ORIGINAL ARTICLE

The Norwegian registry for spine surgery (NORspine): cohort profile

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Abstract

Purpose To review and describe the development, methods and cohort of the lumbosacral part of the Norwegian registry for spine surgery (NORspine).

Methods NORspine was established in 2007. It is government funded, covers all providers and captures consecutive cases undergoing operations for degenerative disorders. Patients' participation is voluntary and requires informed consent. A set of baseline-, process- and outcome-variables (3 and 12 months) recommended by the International Consortium for Health Outcome Measurement is reported by surgeons and patients. The main outcome is the Oswestry disability index (ODI) at 12 months.

Results We show satisfactory data quality assessed by completeness, timeliness, accuracy, relevance and comparability. The coverage rate has been 100% since 2016 and the capture rate has increased to 74% in 2021. The cohort consists of 60,647 (47.6% women) cases with mean age 55.7 years, registered during the years 2007 through 2021. The proportions > 70 years and with an American Society of Anaesthesiologists' Physical Classification System (ASA) score > II has increased gradually to 26.1% and 19.3%, respectively. Mean ODI at baseline was 43.0 (standard deviation 17.3). Most cases were operated with decompression for disc herniation ($n = 26{,}557$, 43.8%) or spinal stenosis ($n = 26{,}545$, 43.8%), and 7417 (12.2%) with additional or primary fusion. The response rate at 12 months follow-up was 71.6%.

Conclusion NORspine is a well-designed population-based comprehensive national clinical quality registry. The register's methods ensure appropriate data for quality surveillance and improvement, and research.

Keywords Quality registry · Spine surgery · Degenerative disorders · Cohort profile · Data quality

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Introduction

The Norwegian Registry for Spine Surgery (NORspine) is a comprehensive national clinical quality registry established in 2007. Cases of patients operated for degenerative disorders in the lumbosacral and cervical spine are recorded in separate registers. This paper is the first of two and comprises the development and methods of the lumbosacral register. The subsequent paper discusses results of quality improvement and research based on data from the register.

Low back and neck pain are major causes of non-fatal health loss worldwide, and in Norway back pain is the most common cause for short-term sick leave and the second most common for disability benefits [1, 2]. A Cochrane review published in 1999 found conflicting evidence on the effectiveness of surgical treatment for degenerative lumbar disorders [3]. Still, 3460 to 4572 patients per year were operated in Norway for such disorders between 1999 and 2005 [4]. Insufficient quality assurance, lack of evidence-based clinical guidelines and the fact that spine surgery is preference-sensitive [5], has contributed to variation in surgical rates and techniques between hospitals, health regions and countries [6, 7].

Registries are useful for surveillance of quality, to attain more uniform and evidence-based clinical practices, as a data source for research, and for development of guidelines [8]. During the 1990s and 2000s, several spine registries emerged [8]. NORspine acquired inspiration from the Swedish spine registry (Swespine) which was the first in Scandinavia [9]. Some other are the Danish national lumbar spine database (DaneSpine), the European Spine Tango, the American Spine Registry, and the Australian Spine Registry [8, 10–12].

NORspine's [13] objectives are to surveil and improve the quality of surgical treatment of degenerative conditions in the lumbosacral spine. Facilitation of and contribution to research are secondary objectives.

Objective

The aim of this report is to review and describe NORspine's development, concepts, methods, cohort and future perspectives.

Development of NORspine

In 2000, the University Hospital of North Norway (UNN) established a single-institution database of consecutive cases operated in the lumbosacral spine. This was expanded to a government funded national registry, the NORspine, in 2007 (version 1.0). The establishment was supervised by a steering committee (advisory board from 2015) consisting of neurosurgeons and orthopaedic surgeons representing the four health regions and the national societies for neurosurgery, orthopaedic surgery and spine surgery.

All Norwegian hospitals providing spine surgery signed data processing agreements. This allowed encrypted online transfer of baseline data through the Norwegian Health Network, or alternatively, through a virtual private network (VPN) to a central data administration unit.

At 3- and 12-month follow-up, all reporting was questionnaire-based, and from 2009 (version 2.0) managed by NORspine's administration without any involvement of the treating hospitals. Follow-up at 24 months was omitted because a study from the UNN database showed little health change but, a significant decrease in response rate from 12 to 24 months [14]. Patients responded at home, returning scannable questionnaires in pre-stamped addressed envelopes. Non-respondents received one reminder. From 2018, all patients received an additional short message service (SMS) reminder about returning the questionnaire. In April 2022, an electronic solution (ePROM) was introduced as the main follow-up routine [15].

To obtain adequate data for quality improvement and research, NORspine's initial priority was data collection and validation. Clinical data were available online for each hospital through interactive and continuously updated reports, which from 2013 included benchmarking. Comprehensive annual reports were published from 2010. National quality indicators with benchmarks were established and revised annually. These enable comparison of results between hospitals and against aggregated national figures.

NORspine version 3.0 was launched in 2019 with revised questionnaires according to the International Consortium for Health Outcomes Measurement (ICHOM) recommendations [16]. Both patients' and surgeons' questionnaires were expanded with new variables. The consent form and the questionnaires were available in Norwegian only until English versions became available from 2022 (Online Resource 1, 2, 3, and 4).

NORspine's methods

Study design

NORspine can be regarded a large population-based study comprising a national cohort. This paper is therefore reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies [17].

We report baseline data for cases operated until December 31, 2021, follow-up data for cases operated until December 31, 2020 and the methods used and administrative development until December 31, 2022.

Setting

Public Norwegian healthcare is a single-payer tax-based system with universal access. Holding a private health insurance is uncommon (10% of the population in 2017) [18]. Healthcare is free of charge with a small co-payment (annual cap for 2022; EUR 270). Public hospitals are organised under the Ministry of Health and Care Services' four regional health authorities. Both public and private hospitals provide spine surgery. Private hospitals treat patients with private insurance and patients who pay out of pocket. They may also contract with a regional health authority and provide publicly funded care for defined time periods.

Organisation and daily operations

The registry is a unit under the neurosurgical department at the UNN, led by an academic director (20%) and staffed with a coordinator/administrative lead (100%), a secretary (50%), and a professor (10% position). Ph.D. students and researchers with external funding from non-commercial sources may be affiliated for specific projects. The National Service Environment for Clinical Quality Registries provides advice on legal issues and statistical support for surveillance of data quality and reporting. The Northern Norway Regional Health Authority ICT Trust is IT vendor and developer. They collaborate with the Norwegian Health Network who coordinates access to secure e-health solutions.

