49: Example of price increases post-contract expiry (example trust, prices for polyaxial pedicle screws, January 2016-May 2018)



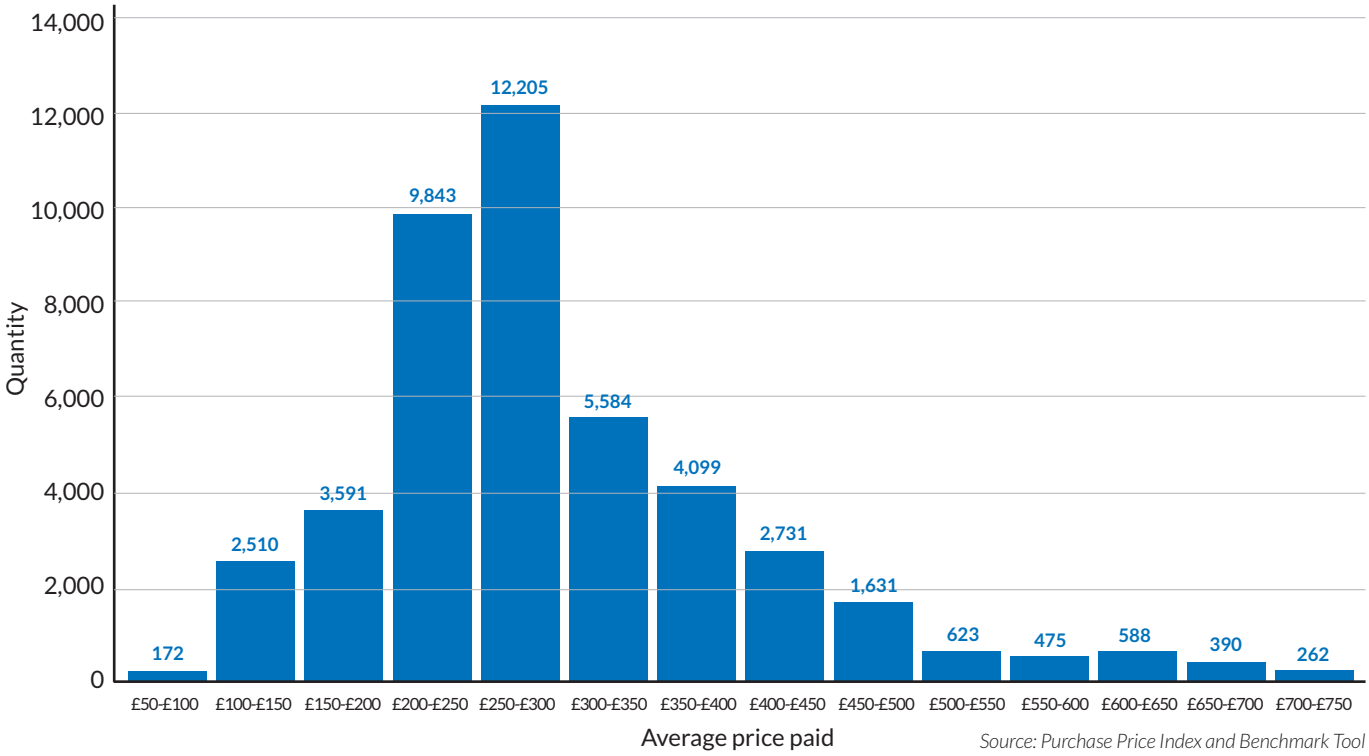
Source: Purchase Price Index and Benchmark Tool

[52] *See for example: Operational productivity and performance in English NHS acute hospitals: Unwarranted variations An independent report for the Department of Health by Lord Carter of Coles, February 2016*

13.3 Price Variation

A closer look at the data on procurement prices shows that there is significant variation across NHS trusts. There are numerous examples where NHS trusts are paying very different prices for the same type of implant. Figure 50 demonstrates the national price distribution and volume of a commonly used implant used in large quantities in the NHS, a polyaxial pedicle screw. NHS England spent £13.2m on this implant in 2017-2018. The variance in price has no justifiable clinical reasoning other than surgeon preference. There is little to no demonstrable peer reviewed evidence to suggest one brand of screw has a superior clinical outcome for patients than another. In France the price for this implant is nationally set at €200. If the NHS in England were move to a price of £200 for a polyaxial screw (still at least 10% more than in France, based on the current exchange rates) it would save an estimated £4.6m per annum.

