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## A practical approach to spine registers in Europe: the Swedish experience

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**Abstract** Today there is growing awareness among spine surgeons of the advantages in using registers to facilitate the analyses and reporting of treatment outcome. The Swedish Spine register is among the first to be used on a national scale and annual reports are published in international journals. In this paper we discuss our experiences and lessons learned from a paper-based version

in 1993, to an online web-based solution in 2005. We emphasise the advantages of registers being owned by the national spine society, a support function available during working hours, online feedback to participating departments and professional assistance in designing a register program for web use. Hopefully, our experiences will be of help to colleagues who are planning to start registering.

**Keywords** Spine register · Outcome · Web-based

### Introduction

Registers have the potential to provide information about the number and type of surgical interventions, adverse events and outcomes such as patient satisfaction, quality of life and cost-effectiveness [9]. The intention may be to give local, regional, or national support, or international services such as the ‘Spine Tango’ [11]. Since information obtained from registers helps to ensure quality in healthcare management, and also assists in analysing cost-effectiveness and thereby in setting priorities among therapeutic alternatives, demand on regular registering is increasing among all involved parties [2].

Thus, spine surgeons can readily accept that participation in registering spine procedures is not an internal affair. A reasonable assumption is that if the profession will not take this challenge seriously and take the lead, we may eventually be forced to accept solutions that could be less favourable to our patients and ourselves. If we decide to maintain a register, we are faced with two basic options:

1. We agree on using one register. This register should be hosted and administered in a way that ensures safety and backup, and should be offered to all departments involved with spinal surgery that wish to use it. Such an arrangement could facilitate data input, data handling and analyses and ultimately, data reporting, in a way that is easily accessible to everyone involved. From a functional and financial point of view this could offer a sound solution. From a psychological perspective, however, it could be difficult. One of the crucial issues is that of ownership and data control and consequently, the right to conduct statistical analyses and publish reports, as well as to decide on availability to external parties.

The ‘Spine Tango’ could fit the above criteria. Spine surgery departments are invited to participate for a nominal sum to cover the administrative costs associated with data analysis and reporting of results. Data are depersonalised, allowing only the

registering clinic to see their own results, but with the opportunity to compare with aggregate data through online reports.

- Alternatively, we could continue to use our various current registers, while accepting the fact that also new ones are being developed. This option may involve difficulties in obtaining adequate numbers to allow relevant statistical analyses and consequently clinical conclusions and recommendations. Comparisons could also be complicated by the use of different outcome instruments and measurement strategies.

However, national registers with adequate reporting routines like the Swedish spine register can produce valuable information [12]. If this option is chosen, it would be preferable for spine surgeons to agree on the use of a basic set of core outcome instruments, preferably suggested by the Spine Society of Europe (SSE), to allow relevant comparisons with data from other registers. Technically these comparisons should be possible by importing selected data to a common data bank in a server hosted by an appropriate institution. National or departmental data could be filtered through a server hosted within the registering country, or the specific department. The filtering process should include coding so that only the reporting department will be able to relate the data to their specific patients in feedback reports. The Spine Tango could probably fulfil this mission.

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### **The Swedish lumbar spine register**

In Sweden, a register covering degenerative disorders of the lumbar spine has been in use since 1993, when the first version was presented by one of the authors (BS).

The primary aim was to prospectively describe the outcome of disc surgery, decompressive surgery and fusion surgery of the lumbar spine, and to report the results annually. Despite nationwide enthusiasm among spinal surgeons, initially the register did not spread across the country. At most, between five and ten departments were contributing, most of them located in the south of Sweden, so the register was in fact ‘regional’.

Below, we will discuss some crucial issues encountered on the path to national acceptance of the register and the strategies we applied in solving the problems during development.

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### **Implementation obstacles: the Swedish experience**

#### **Funding**

From the start in 1993 the register was classified as one of the national quality registers in Sweden. The National

Board of Health and Welfare (SoS) provided funding, a prerequisite for running a national register.