At reporting units, a designated employee, preferably a spine surgeon, is responsible for data processing, while coordinators (usually a nurse or secretary) collect paper-based baseline questionnaires and consent forms, and punch data.

The advisory board guides data collection, management, analysis, and presentation. They define quality indicators, initiate quality improvement measures, direct research, process applications for data access and approve annual reports before publishing.

An annual open meeting gathers the register administration, the advisory board, local coordinators and surgeons, patients' representatives, and any other stakeholders.

Funding

Funding is through the Northern Norway Regional Health Authority. NORspine receives no additional funding from industry or other stakeholders. The operating budget was EUR 242 000 in 2022. This included all labour and running costs for the registry administration. Costs for support from the National Service Environment for Clinical Quality Registries and the Northern Norway Regional Health Authority ICT Trust are embedded in a common budget for services to numerous other registries, and not possible to estimate specifically for NORspine.

User involvement

User involvement is coordinated by the Norwegian Spine Patients Association (Ryggforeningen). Their president is a member of the advisory board. The association facilitates information about and feedback on reports, findings, and recommendations through publications and meetings for users. They also organise user involvement in research- and improvement-projects.

Register cohort

All consecutive patients operated in public and private hospitals for degenerative disorders in the lumbosacral spine are eligible, with exception of patients precluded from consenting because of age < 16 years, severe psychiatric disorder, substantial drug abuse, cognitive impairment, or language barriers. Patients operated for tumours, trauma, primary infection or non-degenerative scoliosis are not eligible.

A reoperation within 90 days is registered as a complication to the index operation and not as a new case. Contrary, another operation after ≥ 90 days is considered a new case, and previously scheduled follow-ups are replaced by new follow-ups, 3 and 12 months after the latest operation.

Participation is voluntary and requires informed consent. Patients have a legal right to access, correct, or delete their data at any time [19]. For providers and healthcare personnel, giving information to eligible patients and reporting to national clinical quality registries became a legal obligation in 2019 [19]. Partaking is free and supported by a small reimbursement for providers (in 2022 EUR 18) for each registered case.

Data collection and variables

NORspine uses a set of baseline-, process- and outcome-variables recommended by the ICHOM [16]. Data are recorded prospectively by patients, surgeons, and local coordinators. Figure 1 shows the data collection process and Table 1 an overview of the variables. The main outcome measure is the Oswestry Disability Index (ODI) at 12-month follow-up. Important secondary outcomes are EuroQol 5 Dimensions 5 Levels (EQ-5D-5L), numeric rating scales (NRS) for back- and leg-pain, and the Global Perceived Effect (GPE) scale.

Patients report sociodemographic, health- and disease-related data such as comorbidities, previous treatments, waiting times and patient-reported outcome measures
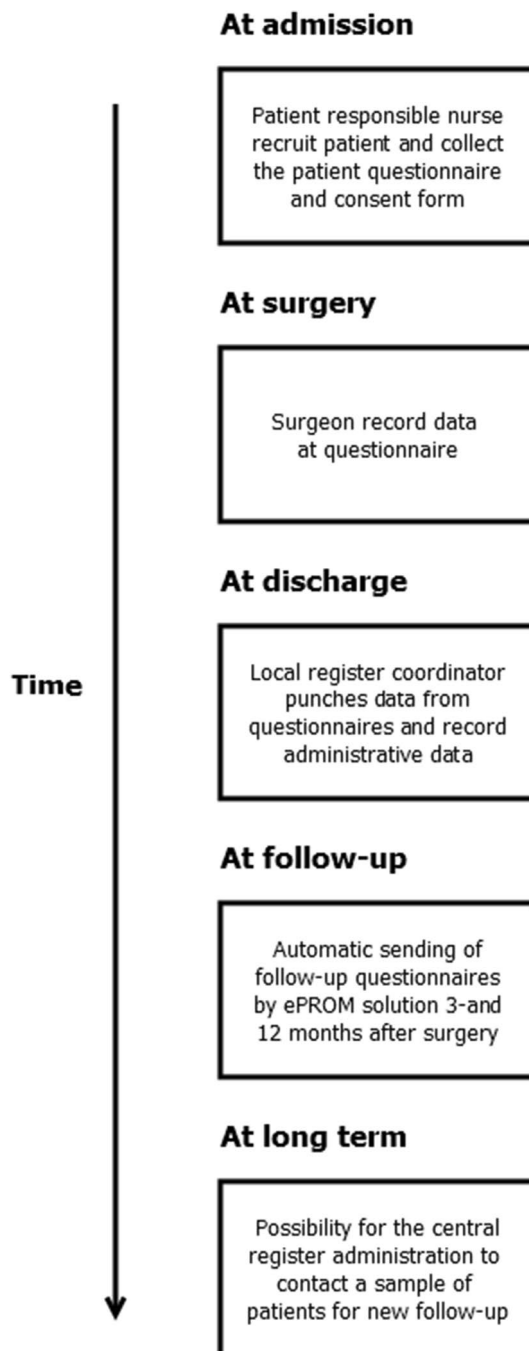
At admission

Patient responsible nurse recruit patient and collect the patient questionnaire and consent form

At surgery

Surgeon record data at questionnaire

At discharge

Local register coordinator punches data from questionnaires and record administrative data

At follow-up

Automatic sending of follow-up questionnaires by ePROM solution 3-and 12 months after surgery

At long term

Possibility for the central register administration to contact a sample of patients for new follow-up

Time

Fig. 1 Data collection process

(PROMs) at baseline. At follow-ups, they report PROMs, patient-reported experience measures (PREMs), and post-operative complications. NORspine has established a possibility for re-contacting sub-groups for long-term follow-ups, e.g. for research purposes. This requires supplemental external funding.

Surgeons report data about clinical and radiological diagnosis(es), relevant comorbidity, previous spine surgery, clinical examination findings, type and duration of surgery

and intraoperative complications. Based on all these variables, a validated algorithm (available upon request) defines main diagnosis and treatment (type of surgery) categories.