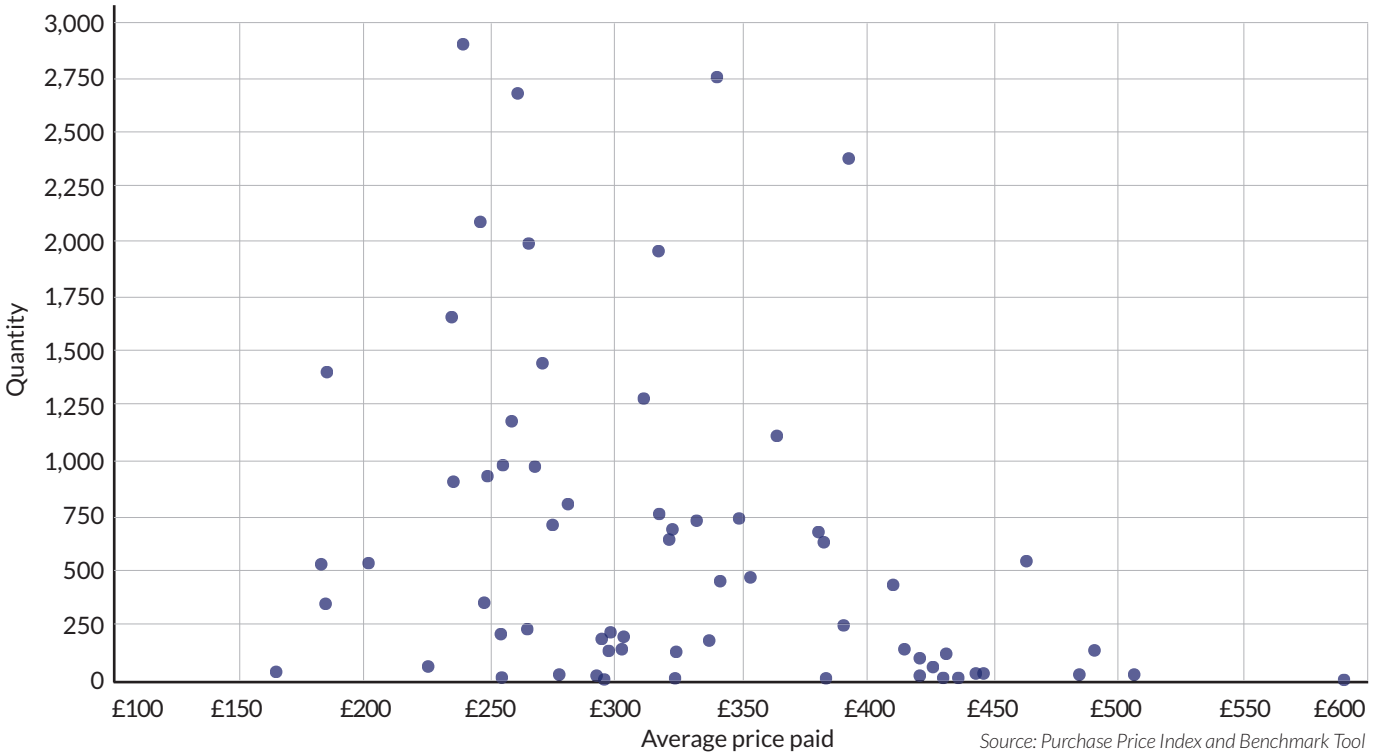
Figure 50: National distribution of prices for polyaxial pedicle screws, by volume (2017/18)



Source: Purchase Price Index and Benchmark Tool

Furthermore, there appears to be no obvious relationship between the price being paid and the volume procured, so other factors are driving the observed variation (Figure 51).

Figure 51: Relationship between price paid and volume purchased, polyaxial pedicle screws, by Trust (2017/18)



Source: Purchase Price Index and Benchmark Tool

Our experience is that this data give trusts highly actionable insights into the variation in their procurement practices. Box 5 highlights how one trust, Lancashire Teaching Hospitals NHS Trust, has made changes to its procurement practices in response to seeing the variation in prices and how it compared.

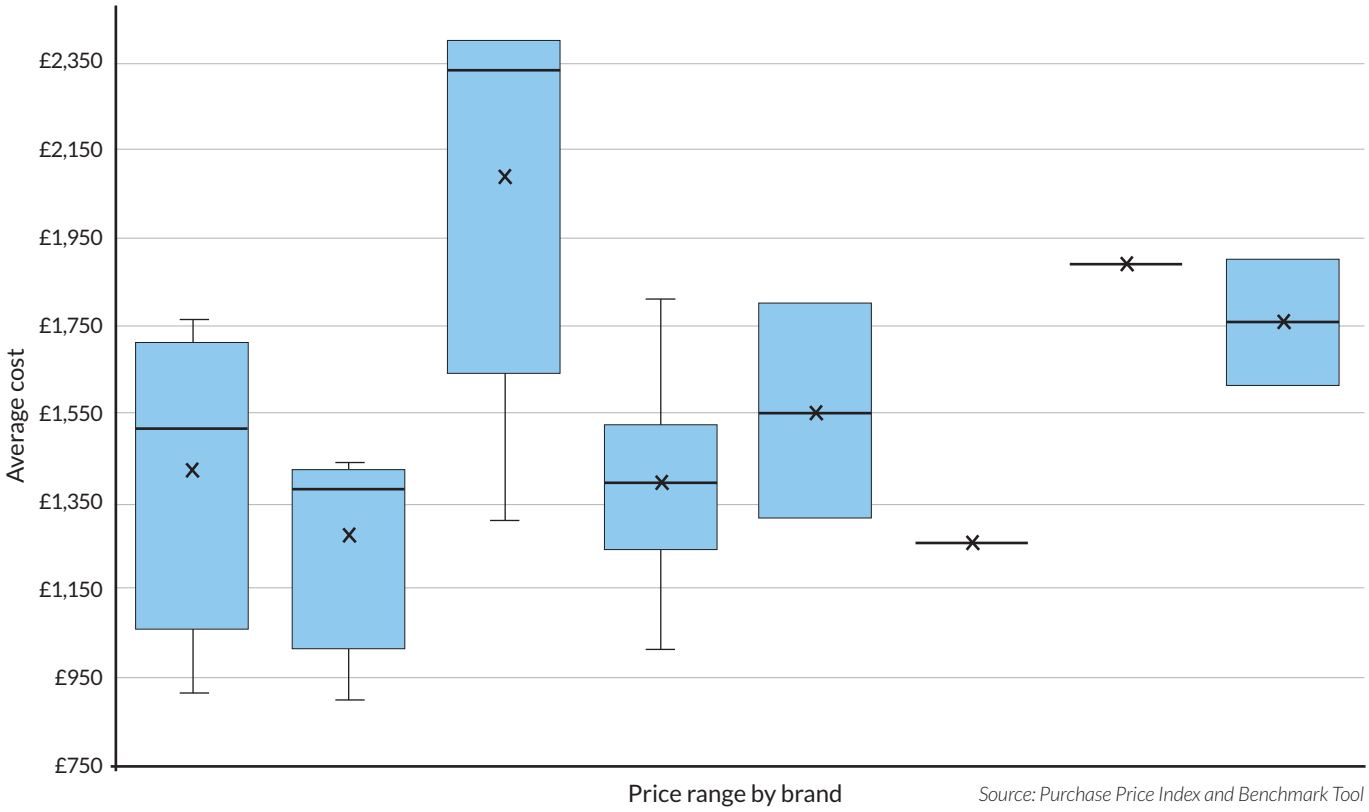
Box 5: Lancashire Teaching Hospitals NHS Trust Procurement Gains

In February 2018 GIRFT, at the invitation of NHSI, met in Preston at The Lancashire Teaching Hospitals NHS Trust with the finance director, the procurement team and the clinical leads in Orthopaedics and Neurosurgery.

