



■ EDITORIAL

Should we all go to the PROM? The first two years of the British Spine Registry

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Following the success of the National Joint Registry, the British Association of Spine Surgeons instituted the British Spine Registry. Since its launch in 2012, over 650 users representing the whole surgical team have registered and during this time, more than 27 000 patients have been entered onto the database.

There has been significant publicity regarding the collection of outcome measures after surgery, including patient-reported scores. Over 12 000 forms have been directly entered by patients themselves, with many more entered by the surgical teams.

Questions abound: who should have access to the data produced by the Registry and how should they use it? How should the results be reported and in what forum?

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The effective and meaningful capture of outcome measures in the healthcare setting can be traced back to Florence Nightingale's investigation of the in-patient mortality of soldiers wounded in the Crimean war in the 1850s.¹ Surgical outcomes and follow-up was introduced in the early 1900s by Earnest Codman in Boston using the 'end result idea'.²

At the most rudimentary level, outcome measures are used to determine the level of 'success', which is defined as the favourable outcome of something attempted.³ They allow dynamic monitoring and changes in the clinical setting and can identify, depending on setup, hospitals, units, individual surgeons or procedures that appear as outliers to the statistical norm either locally or nationally. Perhaps the biggest challenge for spinal surgeons is the unification of the specialty as a professional collective, either by group or by outcome standardisation, whereby a vision of the greater good needs to precede the individual agenda.

Only relatively recently has the formalised collection of outcome data into Registries been recognised as valuable in itself and several examples now exist where this has been shown to benefit patients. A Registry can be defined as 'a systematic collection of a clearly defined

set of health and demographic data for patients with specific health characteristics, held in a central database for a predefined purpose'.⁴

With the advent of published surgeon-level outcomes to which a rank order might be applied and the move towards value-based health care,⁵ individuals and the healthcare system are being driven to collect, store and interpret data, to facilitate enhanced quality while maintaining appropriate downwards pressure on costs.⁶

The Swedish Spine Register,⁷ which was borne out of the arthroplasty experience, led the way for spinal surgery. The Spine Society of Europe's Spine Tango⁸ was the first multi-national register to gain credence.

Establishing the British Spine Registry

Following the success of the National Joint Registry⁹ in 2009 the British Association of Spine Surgeons instituted the design, construction and rollout of the British Spine Registry (BSR) and has since joined forces with the British Scoliosis Society (BSS) and the Society of British Neurological Surgeons, with the aim of nationwide participation.

The stated purpose of the BSR is to collate information on the current state of spinal

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surgery within the United Kingdom in order to identify areas of best practice and so facilitate improved patient care. The BSR, built on the Amplitude platform, (Amplitude Clinical, Droitwich, Worcestershire) was constructed to be a secure Internet based repository freely available to the societies' memberships. Since its launch in 2012, over 650 users have registered more than 27 000 patients onto the database. These users include representatives from all aspects of the surgical team including surgeons and nurses, to admin assistants, physiotherapists, secretaries and doctors in training. Registries have limited value unless the data entry is relevant and complete. Until mandatory status is achieved, it is unlikely the true value of the BSR will be realised. At present, this is largely beyond the direct control of the Spine Societies, but progress made through the British Orthopaedic Association's Quality Outcomes Committee (BOA-QOC)¹⁰ and the funding support for this programme recently announced from NHS England is very welcome and will allow progress towards universal registration and data capture. Greater transparency regarding outcomes, and the recognition of the requirement to measure them, has advanced in recent years¹¹ which will help this process. At the 2014 annual scientific meeting of the BSS in Bristol, it was announced that the Society aimed to achieve 100% data capture by the end of 2016.

There has been significant publicity regarding the collection of outcome measures after surgery, including patient reported scores (PROMs). Collection of such data is central to the function of the BSR and the surgical team can enter scores retrospectively after paper form collection or the data can be entered prospectively by the patient themselves either via an email portal, a personal computer, a tablet or a smartphone while the patient is in outpatients. Over 12 000 forms have been directly submitted by patients themselves, with many more entered by the surgical teams.

Data capture and outcome measures

There are some perceived difficulties regarding the recording of outcomes following spinal interventions, often because of the heterogeneous nature of the conditions being treated, as well as the significant psychosocial component¹² of patients' presentations. Questions arise as to whether the validated and widely accepted generic and disease-specific tools that are currently in use truly discriminate between good and bad operations. In some circumstances they have been shown to be inadequate.¹³ Certain specific patient characteristics such as age¹⁴ might also have an influence. Floor and ceiling effects in addition to the lack of functional outcome can skew results for some tools.^{15,16} For an operation to be successful the patient needs in-depth education covering the pathological origin of the condition, the nature and extent of the intervention, a description of the post-operative journey and realistic expectations of the final outcome of the procedure. Their perception of success (or otherwise) might not be defined just by the narrow parameters of pain and

bodily function recorded in standard questionnaires, but may include aspects such as return to work and sport as well as the more routine activities of daily living. In addition, their internal and external psychosocial environment can play an important role in their perception, which is very difficult to capture accurately and measure in a meaningful way. Several authors have demonstrated that the fulfilment of pre-operative expectations gives rise to the highest post-operative satisfaction.¹⁷⁻¹⁹ It remains a concern that despite thorough education, a mismatch of disease understanding and treatment expectation can still exist between the surgeon and the patient, which may be especially true in patients with low expectations when coupled with poor experiences. Limited outcomes tools may not be able to express fully the true extent of the patient's experience, but they are a start and our ambitions as surgeons should be to work towards creating more representative constructs that do not add an unacceptable burden to the patient experience.