The main categories can be drilled down to more granular subcategories, based on information from the questionnaire (Online Resource 4). Since many diagnoses and treatments coexist, the system is hierarchical. This means that for each case, the most comprehensive type of surgery will define only one of eight unique main treatment categories (e.g. fusion surgery). Next, these are divided into 18 more specified subcategories (e.g. type of fusion technique). These can be further subclassified if additional procedures have been performed (e.g. different types of decompression). A corresponding logic has been established for categorization of the diagnoses. This enables definition and analysis of subgroups of cases defined by specific combinations of diagnoses and treatments at an increasingly granular level (example in Online Resource 5). This also means that diagnosis and treatment categories (which may change over time) are dynamic and can be redefined, since they are not predefined on surgeons' forms in fixed categories.

At discharge, local coordinators report the length of hospital stay and perioperative complications, including death.

Follow-ups apply the electronic reporting system ePROMs [15]. This is a generic solution for collection of patient-reported data for Norwegian clinical quality registries. Electronic questionnaires are mailed through the Norwegian Health Network or a public digital postal service (Digipost). More than 80% of the population are users [20].

Patients get a notification (by e-mail, short message service (SMS), or in the Digipost app, according to individual settings). They complete and return the questionnaire electronically to NORspine's database. Non-respondents (after two digital inquiries) and digitally inactive patients are contacted by ordinary post according to previous routines. Thereafter, one more reminder is sent to non-respondents. Integration with the National Population Register assures continuous updating of addresses, and that deceased patients are not invited to follow-ups. In addition, this enables calculation of mortality rates.

Data quality

Completeness

Completeness is the extent to which all data that could have been registered, are recorded [21]. Coverage rate (at provider level), capture rate (at case level), response rate at follow-ups, and datapoint completeness describe this attribute.

The Norwegian Patient Registry (NPR) records the International Classification of Diseases, 10th revision (ICD-10) codes, and the Nordic Medico-Statistical Committee (NOMESCO) Classification of Surgical Procedures (NCSP)

Table 1 Overview over variables in NORspine version 3.0

	Variable	Baseline[a]	Follow-ups[b]
Administrative variables	Case ID	X	
	Providing hospital and department	X	
	Sociodemographic variables		
	Age at day of surgery	X	
	Gender	X	
Patient reported	Education level	X	
	Work status including sickness- and disability-benefit and work assessment allowance	X	X
	Civil status	X	
	Native tongue, ethnical affiliation and native country	X	
	Fear avoidance beliefs	X	
	Unresolved disability or health insurance claims	X	X
	Health variables		
	Smoking and use of snuff (other tobacco)	X	
	Height and weight	X	
	Clinical variables		
	Earlier conservative treatment for current condition	X	
	Preoperative duration of symptoms (back- and leg-pain)	X	
	Analgesic use	X	X
	New medical conditions or injuries developed during follow-up		X
	Process variables		
	Duration of waiting period from referral to specialist assessment and operation	X	
	New lumbar spine surgery during follow-up		X
	PROMs and PREMs		
	Oswestry disability index	X	X
	EQ-5D-5L	X	X
	EQ-VAS (0–100)	X	X
	NRS back pain over the last week (0–10)	X	X
	NRS leg pain over the last week (0–10)	X	X
	Global Perceived Effectiveness of the operation		X
	Contentedness with the hospital care		X
	Complications		X
Provider reported	Process variables		
	Date of admission to and discharge from hospital	X	
	Date and time of surgery	X	
	Categorisation (urgency of operation, in-/outpatient-surgery)	X	
	Surgeon's and assistant's experience (within spine surgery)	X	
	Patient characteristics		
	Relevant comorbidity (sub grouped)[c]	X	
	ASA classification	X	
	Use of anticoagulant or immunosuppressive drugs	X	
	Earlier lumbar spine surgery (level(s), number and type of operation(s))	X	
	Radiological modality used and findings (subclassified and graded)	X	
	Neurological deficits including paresis and cauda equina syndrome (graded 0 to 5 and duration)	X	
	Clinical tests (Lasegue's test and flexion relief)	X	

Table 1 (continued)

Variable	Baseline[a]	Follow-ups[b]
Operation details		
Operated level(s) (both for decompression and fusion)	X	
Detailed surgical technique[d]	X	
Type of decompression		
Type of fusion		
Other surgical technique		
Two most important NCSP-codes to describe the operation		
Use of Safe surgery checklist	X	
Visual magnifiers	X	
Navigation system	X	
Antibiotic prophylaxis	X	
Thrombosis prophylaxis	X	
Wound drain	X	
Perioperative complications, e.g.:	X	
Nerve root injury		
Dural tear/CSF leakage		
Cardiovascular		
Implant malposition		
Surgery at wrong site		
Reoperation during admission		
Death in hospital		
Duration of surgical procedure	X	

[a]Reported during admission for surgery

[b]Reported at 3-, 12-month and possibly at long-term follow-up

[c]Sub grouped into following categories: Rheumatoid arthritis; Ankylosing spondylitis; Other rheumatoid disease; Gon- or coxarthrosis; Anxiety or depression; Generalised pain disorders; Chronic neurological disease; Cerebrovascular disease; Coronary heart disease; Vascular claudication; Chronic pulmonary disease; Cancer; Osteoporosis; Hypertension; Diabetes mellitus; Other endocrinological disease; Other

[d]For possibility for classification into the following categories: Surgery due to disc herniation (subgrouped into microsurgery and open surgery); Midline preserving decompression; Fusion surgery (subgrouped into PLF, PLIF, TLIF, ALIF, XLIF and undefined); Laminectomy; Implantation of disc prothesis; Revision or removal of implant; Osteotomy; Implantation of expanding intraspinal implant; Other undefined

codes for all publicly funded specialist health care. Reporting is prerequisite for reimbursement. Standardised methods for calculation of the capture rate based on merging of NPR (denominator) and NORspine (numerator) data were developed in 2011, and rates were calculated back to 2008. Only cases with complete baseline datasets are included in these analyses. Capture rate analyses are routinely repeated biannually. Three studies [4, 7, 22] applied this method to calculate age- and sex-adjusted surgical rates at national and provider level, and the rates were comparable to those found in NORspine´s analyses [23].

Timeliness

Data must be available in time for surveillance of quality and scheduling of follow-ups. NORspine therefore surveils time from the operation to completion and punching of data from the baseline questionnaires.