For the first time data from the PPIB tool, which had been categorised into meaningful clinical constructs was demonstrated and discussed. The national variance in price for spinal implants was demonstrated according to the GIRFT implant classification and potential savings discussed. Neurosurgery and Orthopaedics agreed to move to a single supplier and negotiations with implant companies commenced. In September 2018, a settlement negotiated by the procurement team has delivered significant savings for the trust. This included navigation equipment worth £ 700,000, including all servicing, maintenance and accidental damage cover over four years, and a recurring annual saving in excess of £100,000 for four years.

Part of the observed variation in prices can be explained by product mix – different manufacturers charge different prices for the same implant. As an example, there are currently 8 different types of cervical disc replacement implants supplied to NHS trusts in England. Even though there is no significant difference in clinical outcome across this range of products, prices vary significantly, ranging from £897 to £2399. The variation between brands and across trusts is shown in Figure 52.

Figure 52: Price variation for cervical disc replacement - average price by brand and variation across trusts (2017/18)

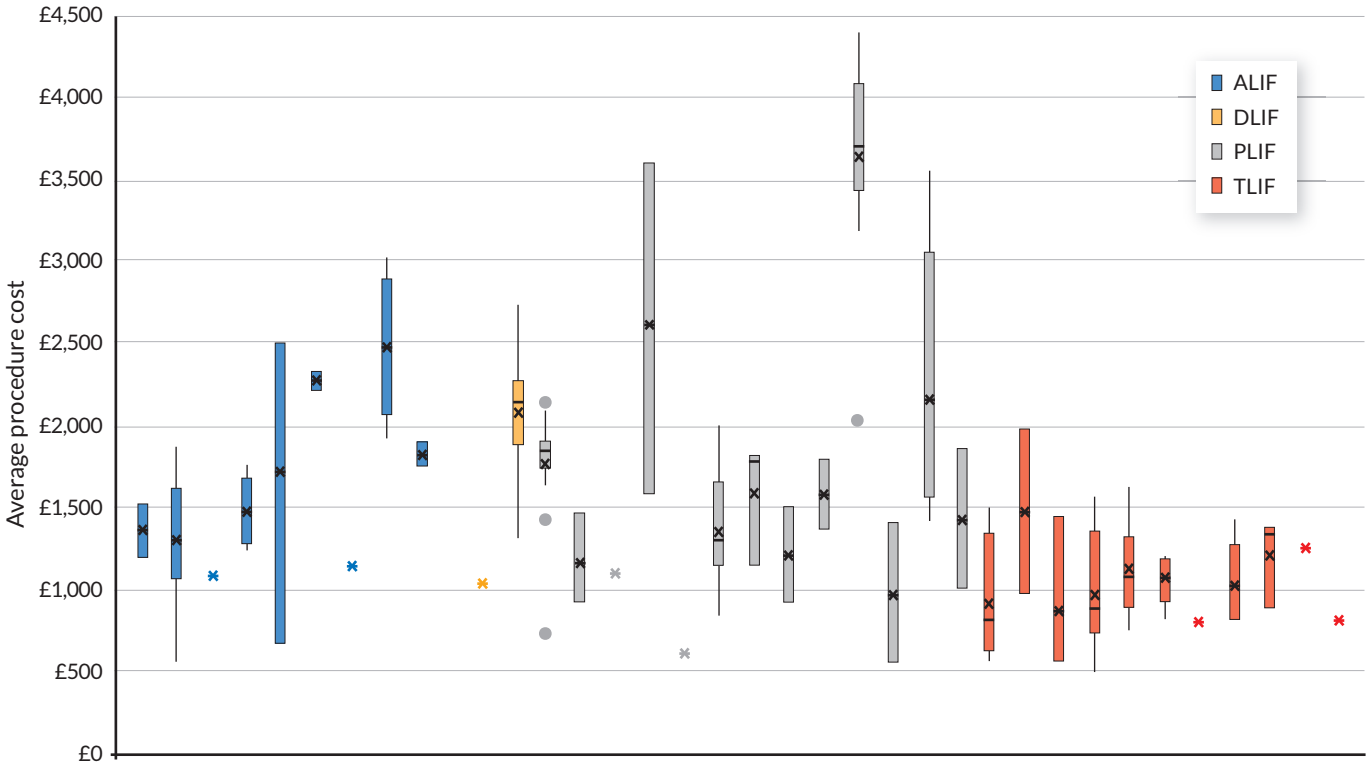


Source: Purchase Price Index and Benchmark Tool

The obvious question is why some trusts pay more for implants when cheaper alternatives are available. Clinical preference is likely an important driver of this – clinicians often have a preference for a particular manufacturer or type of implant and the reasons for this are varied.

Data from trusts support this hypothesis. Figure 53 looks at the example of implants used for lumbar interbody fusion. There are four main surgical approaches utilised to obtain interbody fusion: anterior lumbar interbody fusion (ALIF), transforaminal lumbar interbody fusion (TLIF), posterior lumbar interbody fusion (PLIF) and Direct Lateral Interbody Fusion/Oblique Lateral Interbody Fusion (DLIF). The choice of approach to interbody fusion is largely that of the clinician, and there is very poor evidence that any one has a superior clinical outcome. Yet there is wide variation, both in the type of fusion used, the brand used, and the price variation across trusts. Figure 53 shows the range of prices paid by trusts, by brand and by implant type.