#### *Problem/solution: loss of funding because of insufficient national coverage*

Since only a few spine departments in the country became affiliated with the register, funding was withdrawn in 1998. The solution was to transfer the register from a local administrator to the Swedish Society of Spinal Surgeons, and a ‘register group’ was established directly under the board with responsibility for implementation, support and feedback (see below, sections ‘Implementation—support’ and ‘Statistical analyses and reports’). A report covering 2,553 surgical procedures during 1999, approximately half of the annual lumbar procedures in the country, convinced the authorities that the register had gone national and limited funding was resumed.

#### **Outcome instruments, measurement strategies and administration**

In contrast to the Swedish hip and knee registers, using reoperation as the endpoint of outcome is meaningless. Instead a significant amount of both preoperative and postoperative outcome parameters on pain and function have to be gathered for the individual patient. This could be a problem, but it also means that treated patient groups are thoroughly described and a comprehensive description of patient-related outcome becomes available.

#### *Problem/solution: lack of commitment by individual surgeons*

Since the early version was administered locally, colleagues felt that they were not involved in the process of designing the register, or in deciding on measurement strategies and reporting. Other important issues were the lack of support and feedback. There was also an underlying tone of rivalry between the large university departments and an uncertainty as to who ‘owned the data’ and consequently, who could benefit from analysing and producing scientific reports.

The register group was therefore mandated to suggest a set of questionnaires with a relevant layout, outcome instruments and outcome measurement strategies. The initial register served as a base and the idea was to keep it simple. The register was intended to meet current and, to the extent foreseen, future standards.

A minimum number of outcome instruments commonly used in clinical trials were included. Basic demographic patient data were reported, as well as the surgical procedure including complications. Variables

reported in the preoperative patient-based questionnaire were: age, sex, smoking habits, previous lumbar spine surgery, work capacity, type of work and duration of back and leg pain. Consumption of analgesics and walking distance, and back and leg pain on a visual analogue scale (VAS) were recorded. The EQ-5D [1] and SF-36 questionnaires [14] were used to measure quality of life. The latter makes it possible to perform economic analyses. The patient usually completes these forms on the day before surgery, in approximately 20–30 min.

Follow-up questionnaires are mailed out and should be completed at 1, 2, 5 and 10 years after surgery. The same questions found in the preoperative questionnaire are asked, as well as return to work, duration of sick leave, complications and reoperation. The patient also gives an overall estimate of surgical outcome (much better, better, unchanged and worse) and satisfaction with treatment (satisfied, uncertain and dissatisfied). A comprehensive algorithm for processing the questionnaires is provided to each participating department.

In order to positively influence the compliance, the register has been discussed at annual meetings since 1998, including participation by secretaries and surgeons. It is also routinely discussed at the Spine Society's annual meetings. In addition, annual reports are distributed to all participating clinics and to the National Board of Health and Welfare (SoS).

#### Data handling

In the initial paper-based register, surgeons and patients completed the questionnaires. Secretaries then transferred the data to local data files. At regular intervals the data files were sent to the administrative department and imported into the aggregate national data bank.

#### *Problem/solution: time consuming secretarial work because of paper-based registration*

The early paper-based model was static and heavily dependent on the work of secretaries at both the data processing departments and the data administrative centre. In addition, since spine surgeons—at least in Sweden—have limited time for (or interest in) completing forms, the registration procedure was problematic. In times of economic restrictions and increasing workload, data reports were not frequently delayed and incomplete registration was a problem.

As a solution, outcome questionnaires were reorganised and made entirely patient-based.

The surgeon completed a simple two-page questionnaire including a minimum of data regarding the surgical procedure, including the implant used, antibiotic prophylaxis and complications, reoperation and

hospitalisation time. The name of the department was registered, but not the name of the surgeon, although this remains an option. The surgeon could complete questionnaire in less than 1 min.

#### Implementation: support

After implementing the register the main challenge is to make registration and reporting part of daily routine.

#### *Problem/solution: unclear agreements concerning technical support and development*

There were numerous questions regarding registration procedures from the participating departments and in order to ensure compliance, a readily accessible support function should be available during working hours. Therefore, an 'implementation and support team' was established within the register group. The responsibility was given to one of the authors (PF). At that time he was not affiliated with any of the university clinics, which may have been an advantage. The group as a whole possessed a considerable knowledge of quality development and process handling, which facilitated the mission.