Accuracy

Accuracy expresses the extent to which registered data are true [21]. It is important to use instruments with high validity and reliability to obtain accurate measurements and decrease the risk of information bias [24].

The register´s software has embedded logical restrictions to prevent registration of false and obviously erroneous values, and flag outliers. In addition, logical checks to identify outliers and systematic errors are performed annually.

The PROMs are valid and reliable in a Norwegian setting [16, 25–27].

Relevance and comparability

The dataset is in line with the ICHOM [16] recommendations, which facilitates comparability with other register cohorts [28]. This is exemplified by three studies merging

data with other Scandinavian registries [29–31] and one study comparing data with the Research Patient Data Registry in Massachusetts, USA [32]. Registration of all known important predictors for outcome facilitates case mix adjustment, prognostic factor research, and predictive modelling.

Uninterrupted data collection, classification of diagnoses, treatment categories and outcome measures since 2007 assure internal temporal comparability.

Data availability

All providers have real-time online access to their data for quality improvement purposes. They may subscribe for quarterly automatically generated PDF reports for benchmarking with other providers.

Patients also consent to their use of data for research purposes. This includes merging with electronic heath record (EHR) data, other Norwegian health registries, and spine registries in other countries. Patients also consent to be contacted beyond the scheduled follow-ups, enabling long-term follow-ups, and recruitment to NORspine-associated studies.

Researchers are welcome to submit applications for data. Until 2022, NORspine had contributed to 73 peer-reviewed international publications.

Quality reporting

Benchmarking

A minimal clinical important change (MCIC) is the smallest improvement on an outcome scale being perceived as beneficial by a patient [33]. An expert panel workshop which based it's assessment on a literature review suggested a MCIC cut-off for ODI at 10 points reduction from baseline [34].

Instead of reporting MCIC, it is recommended to report substantial improvements for benchmarking [35]. This is to ensure that differences are perceived as truly beneficial, reflecting treatment success for the patient. Such criteria can be used to compare surgical effectiveness, both temporally and between surgical departments or interventions [33, 36]. In contrast to MCIC, a success criterion can serve as a more ambitious and motivating benchmark for clinicians and registries aiming to improve quality. The GPE scale assesses the patient's global perceived effect of the operation on a balanced 7-point Likert scale, from *completely recovered* to *worse than ever*. Accordingly, NORspine has developed GPE-anchored criteria for classification of outcomes [36–39].

Quality indicators

The advisory board now recommends five quality indicators (QI); three process- and two outcome measures. Seven former QIs were omitted in 2022 because their objective was achieved or they had overlapping purposes with other QIs. Table 2 summarises present and former QIs and presents aggregated national results for 2021.

The process indicators are evidence based and the outcome indicators aim to motivate surgeons to find measures to increase the proportion of cases with successful outcomes. Among patients operated for LDH and LSS, long duration of symptoms and minor leg pain are predictors for unfavourable outcomes [40, 41].

Data handling and analysis in this report

We retrieved a dataset containing all cases registered between 1 January 2007 and 31 December 2021. For 15,943 cases scored with EQ-5D-5L, we used a 5L crosswalk to derive corresponding EQ-5D-3L values [42].

Considering the *central limit theorem*, means of continuous variables were presumed to be normally distributed due to the large sample size. We present descriptive data as means with standard deviations (SD) or 95% confidence intervals (CI) and counts with percentages for proportions. Mean difference between groups were analysed with two-way students t-test for continuous variables and Pearson's chi-squared test for categorical variables. The statistical significance level was set to $p < 0.05$. We used the Statistical Package for the Social Sciences (SPSS; version 28 (IBM Armonk, NY: IBM Corp)) for statistical analysis.

Results

Data quality

Completeness

The coverage rate has been stable at 100% for public and private providers since 2016.

Analyses based on comparison with the NPR showed that the number of cases and the capture rate increased gradually to 5980 and 74% in 2021 (Fig. 2) [23]. A dropout analysis revealed incomplete reporting of emergency surgery, especially during weekends and holidays, while the capture rate for elective surgery was 76% [23]. A supplemental analysis in 2021, which also included cases operated without public funding at private hospitals, indicated a total capture rate of 81% [23].

Table 2 Quality indicators (QIs)

	Quality indicator	High benchmark	Moderate benchmark	National result (2021)
Present process indicators	Proportion of cases with waiting time under three months from decision-making to surgery[a]	> 80%	50–80%	60.9%
	Proportion of cases with minor leg pain (NRS ≤ 3) and no paresis before surgery for LDH[b]	< 3%	–	6.1%
	Proportion of primary operations for LDS where fusion surgery is utilised[c]	≤ National results	–	–
Present outcome indicators	Proportion of cases reporting considerable improved function in everyday life (ODI) after surgery for LDH[d]	≥ National results	–	68.0%
	Proportion of cases reporting considerably improved function in everyday life (ODI) after surgery for LSS[e]	≥ National results	–	65.5%
Former process indicators[f]	Proportion of baseline questionnaires not registered within three months postoperatively[g]	< 3%	3–10%	7.5%
	Proportion of cases with use of safe surgery checklist[h]	> 95%	60–95%	> 99%
	Proportion of cases with duration of leg pain > 12 months before surgery for LDH	< 20%	–	24.5%
Former outcome indicators[f]	Proportion of cases suffering surgical site infection after surgery for LDH	< 2%	–	1.1%
	Proportion of cases suffering surgical site infection after surgery for LSS	< 3%	–	2.4%
	Proportion of cases with dural tear on the occasion of surgery for LDH	< 2%	–	0.7% [i]
	Proportion of cases with dural tear on the occasion of surgery for LSS	< 3%	–	2.5% [i]

[a]From preoperative shared decision-making between patient and surgeon

[b]To reduce proportion of patients operated with a faulty indication

[c]New in 2022

[d]≥ 20-point improvement of ODI-score from baseline to 12-month follow-up

[e]≥ 30% improvement of ODI-score from baseline to 12-month follow-up

[f]Omitted in 2022

[g]To increase proportion available for 3-month follow-up and thereby improve data quality

[h]To improve patient safety at the operation theatre

[i]Aggregated for 2020 and 2021

Published studies report response rates at 12-month follow-up ranging from 65 to 85% in 9 different sub-sets of the cohort [36–38, 43–48]. Internal audits of the total cohort show stable response rates around 70–75% [49]. A recent re-catch study [50] of 474 cases operated at four hospitals found a rate of 70%. Non-respondents were younger and more frequently smokers than respondents, but there were no differences in outcomes between the groups. An older study [14] found a response rate of 78%, and the non-respondents were younger, had shorter hospital stays, and were more likely to live alone. Non-respondents had fewer complications, but there were no differences in PROMs between groups.