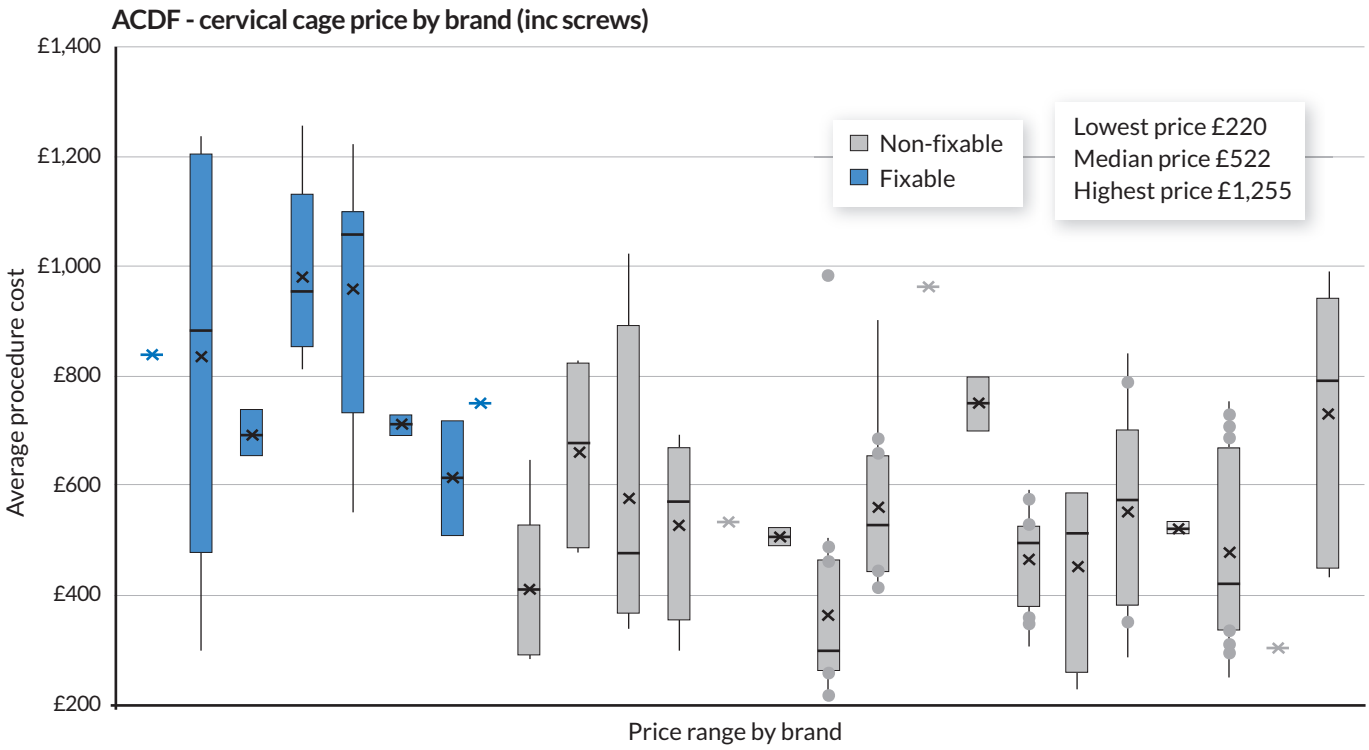
Figure 53: Lumbar interbody fusions – price range across trusts by brand and by type of implant (2017/18)