All surgeons in the register group were available for discussions with the users concerning methodological aspects and, more importantly, three part-time secretaries were available for registration and administrative purposes, as well as practical support. A specially trained secretary was available by telephone during working hours and she also visited most participating departments for on-site assistance.

#### Register content

So far, the Swedish register has been limited to the lumbar spine. In 2004 a decision was taken to include all disorders and surgical procedures related to the entire spine, which should be accomplished in the beginning of 2006.

#### *Problem/solution: defining what instruments should be included*

A committee within the Spine Society was set up in February 2005, including leading spine surgeons from different fields. The mission was to recommend relevant outcome instruments and measurement strategies following the same criteria as for the lumbar spine: questionnaires should be as simple as possible, in accordance with and adaptable to future standards. The results will be presented to the society at the end of 2005.

## Statistical analyses and reports

The initial computer application used FileMakerPro software and included an export function to the Statview or SPSS programs for statistical evaluation. Annual reports containing data for the whole of Sweden were compiled and reported in international journals [10, 12].

### *Problem/solution: data feedback*

It was not possible to export online feedback reports to the participating departments. This was a definite drawback, since many individual surgeons and departments demanded immediate access to their own database and results.

In response to this demand, feedback of personal clinical data compared with the aggregated national mean was provided following the establishment of the register support group in 1998. A service offering statistical analysis and illustrations of the results has been provided on request, free of charge and has been extensively used, especially by private clinics.

However, the work involved in arranging and submitting data manually to the 'support group' in order to obtain feedback was considered time consuming. Thus, although this function has been regarded as extremely valuable, interest has exceeded utilisation. In addition, individuals wished to ask their own questions, since it is not always possible to anticipate all questions that arise during the analyses. Also, statistical analyses are time consuming and have been conducted by dedicated spine surgeons without reimbursement (in their spare time).

As a solution, the national Spine Society decided that a less work-intensive and automated web-based register solution should be developed. The goal should be to ensure the import and export of data, to simplify statistical analyses and to facilitate online feedback and annual reporting with a minimum of effort.

## Going web-based

The register became web-based in 2000, with the responsibility given to one interested colleague and supported by one local programmer/software provider. A process was initiated where data from the old FileMaker database was imported into a local application. The project received funding from the National Board of Health and Welfare (SoS), as well as from regional healthcare organisations.

### *Problem/solution: time-consuming developmental work and no professional agreement stating responsibilities*

No agreement stating responsibilities regarding fulfilment of assignments and duties was signed with the

surgeon responsible for the register or with the software provider. It soon became obvious that this was not an acceptable arrangement. Problems arose with time schedules, modifying the register's 'question base' and obtaining feedback and reports in a timely manner.

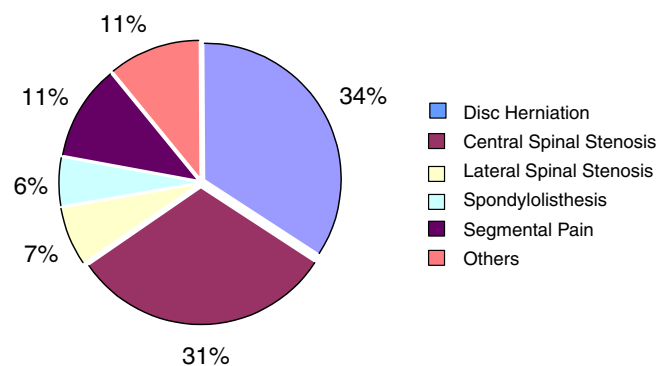
Consequently, at the end of 2004 the Spine Society decided on a tender process with the intention of purchasing a professional application with the potential to meet all current and future requirements. This process has been the responsibility of the 'register group' and was conducted in close cooperation with the company. In our opinion, such a professional arrangement is absolutely mandatory for a successful result. For the Swedish register, the process for the whole spine will be completed during the first half of 2006.

## Results

The actions taken by the society in 1998 rapidly reversed the negative trend towards low participation. During the new implementation and support phase, participation improved from 12 in 1998 to 27 in 1999 and 32 in 2000. Today 40 out of 45 departments are participating. The first year with acceptable participation, was 1999 when 2,553 patients were included out of the approximately 5,000 lumbar spine procedures estimated to be performed in Sweden each year.