Datapoint completeness is evaluated annually, and the mean was found stable above 97% for important variables [23].

Timeliness

Time from the operation to completion of the baseline questionnaires is satisfactory (median 1 and 0 days for patients' and surgeons' questionnaires, respectively) [23]. In 2021, 53% of the baseline data were punched and available within 4 weeks. Contrary, 7.5% of the cases were unavailable for 3-month follow-up due to delayed registration at baseline [23].

Fig. 2 Time trends for annual number of cases and capture rate, 2008–2021
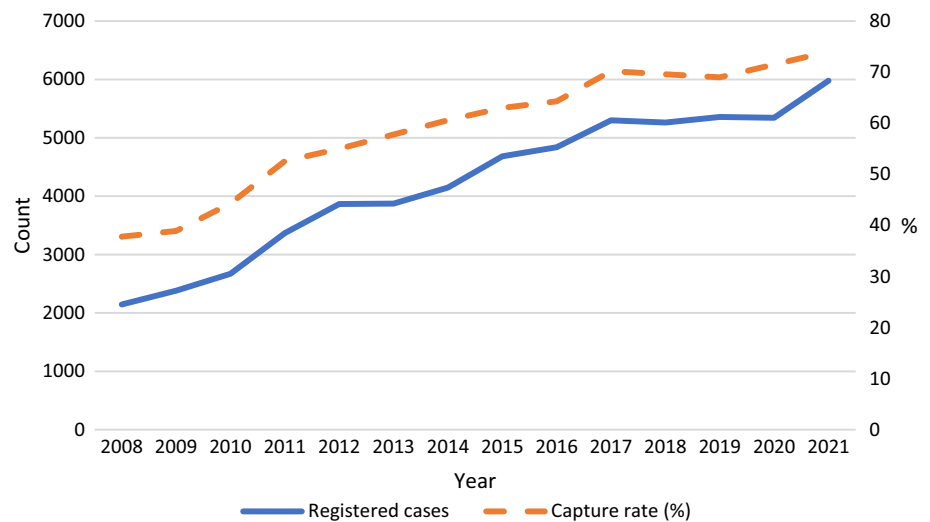
Accuracy

An audit in 2010 revealed error rates of 0.3% during punching of data and 0.04% after scanning of forms [23].

In 2012, a study re-examined magnetic resonance images (MRI) of 178 cases registered with lumbar disc herniation (LDH) and confirmed the diagnosis at the operated level in all [51]. A similar study from 2016 re-assessed MRIs of 202 cases registered with lumbar spinal stenosis (LSS) and confirmed the diagnosis for all [43]. In 2022, a study compared baseline data in the EHR at four public hospitals with data in NORspine [52]. It showed strong to excellent agreement for perioperative details (kappa ranging from 0.76 to 0.98) and excellent for patient-reported variables (kappa ranging from 0.93 to 0.99) [52]. The study reported weak agreement for surgeon-reported complications (kappa = 0.51) and moderate for The American Society of Anesthesiologists Physical Status Classification System (ASA classification) (kappa = 0.73).

An internal audit compared data in EHRs to NORspine's algorithm-based classifications of treatments (types of surgery), and found only 3% misclassification [53].

Benchmarks

NORspine has conducted several GPE-anchored receiver operating curve analyses [33] to define criteria for success, failure and worsening at 12-month follow-up [36–39]. Table 3 shows these benchmarks, which are part of the routine reporting from the registry. As an example, the figure in Online Resource 6 shows boxplots of the ODI change stratified by GPE outcome categories, and relative to the MCIC and NORspine's success criterium for patients operated for LDH.

The cohort

Table 4 shows an overview of the cohort's baseline characteristics.

Until 31 December 2021, 60,647 cases were registered. 28,865 (47.6%) were females and the mean age was 55.7 years. The proportion > 70 years increased from 12.0% in 2008 to 26.1% in 2021 and the proportion with ASA classification > II from 9.9% in 2012 to 19.3% in 2021 (Fig. 3).

Mean scores (SD) for the PROMs at baseline was ODI 43.0 (17.3); NRS for leg pain 6.7 (2.3); NRS for back pain 6.5 (2.3); and EQ-5D-3L 0.35 (0.33).

Of the total cohort, 26,557 (43.8%) and 26,545 (43.8%) were operated with decompressive surgery for LDH and LSS, respectively. Among cases operated for LSS, 4002 (15.1%) had additional lumbar degenerative spondylolisthesis (LDS).

Totally, 7417 (12.2%) had undergone fusion surgery. In this group, 3739 (50.4%) had LSS (of which 1 385 (37.0%) had additional LDS), and 1383 (18.6%) had isthmic spondylolisthesis.

For cases registered until the end of 2020, the response rate was 71.8% at 3- and 71.6% at 12-month follow-up.

Table 3 Criteria for success, failure and worsening in the NORspine cohort

	LDH surgery	LSS surgery
Success	ODI reduction ≥ 20 points	ODI reduction ≥ 30%
Failure	ODI reduction < 33%	ODI reduction < 20%
Worsening	ODI raw score > 48 points at follow-up	ODI raw score ≥ 39 points at follow-up

Respondents and non-respondents

Table 5 provides an overview of differences in baseline characteristics between respondents and non-respondents at 12-month follow-up for all cases until 31 December 2020 ($n = 54,644$). All characteristics, except perioperative complications, were statistically significantly different between the groups.

The respondents were older than the non-respondents, with a mean age of 57.7 (95% CI 57.6 to 57.9) and 49.9 (95% CI 49.7 to 50.2) years, respectively. There were lower proportions living alone, receiving sickness benefits, being a current smoker and having anxiety and/or depression, and a higher proportion reporting any relevant comorbidity among the respondents compared with the non-respondents (Table 5).