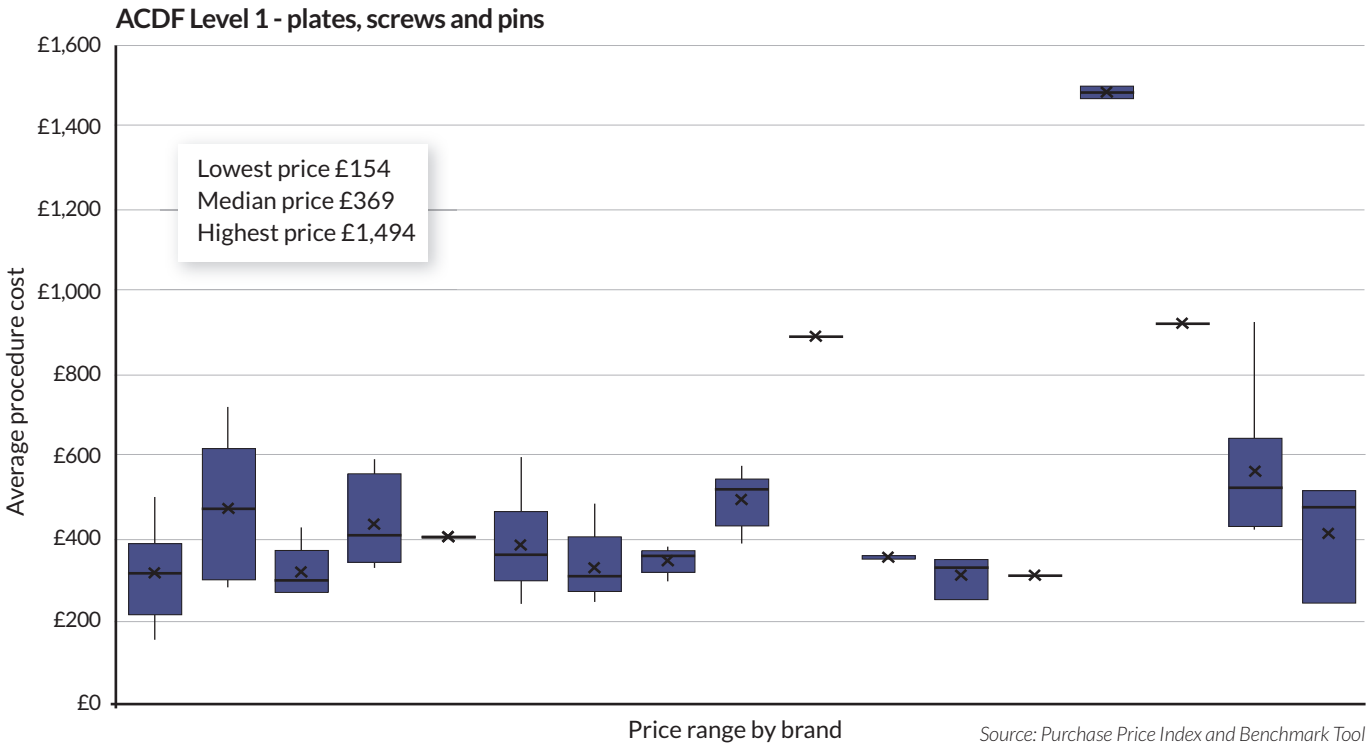


Source: Purchase Price Index and Benchmark Tool

Approximately 6,593 anterior cervical decompressions and fusions were undertaken in 2017-2018 in England. This procedure involves the fusing of one or more cervical vertebra together having removed the disc between them. Surgeons replace the disc with either a patient's own bone, or a spacer known as a cage filled with bone graft. Surgeons may leave this without any method of fixation, fix the cage with screws, or hold it in place with a plate. Figure 54 demonstrates the variance in price in England for these different implants. The cheapest combination of implants to achieve the surgical goal of fusion is £200 and the most expensive potentially £2,494. Again, a great deal of variation exists both in what a trust is paying for an implant, and the cost of different brands of implants with the same surgical goal.

Figure 54: Anterior Cervical Cages Fixable and Stand Alone and a Single Level Plate – price range across trusts by brand (2017/18)





Source: Purchase Price Index and Benchmark Tool

It is impossible to judge whether this variation is delivering good value to the NHS. At present, there is limited consistent data available to conclude whether the outcomes of an implant from one manufacturer are superior to those achieved with another. If clinical preference is the justification for this variation, it should be backed by evidence. In Section 9, we recommended that all surgical procedures should be recorded in the British Spine Registry, in keeping with many other specialties. This would begin to collect the evidence base required to judge whether particular brands of implant deliver better outcomes and hence conclude whether the current preferences are grounded in evidence.

For this recommendation to be effective, it needs to be supplemented by better information about pricing – so a price differential can be judged against the anticipated benefit – and greater clinical involvement in procurement decisions to support the right procurement decisions. These decisions need to be grounded in clinical evidence and then supported by good procurement practice. Clinicians and procurement teams will need to work together to achieve this.

There are other reasons why the headline price of an implant could potentially mask its true cost or value to the NHS. For example, it is common practice for implant manufacturers to support the NHS by funding support staff, research posts, and training and development activities. The variation in prices observed in the data could in part be explained by the value of this hidden support. Whilst this additional support provides funding that might not otherwise be available for certain activities, we cannot judge whether, overall, these practices are delivering value to the NHS because they are hidden.

The only way to make an informed judgement about the benefits of competition on non-price dimensions, is to have more transparent information about the size and scale of these benefits. Other countries, such as the US and France, have introduced regulatory requirements to publish information about the financial relationships between manufacturers, physicians and hospitals. These aim to ensure that there is greater transparency and scrutiny over financial and non-financial relationships, similar to those seen in sectors such as financial services. The Physician Payments Sunshine Act in the US is a good example. Introduced in 2007, the Act requires manufacturers of drugs, devices and other medical supplies to publish data on their financial relationships with clinicians and hospitals. The Act applies to supplies covered by federal health care programmes, such as Medicare and Medicaid.

The UK equivalent - the 2016 Sunshine Rule - requires providers to maintain and publish a register of gifts, hospitality and conflicts of interest. Whilst subjecting the NHS to these requirements does not necessarily remove the price variation seen in the data, it would provide greater transparency about the reasons for it and whether the variations can be justified by the overall value delivered. Again, this would require clinicians and procurement teams to work together so that they collectively make informed judgements, based on transparent data.