Other important questions that should be asked of the BSR include 'Who should have access to the data produced by the Registry and how can they use it?' 'How should the results be reported and in what forum?'

Since 2009 it has been a mandatory requirement for all facilities providing care to NHS patients undergoing hip and knee arthroplasty, groin hernia repair and varicose vein surgery to participate in the national PROMs programmes.²⁰ This follows the successful long-term capture of cardiothoracic data by The National Adult Cardiac Surgery Audit.²¹

In 2012 this concept was adapted further by the Health Quality Improvement Partnership (HQIP), first formed in 2008 with the mission statement of 'promoting quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales'²² with the collection of individual Consultant Outcome measures. Initially, ten specialties were included, with an additional three added throughout 2014.²³

Achievements so far

The data from the BSR already provide an annual review at the National Meetings of the Spine Societies, as well as a comparison of unit level results such as deep infection rates in scoliosis correction surgery. It could provide more refined data should it become accepted that surgeon-level outcomes are required to meet the stated ambition of Sir Bruce Keogh, the Medical Director of the NHS.²⁴ NHS trusts in England are already obliged to provide PROMS outcomes for surgery, but this has been implemented in a patchy and haphazard manner.²⁵ The BSR is a valuable resource that would allow a systematic implementation of this policy.

The BSR Steering Committee recently reviewed the data from the Registry's first two years, following which it was decided to focus on collecting detailed data on a small number of specific procedures to encompass as many surgeons'

practices as possible, giving a more reliable overview of current spinal activity in the United Kingdom. To this end, a mandatory dataset has been determined and these fields will be collected for primary lumbar decompression/discectomies, primary anterior cervical discectomy with fusion and surgery for adolescent idiopathic scoliosis. The Registry will still enable the wider collection of data covering all aspects of spinal care, but the emphasis for audit purposes will be concentrated into these three main areas.

Based upon current evidence and practice, the BSR team resolved to collect PROMs for these specific procedures at predetermined time points. The standard patient questionnaires will include the EuroQoL EQ-5D,²⁶ a visual analogue score for back and leg pain²⁷ and the Oswestry Disability Index.²⁸ The equivalent scores will be used for the cervical surgery patients. A satisfaction assessment akin to the Friends and Family²⁹ tool will be appended at the final follow-up stage.

Practical problems remain with regard to the collection of data. The primary focus has been to encourage early and comprehensive patient engagement. The BSR has been designed to enable multiple modes of capture, either by secure email, or via touchscreen input on a tablet or kiosk computer while the patient is in outpatients, which should reduce questionnaire fatigue. Despite this, many units struggle to facilitate data entry due to the pressures of numbers in clinics and poor infrastructure investment at hospital level.³⁰ Surgeons across the country have recognised the imperative for quality data collection and fully support the concept of the BSR. However, support is needed from NHS trusts and private providers that offer NHS treatment in terms of recognition of the time and logistical requirements of capturing this type of data on large numbers of patients.

Future development

It is an imperative that duplication of effort is avoided. It is hoped, therefore, that the current push by the existing Registries, along with the combined approach of the BOA-QOC¹⁰ will be supported and universally adopted, and that with the support and input of the appropriate stakeholders, a mutually satisfactory solution will emerge. To this end, the BSR is in discussion with NHS England, the National Institute for Health and Care Excellence, HQIP, the Private Healthcare Information Network and the Association of British Healthcare Industries, amongst others, to enshrine the BSR as the central resource for spinal surgical data for the United Kingdom. Recurring funding to ensure expansion of the Registry is being sought independently of the spine societies.

While primarily aimed at the unit level audit process, the BSR already gives a national picture of spinal surgery including case mix, volumes and trends,³¹ which informs debate and policy making. An additional intention of the design is to facilitate national research via multicentre trials supported by a low-cost data capture system that is secure, reliable and accessible.

We are at a turning point where the value of unit level data is agreed, but the funding to enable collection is limited, despite the national mandate to do so.

Recognition and acceptance of the BSR and its sister registries under the BOA-QOC umbrella is gathering pace, and it is vital that this continues through wider publicity, awareness and support of the surgeons and their teams at unit level.

Currently, surgeons and their teams, under the auspices of the Societies, own and control the data on the BSR.¹¹ This should ensure the accuracy and reliability of such information with specific reference to the surgical detail. Unless the uptake of the BSR increases beyond the current 15%, thus giving true validity to the results, external agencies will take control or impose a different solution. For the sake of our profession and more pertinently, that of our patients, we must ensure that this does not become necessary by producing a registry that is secure, reliable and first and foremost, used by its main constituency.

Author contributions:

L. M. Breakwell: Co-designer and Co-Chair of the BSR, Main author on details pertaining to the BSR.

A. A. Cole: Co-designer and Co-Chair of the BSR.

N. Birch: Researched background of registries and the science of outcome scores.

C. Heywood: Background research and main author of details re registries in general and the limitations of PROMs.

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