Discussion

This report on NORspine's development, methods and cohort illustrates that establishing a national register is a laborious time- and resource-demanding process. It was made possible by a few enthusiastic spine surgeons supported by national professional societies and funding from health authorities. Thereafter, continuous development and improvement have been necessary to ensure data quality, data management and reporting. During this phase, waning attention from the funding authorities has been a challenge.

Nevertheless, we show that NORspine now is a well-designed and comprehensive national clinical quality register for lumbosacral spine surgery. It contains continuously updated validated data of acceptable quality on a large national cohort of cases.

Since the initiation in 2007, patients' age and the proportion with ASA classification > II have increased. This indicates that spine surgeons are faced with more resource-demanding and complex cases, due to an ageing and frailer patient population.

Interpretation

Other spine registries

In 2002, Arts et al. suggested a generic framework for the organisation of and data quality in medical registries [21]. Drolet and Johnson detailed the requirements in 2008 by suggesting that registries must contain mergeable (M) and standardised data (D) collected according to specific rules (R) and that cases should be observed (O) over time for knowledge (K) about outcomes (the MDR-OK framework) [54]. Van Hoof et al. specifically reviewed the literature about spine registries in 2015, and developed

recommendations to improve the quality of studies from such registries [8]. In addition to adherence to the MDR-OK, they recommended that registries should incorporate strategies to improve the quality of care, follow-up for at least one year, register the prognostic factors recommended by ICHOM to enable case-mix adjustments and link with EHRs to avoid double data entry. NORspine was organised and developed in accordance with these requirements, and now complies with all recommendations except integration with the EHR.

The design of NORspine, Swespine and DaneSpine are similar [9, 10, 23, 55, 56]. One difference is that NORspine requires informed consent, while Swespine and Danespine have opt-out legal regulations. This may contribute to the difference in capture rates, which were 81% in NORspine and 86% in Swespine in 2021 [23, 56]. In addition, NORspine's capture rate is strictly defined, i.e. only cases with complete datasets, comprising both patients' and surgeons' baseline forms, are included. Importantly, the methods for calculation of capture rate might differ between spine registries, and should be documented.

Two studies compared cohorts operated for LDH and LSS across the three Scandinavian registries [29, 30]. They found that the gender distribution, mean age and BMI were similar at baseline. Otherwise there were only minor differences in baseline characteristics, which could easily be controlled for in pooled analyses [46, 47]. The Scandinavian countries comprise a relatively homogeneous population, and have similar social security and health care systems enabling merging and comparison of population-based data [29]. Still, the surgical rate for LDH in Sweden seems to be only half of those in Denmark and Norway [30]. Further standardisation of registry protocols across countries could improve the understanding of such discrepancies, and facilitate analyses of the potential impact of utilisation rates on outcomes.

Spine Tango, the American Spine Registry, and the Australian Spine Registry are based on institutional memberships [11, 12, 57, 58]. Optional participation for providers probably causes selection of institutions with a special interest in spine surgery or quality improvement, and capture skewed towards complex cases undergoing more specialised surgery. Therefore, the external validity of these registries is likely to be lower than for the population-based Scandinavian registries. They do, however, provide useful insights into other aspects, e.g. comparison of outcomes of specific procedures, when baseline characteristics are well described. This means that data merging across registries with different capture profiles requires careful case mix adjustment.

Strengths and limitations

NORspine assesses data quality by accuracy, completeness, relevance, timeliness and comparability [21, 23, 59]. It is a

Table 4 Baseline characteristics of the NORspine cohort

	LDH surgery		LSS surgery		Other surgery		Total cohort	
Total cases, *n* (%)	26,557	(43.8)	26,545	(43.8)	7545	(12.4)	60,647	(100)
Gender female, *n* (%)	11,066	(41.7)	13,883	(52.3)	3916	(51.9)	28,865	(47.6)
Missing	0	–	0	–	0	–	0	–
Mean age, years, (SD)	46.9	(14.1)	65.2	(11.8)	53.3	(14.4)	55.7	(15.7)
Age years > 70 years, *n* (%)	1640	(6.2)	9934	(37.4)	999	(13.2)	12,573	(20.8)
Missing, *n* (%)	98	(0.4)	45	(0.2)	17	(0.2)	160	(0.3)
Ethnical/cultural affiliation, *n* (%)[a]								
Norwegian	5809	(87.6)	7644	(88.3)	1241	(87.5)	14,694	(88.0)
Other	609	(9.2)	543	(6.2)	117	(8.3)	1269	(7.4)
Missing	211	(3.1)	472	(5.5)	60	(4.2)	743	(4.4)
Educational level, *n* (%)								
Tertiary	10,267	(38.7)	8281	(31.2)	2454	(32.5)	21,002	(34.6)
Missing	343	(1.3)	866	(3.3)	120	(1.6)	1329	(2.2)
Work status, *n* (%)								
Unemployed	391	(1.5)	186	(0.7)	78	(1.0)	655	(1.1)
Currently working[b]	7334	(27.6)	4388	(16.5)	1508	(20.0)	13,230	(21.8)
Sickness and disability benefit[c]	15,533	(58.5)	8872	(33.4)	4275	(56.7)	28,680	(47.2)
Retired	2516	(9.5)	12,054	(45.4)	1418	(18.8)	15,988	(26.4)
Missing	783	(2.9)	1045	(4.0)	266	(3.5)	2094	(3.5)
Current smoker, *n* (%)	6450	(24.3)	4966	(18.7)	1753	(23.2)	13,169	(21.7)
Missing	251	(0.9)	259	(1.0)	101	(1.3)	611	(1.0)
Mean BMI, kg/m^2 (SD)	27.0	(4.6)	27.7	(4.5)	27.1	(4.4)	27.3	(4.6)
Missing, *n* (%)	1499	(5.6)	1108	(4.2)	494	(6.5)	3101	(5.1)
ASA classification > II, *n* (%)	1706	(6.4)	5980	(22.5)	782	(10.3)	8466	(13.9)
Missing	347	(1.3)	340	(1.3)	139	(1.9)	826	(1.4)
Any relevant comorbidity, *n* (%)	8392	(31.6)	17,251	(65.0)	3164	(41.9)	28,807	(47.5)
Gon- or coxarthrosis	386	(1.5)	1848	(7.0)	211	(2.8)	2445	(4.0)
Anxiety or depression	665	(2.5)	831	(3.1)	220	(2.9)	1716	(2.8)
Generalized pain disorders	396	(1.5)	599	(2.3)	186	(2.5)	1181	(1.9)
Coronary heart disease	1569	(5.9)	5457	(20.6)	666	(8.8)	7692	(12.7)
Hypertension	2467	(9.3)	7527	(28.4)	974	(12.9)	10,968	(18.1)
Missing	2065	(7.8)	1434	(5.4)	657	(8.7)	4156	(6.9)
Previous lumbar spine surgery, *n* (%)	6014	(22.6)	7202	(27.1)	3054	(40.5)	16,270	(26.8)
Missing	173	(0.7)	199	(0.7)	66	(0.9)	438	(0.7)
ODI, mean (SD)	46.2	(18.9)	40.1	(15.3)	42.2	(15.5)	43.0	(17.3)
Missing, *n* (%)	212	(0.8)	365	(1.4)	55	(0.7)	632	(1.0)
Leg pain (NRS score), mean (SD)	7.0	(2.2)	6.6	(2.2)	6.0	(2.7)	6.7	(2.3)
Missing, *n* (%)	823	(3.1)	2124	(8.0)	458	(6.1)	3405	(5.6)
Back pain (NRS score), mean (SD)	6.4	(2.4)	6.6	(2.2)	6.7	(2.0)	6.5	(2.3)
Missing, *n* (%)	840	(3.2)	1845	(7.0)	283	(3.8)	2968	(4.9)
Duration of leg pain > 12 months, *n* (%)	6228	(23.4)	15,899	(59.9)	4344	(57.6)	26,471	(43.7)
Missing	1216	(4.6)	1722	(6.5)	487	(6.4)	3425	(5.7)
Duration of back pain > 12 months, *n* (%)	9228	(34.7)	18,937	(71.4)	5406	(71.7)	33,571	(55.3)
Missing, *n* (%)	986	(3.8)	1273	(4.8)	363	(4.8)	2622	(4.3)
EQ-5D-3L, mean (SD)[d]	0.26	(0.62)	0.40	(0.30)	0.34	(0.32)	0.35	(0.33)
Missing	1087	(4.1)	1763	(6.6)	387	(5.1)	3237	(5.3)
Use of painkillers, *n* (%)	22,610	(85.1)	21,422	(80.7)	6239	(82.7)	50,271	(82.9)
Missing	239	(0.9)	291	(1.1)	67	(0.9)	597	(1.0)
Operation category, *n* (%)								
Elective	21,095	(79.4)	25,855	(97.4)	7211	(95.6)	54,161	(89.3)