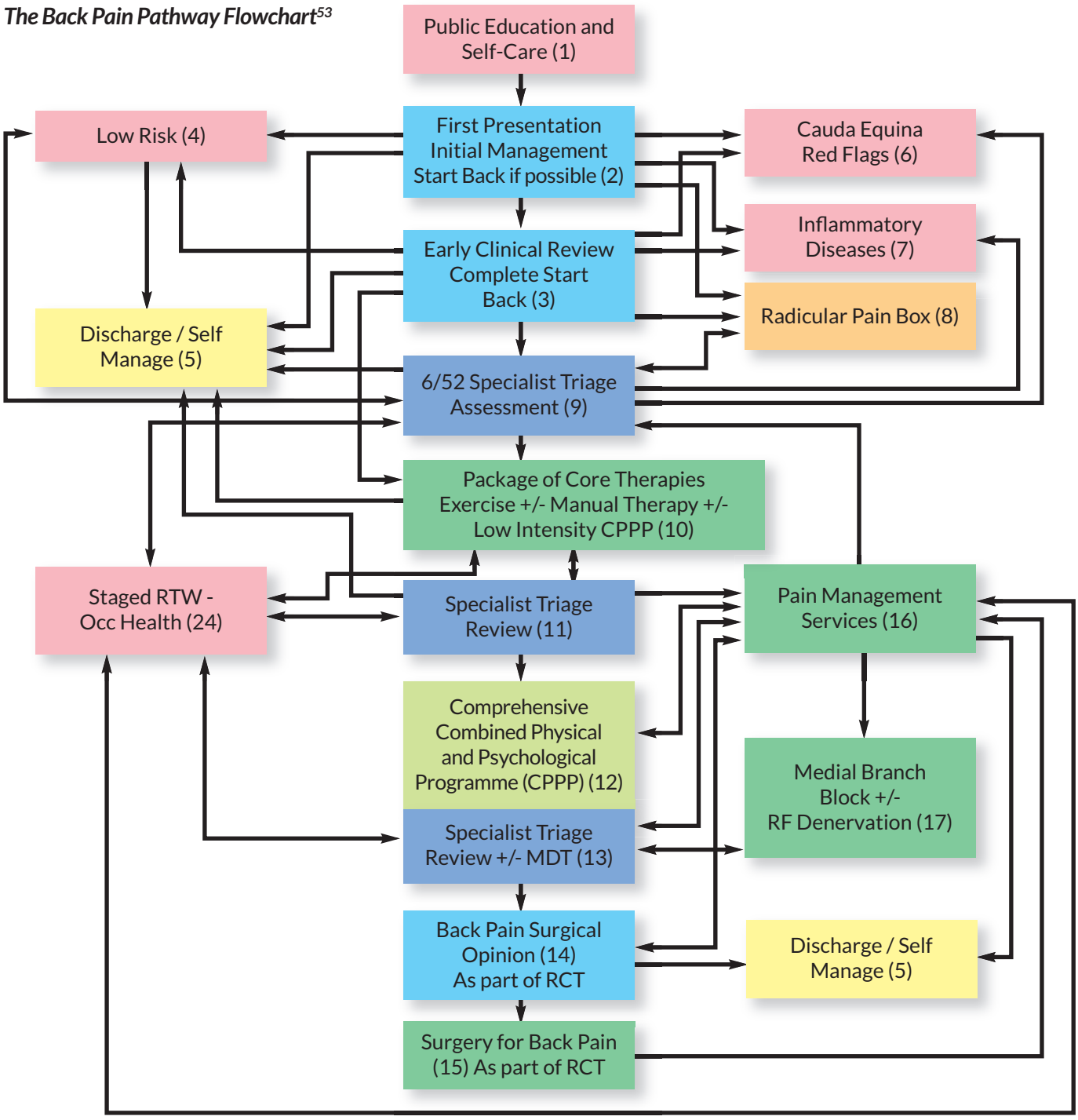
Recommendation	Actions	Timescale
21. Instigate pricing transparency in procurement for spinal surgery and use the resulting insight to deliver more cost-effective procurement	• Use of a standard GIRFT categorisation for spinal constructs to allow meaningful comparison for procurement departments and clinicians (see Appendix E)	Progress to have been made by early April 2019
	• Use of the national category towers to achieve best value in the market place rapidly	Progress to have been achieved by July 2019
	• GIRFT and PPIB to identify centres of good procurement performance, and providers to implement the best practice identified	Agreement on proposals by March 2019
	• Trust management to ensure this list is used to reduce costs.	Ongoing
22. Industry to publish details of financial and non-financial support they provide directly or indirectly to individuals or units	• Association of British HealthTech Industries to publish details of support given to health care organisations	By April 2020
	• Association of British HealthTech Industries to actively police its own Code, whereby direct financial support for individual health care professionals will not permitted under the ABHI Code from 1st January 2019	From January 2019
	• Individuals clinicians and trusts to meet their existing duties of reporting gifts, hospitality, outside employment, shareholdings and other ownership interests, patents, loyalty interests, donations, sponsored events, sponsored research, sponsored posts, and clinical private practice. This information should be publicly disclosed at trust level via registers of interest.	Ongoing

Appendix A: The National Back Pain and Radicular Pain Pathway

The National Back Pain and Radicular Pain Pathway was developed by a clinical group consisting of accredited representatives from each of the stakeholder groups involved in the diagnosis and management of lower back pain and radicular pain. The group used existing evidence and guidelines to agree a pathway of care for patients with lower back pain and radicular pain. The pathway was agreed by all 30 stakeholders involved in the clinical group and was first published in June 2014. The pathway has since been implemented in many CCGs. The pathway has been updated to incorporate NICE guidance (Low back pain and sciatica in over 16s: assessment and management (NG59)). The published pathway is widely available, including via the United Kingdom Spinal Societies Board (www.ukssb.com).