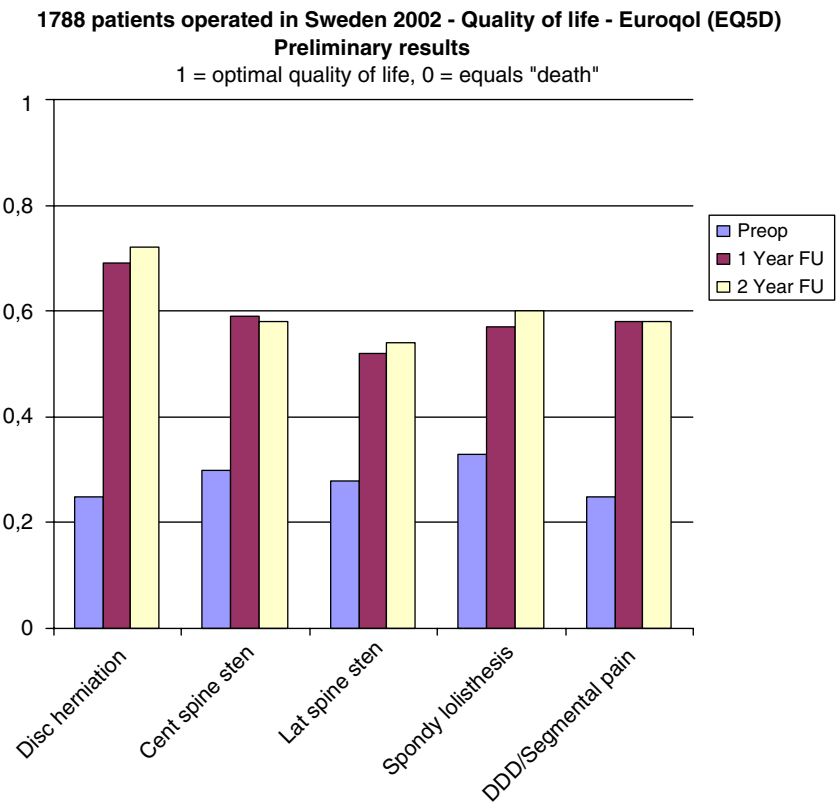
Register results from 2003 is presented in a supplement to *Acta Orthopaedica Scandinavica* [10] and the following illustrations are examples of what can be extracted. At the time of the compilation of data, 35/45 departments had registered 2,894 patients who had undergone surgical treatment for degenerative lumbar spine disorders such as disc herniation, central or lateral spinal stenosis, spondylolisthesis or segmental (discogenic) pain. In all, 34% of registered procedures were related to disc herniation and 11% to segmental pain (Fig. 1).

In the current paper, only outcome result reflecting changes in health-related quality of life is presented, as



**Fig. 1** Lumbar spine procedures

**Fig. 2** One thousand seven hundred and eighty-eight patients operated in Sweden 2002—quality of life—Euroqol (EQ5D): preliminary results



demonstrated using the preference-based instrument Euroqol (EQ-5D) [1]. This instrument also offers the option of cost-effectiveness analysis.

Analyses of the data collected demonstrate that surgical interventions have resulted in considerable improvement in quality of life after 1 and 2 years. The difference is comparable to that achieved after hip arthroplasty, which is an average improvement of 0.37 (Personal communication with Göran Garellick, Orthopaedic surgeon at the Sahlgrenska University Hospital, Göteborg, Sweden) (Fig. 2).

#### Lessons learned: summary

##### *Implementation of a national spine register*

When the society was given the responsibility and initiated the actions described above, affiliation rate increased from 15 to 80% in a few years. Establishing a 'Register Group' responsible for the 'field work' was one important factor for success. Other important factors included transforming ownership of all data to the society, involving all members in formulating the register, finding key individuals willing to do the work, making the register mainly patient-based and communicating with politicians and administrators responsible for fund allocation.

Another psychological circumstance that might have played a role in the implementation phase was that 25 leading spine surgeons in the country (total approximately 100) had been engaged in the Swedish lumbar spine study. This large study was planned 1990–1992, ran until 1998 and has been reported since 2001 [3–8]. Meetings, characterised by intense daily discussions and friendly evening sessions, have been arranged at least annually. The collegial friendship thus established between doctors may have played a role when discussing the national spine register.