Table 4 (continued)

	LDH surgery		LSS surgery		Other surgery		Total cohort	
Missing	147	(0.5)	122	(0.5)	79	(1.1)	348	(0.6)
Outpatient surgery, *n* (%)	7640	(28.8)	3727	(14.0)	478	(6.3)	11,845	(19.5)
Missing	712	(2.7)	611	(1.3)	328	(4.4)	1651	(2.8)
Diagnosed with LDS, *n* (%)	187	(0.7)	4002	(15.1)	777	(89.7)	4966	(8.2)
Operated with fusion surgery	0	–	1385	(34.6)	572	(73.6)	1957	(39.4)
Diagnosed with isthmic spondylolisthesis, *n* (%)	69	(0.3)	790	(3.0)	892	(41.9)	1751	(2.9)
Operated with fusion surgery	1	(1.4)	589	(74.6)	793	(88.9)	1383	(79.0)
Type of surgery, *n* (%)								
Microscopic LDH surgery	24,897	(93.7)	0	–	0	–	24,897	(41.1)
Open LDH surgery	1606	(6.0)	0	–	0	–	1606	(2.6)
Middle line preserving decompression	0	–	19,824	(74.7)	2070	(27.4)	21,894	(36.1)
Laminectomy	0	–	2754	(10.4)	345	(4.6)	3099	(5.1)
Fusion surgery	54	(0.2)	3739	(14.1)	3624	(48.0)	7417	(12.2)
Posterior lateral fusion	3	(5.6)	2055	(55.0)	1088	(30.0)	3146	(42.4)
PLIF	1	(1.9)	130	(3.5)	116	(3.2)	247	(3.3)
TLIF	43	(79.6)	1514	(40.5)	1577	(43.5)	3134	(42.3)
ALIF	4	(7.4)	14	(0.4)	643	(17.8)	661	(8.9)
XLIF	2	(3.7)	7	(0.2)	81	(2.2)	90	(1.2)
Undefined	1	(1.9)	19	(0.5)	119	(3.3)	139	(1.9)
Disc prothesis	0	–	9	(0.0)	611	(8.1)	620	(1.0)
Expanding intraspinal implant	0	–	91	(0.3)	0	–	91	(0.2)
Revision or removal of implant	0	–	67	(0.3)	341	(4.5)	408	(0.7)
Osteotomy	0	–	46	(0.2)	62	(0.8)	108	(0.2)
Other undefined	0	–	15	(0.1)	492	(6.5)	507	(0.8)
Respondents, *n* (%)[e]								
At 3 months	16,409	(67.5)	17,817	(76.5)	5019	(69.1)	39,245	(71.8)
At 12 months	16,084	(66.2)	17,880	(76.8)	5158	(73.1)	39,122	(71.6)
At 3 or 12 months	19,174	(78.9)	20,032	(86.0)	5958	(84.4)	45,164	(82.7)

[a]Data as of 2019, *n* = 16,706

[b]Including students and homemakers

[c]Including work assessment allowance

[d]EQ-5D version 3L until 2019 and version 5L as of 2019

[e]For patients included until end of 2020 (*n* = 54,644)