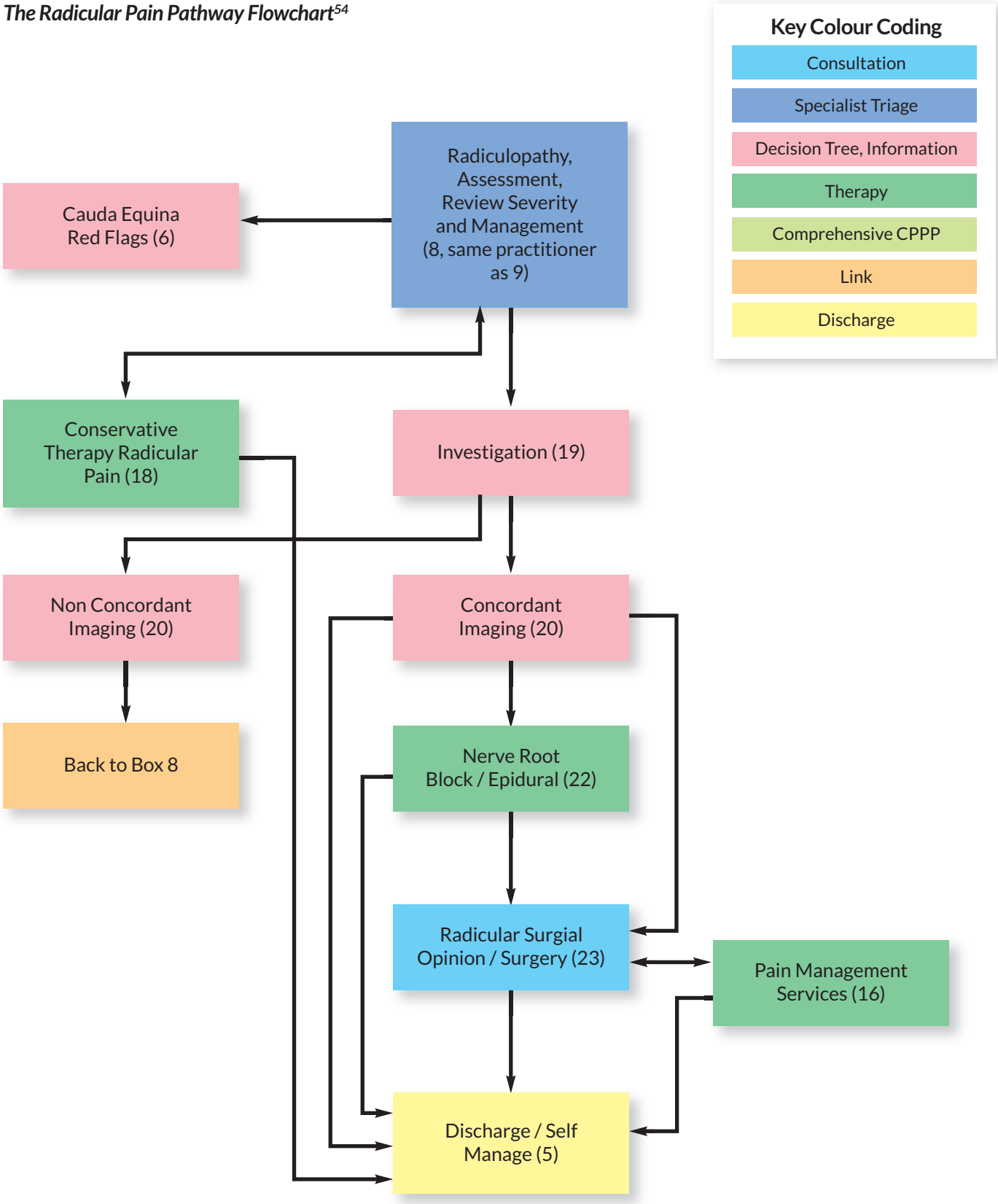
A summary is presented below.

***The Back Pain Pathway Flowchart*[53]**



[53] *National Back Pain and Radicular Pain Pathway, Third Edition 3.0 30th June 2017 (accessed via https://www.ukssb.com/improving-spinal-care-project)*

The Radicular Pain Pathway Flowchart[54]



[54] *National Back Pain and Radicular Pain Pathway, Third Edition 3.0 30th June 2017 (accessed via https://www.ukssb.com/improving-spinal-care-project))*

Appendix B: Standards of Care for Investigation and Management of Cauda Equina Syndrome[55]

Background

Cauda Equina Syndrome (CES) is a relatively rare but disabling condition which can result in motor and sensory deficits, incontinence of urine and faeces, and loss of sexual function.

Any patient with a possible diagnosis of threatened /partial/complete CES requires urgent investigation.

Presentation

A patient presenting with back pain and/or sciatic pain with any disturbance of their bladder or bowel function and/or saddle or genital sensory disturbance or bilateral leg pain should be suspected of having a threatened or actual CES.

Imaging

The reliability of clinical diagnosis of threatened or actual CES is low and there should be a low threshold for investigation with an emergency MRI scan at the request of the examining clinician and MRI must be available at the referring hospital 24/7.

The decision to perform an MRI does not require discussion with the local spinal services.

The MRI must be undertaken as an emergency in the patient's local hospital and a diagnosis achieved prior to any discussion with the spinal services.

The MRI must take precedence over routine cases and any reasons for a delay or a decision not to perform an emergency scan should be clearly documented.

If MRI is contraindicated, discussion with local spinal services is appropriate.

There are four potential outcomes from the investigation

1. Cauda equina compression confirmed leading to immediate referral to an appropriate surgical service.
2. Cauda equina compression excluded but a potential structural explanation of pain identified. This should precipitate appropriate advice about potential future cauda equina symptoms and may include referral via local spinal pathways during working hours.
3. Non-compressive pathology may be identified (e.g. demyelination) which should precipitate referral to the appropriate service.
4. No explanation of the patient's symptoms may be apparent. An appropriate plan for further management is required and may include a cervico-thoracic MRI and referral to continence services.

Surgery

Nothing is to be gained by delaying surgery and should be undertaken at the earliest opportunity, considering the duration and clinical course of symptoms and signs, and the potential for increased morbidity while operating in the night. We do not consider that there is anything in the literature that justifies contravention of this principle and reasons for any delay in surgery should be clearly documented.

Post-Operative Care

All patients with ongoing sphincter disturbance should be promptly referred to local continence services which may include colorectal and urological services or spinal cord injury services.

[55] *Available at www.sbns.org.uk*

Appendix C: Specialised Providers of Complex Spinal Surgery (2017/18)

The list below reflects the providers categorised as specialised based on the Prescribed Services Identification Code Set (2017/18). It is included here for information because it is the categorisation that is used in the charts and tables in this report where specialised providers are identified separately to other trusts.