Another potential influence on the process was the growing awareness during the 1990s that administrators and politicians responsible for healthcare economics and for setting priorities among different treatment alternatives would request register-based reports. In addition, two big private spine clinics with a considerable annual volume of the total national spine procedures were asking for register data to be used for marketing and negotiation purposes. This growing interest created a favourable platform when discussing affiliation with a national spine register.

Finally, interest from the funding authorities was substantiated in 2003, when the National Board of Health and Welfare established the 'National Centre of Excellence for Orthopaedic disorders' (NKO). The mission was to support quality registers within the field of musculoskeletal disorders and to help produce reports

that could be used to compare results from different specialities.

### *Spine data in a healthcare context*

Although indications for surgical interventions for spinal disorders are few in relation to lifetime incidence and prevalence, due to the high prevalence surgery is still very common. In Sweden, surgeons perform approximately 80 procedures per 100,000 inhabitants annually, a total of about 7,200. Since there are approximately 50 departments that treat spine disorders (45 orthopaedic and 5 neurosurgical), this should mean 150 procedures per unit. Obviously, some departments perform rather few procedures, while others may count up to 700. Other countries, or regions within countries, report considerably higher numbers [13]. Data from national registers could be used to discuss relevant numbers of surgical procedures per inhabitants.

### *Economics in registering*

Despite professional help, the workload involved for surgeons in terms of implementation, support and reporting will be considerable. This commitment is not to be taken lightly and one considerable problem is that until now, dedicated doctors have done the work during their spare time. If register data are requested because they can help in making relevant assumptions about cost-utility and cost-effectiveness in spine surgery and thus in setting priorities among healthcare activities, then it should be obvious that all involved should be given the time and financing necessary to accomplish the task. This issue is a matter of urgency, at least in Sweden.

### *Data handling*

It is important to consider where to place the server to host register data. In Sweden today, this should preferably be outside the universities, as easy access to data could otherwise be hindered by policies characterised by static security bureaucracy, and not by accessibility and support. The situation could be different in other countries. Because of this situation, we signed an agreement with a company that could offer relevant up-to-date software that could be developed and that is capable of handling the register according to our demands. The agreement clearly stated economic terms and conditions, as well as all other responsibilities, including consequences in case of non-deliverance.

A national register should be able to communicate with other national and international registers, like the Spine Tango, as this will enable comparisons between diagnostic entities as well as between nations. This calls

for well planned strategies and flexible data applications, which should be taken into consideration from the start.

Compliance with registering depends on several conditions. It should be emphasised that results associated with a specific department should be regarded as the property of this department. The contributing department must be able to compare results online with national or international data. At present, at least in Sweden, the authorities are pushing for opening up register data for the public, both on a clinical, but also on a doctor's level. The profession should be prepared by internally choosing data that can be analysed and understood by the patients and laymen (see below).

### *Register era*

There are many reasons for spine surgeons to adopt the strategy of registering, including the goal of placing spine surgery on the frontline to enhance the credibility of our profession.

Strong determinants may also be reimbursement associated with registering. Non-participating departments may encounter economic disadvantages on the healthcare market. If we believe that registering will be mandatory in the near future, we should initiate this process within the profession, which would give the advantage of deciding on the variables we consider relevant in spine surgery, which we chose to report for comparative purposes.

### *Summary and future direction*

The experiences from Sweden speak in favour of a national register being administered by a national organisation. From the point of legacy and functionality, this has proved to be an advantage. We conclude that spine surgeons should include their patients in registers in order to transparently document efficiency of treatment. The Swedish experience so far is limited to the degenerative lumbar spine. For the future we expect to continue in the following areas:

- extension to the cervical and thoracic spine (beginning of 2006)
- inclusion of deformities, fractures, tumours and infections (beginning of 2006)
- online real-time reporting to participating clinics (October 2005)
- online national standard reports accessible to the public (2006)
- cooperation with international spine registers and national orthopaedic registers (2006)
- internet based follow-up questionnaires (2006).

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