- Alder Hey Children's NHS Foundation Trust
- Barking, Havering and Redbridge University Hospitals NHS Trust
- Barts Health NHS Trust
- Brighton and Susses University Hospitals NHS Trust
- Buckinghamshire Healthcare NHS Trust
- Cambridge University Hospitals NHS Foundation Trust
- Central Manchester University Hospitals NHS Foundation Trust
- Derby Teaching Hospitals NHS Foundation Trust
- Great Ormond Street Hospital for Children NHS Foundation Trust
- Guy's and St Thomas' NHS Foundation Trust
- Hull and East Yorkshire Hospitals NHS Trust
- Ipswich Hospital NHS Trust
- King's College Hospitals NHS Foundation Trust
- Lancashire Teaching Hospitals NHS Foundation Trust
- Leeds Teaching Hospitals NHS Trust
- Norfolk and Norwich University Hospitals NHS Foundation Trust
- North Bristol NHS Trust
- North Tees and Hartlepool NHS Foundation Trust
- Nottingham University Hospitals NHS Trust
- Oxford University Hospitals NHS Foundation Trust
- Plymouth Hospitals NHS Trust
- Royal Devon and Exeter NHS Foundation Trust
- Royal National Orthopaedic Hospital NHS Trust
- Salford Royal NHS Foundation Trust
- Sheffield Children's NHS Foundation Trust
- Sheffield Teaching Hospitals NHS Foundation Trust
- South Tees Hospitals NHS Foundation Trust
- St George's University Hospitals NHS Foundation Trust
- Taunton and Somerset NHS Foundation Trust
- The Newcastle Upon Tyne Hospitals NHS Foundation Trust
- The Robert Jones and Agnes Hunt Orthopaedic Hospital NHs Foundation Trust
- The Royal Orthopaedic Hospital NHS Foundation Trust
- The Walton Centre NHS Foundation Trust
- University College London Hospitals NHS Foundation Trust
- University Hospitals Southampton NHS Foundation Trust
- University Hospitals Birmingham NHS Foundation Trust
- University Hospitals Bristol NHS Foundation Trust
- University Hospitals Coventry and Warwickshire NHS Trust
- University Hospitals of Leicester NHS Trust
- University Hospitals of North Midlands NHS Trust

Appendix D: Beyond Compliance (Risk Assessment Framework)

For the Beyond Compliance process to work effectively the level of risk inherent in a new device, modification to an existing device or an extension to a range is assessed early on in the Beyond Compliance process. Categories of risk are set out below, which in turn impact recommendations on speed of market entry and the oversight given through the Beyond Compliance process.

LEVEL 1 RISK	The risk is thought to be minimal. An example would include an extension to a range of sizes
Anticipated rate of introduction	No restriction
Monitoring	Through the BC process. Data reviewed and reported 6 monthly or annually

LEVEL 2 RISK	For example, where there has been one significant change away from the benchmark implant
Anticipated rate of introduction	To be agreed between the manufacturer and the rapporteurs and referenced in the assessment
Monitoring	Through the BC process. Initially 3-monthly, with tripartite meetings

LEVEL 3 RISK	For example, where there are two or more significant changes from the benchmark implant
Anticipated rate of introduction	To be agreed between the manufacturer and the rapporteurs and referenced in the assessment. It is anticipated the rate of release will be slower than with a product which has attracted a lower risk rating
Monitoring	Through the BC process. Staged release and periodic tripartite reviews

LEVEL 4 RISK	Where there is a no useful benchmark implant and/or where there is a significant multiple change away from the accepted benchmark implant. In this type of analysis, it is likely there may be liason with the appropriate notified body
Anticipated rate of introduction	Very limited introduction as agreed in the risk assessment
Monitoring	Close monitoring through the BC process and regular tripartite reviews

LEVEL 5 RISK	Where there is an absence of evidence with a satifactory track record or where any similar implants have previously performed unacceptably
Anticipated rate of introduction	Strictly limited
Monitoring	Strictly monitored through the BC process and frequent tripartite reviews

Source: www.beyondcompliance.org.uk (accessed 22nd August 2018)

Appendix E: The GIRFT Categorisation for Spinal Constructs

PROCEDURE INFORMATION

Posterior Scoliosis Correction:

16 Pedicle screw (construct of 8 monoblock screws and 8 standard poly screws)
2 x 300 + rods
16 set screws
1 Cross link including screws
Posterior Scoliosis Correction Total

Anterior Cervical Interbody Fusion Single Level:

Fixed cage
Fixed cage screws
Fixed Cage Total
Non Fixable Cage
Non Fixable Cage TotalFixed cage
1 level plate
Screws for plate
Fixation Pins
Single Level Plate Total

1 Level Posterior Lumbar Fusion:

4 x Pedicle screws
4 x set screws
2 Rods 20-100mm
1 Level Posterior Lumbar Fusion Total

Posterior Cervical Fusion:

8 x Screws
2 x 120 rods
8 set screws
Posterior Cervical Fusion Total

Interbody Fusion Cage:

TLIF Cage
PLIF (2 Cages)
DLIF including consumables
ALIF Cage
Fixable ALIF Cage plus Fixation e.g. screws/blades

Anterior Lumbar Fixation Plate with Screws:

Anterior Lumbar fixation plate
Screws
Anterior Lumbar Fixation Plate with Screws Total

Cervical Corpectomy Single Level:

Corpectomy cage
Screws for cage
Endplates x2
Cervical Corpectomy Single Level Total

Thoracic Corpectomy Cage Single Level:

Corpectomy cage
Screws for cage
Endplates x2
Thoracic Corpectomy Cage Single Level Total

Lumbar Corpectomy Cage Single Level:

Corpectomy cage
Screws for cage
Endplates x2
Lumbar Corpectomy Cage Single Level Total

Kyphoplasty Single Level:

All consumables including needles please list below
Kyphoplasty Single Level Total

Vertebroplasty Single Level:

All consumables including needles please list below
Vertebroplasty Single Level Total

MIS 1 level Posterior Lumbar Fusion:

4 x MIS Screw including all consumables
2 x rods 20-100mm
4 x set screws
MIS 1 level fusion Total

PROCEDURE INFORMATION (continued)

Cervical Disc Replacement:

Cervical Disc replacement include consumables

Cervical Disc Replacement Total

Lumbar Disc Replacement:

Lumbar disc replacement include consumables

Lumbar Disc Replacement Total

5cc Bone Graft:

5cc Bone Graft Total

10cc Bone Graft:

10cc Bone Graft Total

Flowable Haemostats:

Flowable Haemostats Cost per ml

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visit our website: www.GettingItRightFirstTime.co.uk
or email us on info@GettingItRightFirstTime.co.uk

You can also follow us on Twitter @NHSGIRFT and
LinkedIn: www.linkedin.com/company/getting-it-right-first-time-girft

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