Fig. 3 Time trends for proportion of cases > 70 years and ASA classification > II, 2007–2021
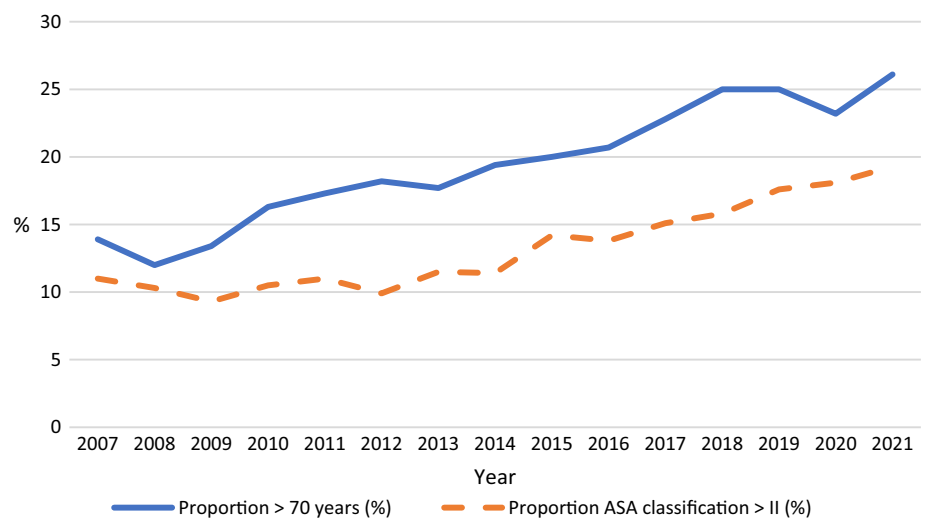
Table 5 Baseline characteristics for respondents and non-respondents at 12-month follow-up [a]

	Missing, n (%)	All (n = 54,644)	Respondents (n = 39,122)	Non-respondents (n = 15,522)
Gender, female, n (%)	0	25,847 (47.3)	18,882 (48.3)	6965 (44.9)
Age (years), mean (95% CI)	160 (0.3)	55.5 (55.4 to 55.6)	57.7 (57.6 to 57.9)	49.9 (49.7 to 50.2)
Living alone, n (%)	456 (0.8)	13,953 (25.7)	9341 (24.1)	4612 (30.0)
Native Norwegian speaker, n (%)	407 (0.7)	51,011 (94.1)	36,758 (94.6)	14,253 (92.6)
Tertiary educational level, n (%)	1035 (1.9)	18,748 (35.0)	13,760 (35.8)	4988 (32.8)
Receiving sickness benefits, n (%)	1776 (3.3)	16,948 (32.1)	11,189 (29.5)	5759 (38.4)
Current smoker, n (%)	541 (1.0)	12,311 (22.8)	7809 (20.2)	4502 (29.3)
BMI (kg/m^2), mean (95% CI)	2922 (5.3)	27.3 (27.2 to 27.3)	27.2 (27.2 to 27.2)	27.4 (27.4 to 27.5)
ASA classification > II, n (%)	721 (1.3)	7327 (13.6)	5641 (14.6)	1687 (11.0)
Any relevant comorbidity, n (%)	4156 (7.6)	25,338 (50.2)	18,938 (52.4)	6400 (44.7)
Anxiety and/or depression, n (%)		1482 (2.9)	904 (2.5)	578 (4.0)
Previous lumbar spine surgery, n (%)	438 (0.8)	14,595 (26.9)	10,126 (26.1)	4469 (29.0)
ODI, mean (95% CI)	462 (0.8)	43.1 (43.0 to 43.3)	42.6 (42.5 to 42.8)	44.3 (44.1 to 44.6)
Leg pain (NRS score), mean (95% CI)	2850 (5.2)	6.7 (6.7 to 6.7)	6.7 (6.7 to 6.7)	6.8 (6.7 to 6.8)
Back pain (NRS score), mean (95% CI)	2515 (4.6)	6.5 (6.5 to 6.5)	6.5 (6.5 to 6.5)	6.6 (6.5 to 6.6)
Duration of leg pain > 12 months, n (%)	3177 (5.8)	23,753 (46.2)	17,241 (46.8)	6512 (44.6)
Duration of back pain > 12 months, n (%)	2467 (4.5)	30,004 (57.5)	21,722 (58.1)	8282 (55.9)
EQ-5D-3L, mean (95% CI)	2949 (5.4)	0.34 (0.33 to 0.34)	0.35 (0.34 to 0.35)	0.31 (0.30 to 0.31)
Use of painkillers, n (%)	557 (1.0)	45,204 (83.6)	32,176 (83.1)	13,028 (84.9)
Fusion surgery, n (%)	0	6891 (12.6)	5093 (13.0)	1798 (11.6)
Peroperative complications, n (%)*	262 (0.5)	2022 (3.7)	1467 (3.8)	555 (3.6)
Length of hospital stay (days), mean (95% CI)	9362 (17.1)	2.7 (2.7 to 2.7)	2.8 (2.7 to 2.8)	2.6 (2.5 to 2.6)

[a]For cases registered until end of 2020

*p value = 0.356

Selection bias

Voluntary participation and recruitment based on informed consent ensure legitimacy in the public. However, self-selection could cause skewed capture and introduce attrition bias.

NORspine's cohort has a lower proportion of cases undergoing emergency surgery than the target population. Patients having emergency surgery for LDH have greater clinical improvement than those undergoing scheduled operations [60]. Thus, interpretation of results should take this into account.

Until 2022, when English questionnaires became available, language barriers restricted inclusion to Norwegian speakers. Not being a native Norwegian speaker is associated with increased odds of failure after surgery for LSS [40]. Language barriers could impair the communication between surgeons and patients and cause less accurate selection for surgery. This means that if patients with language barriers are underrepresented, treatment effects in the total cohort could be overestimated.

Otherwise, little is known about possible bias introduced by incomplete capture. This could be studied by a more comprehensive comparison of data in NORspine and the EHR.

The Norwegian National Service Environment for Clinical Quality Registries has set the benchmark for capture rate at 80%. Like Prang et al. [59], we found no evidence for this recommendation, which may descend from the assumption that a response rate above 80% at follow-up is necessary to achieve a representative sample in cohort studies [61]. NORspine's method for capture analysis has been peer-reviewed [4, 7, 22], indicating that the method is considered robust. Achieving a capture rate above 80% remains a goal, despite unclarity about it's validity.

A review of spine registries recommended 12-month follow-up rate at 60 to 80% [8]. Re-catch studies of sub-cohorts in NORspine suggest that 27 and 22% loss to follow-up may not bias outcomes [14, 50]. This is in accordance with a similar study from DaneSpine and a study comparing Swespine data with data captured in a prospective observational study [62, 63]. These findings indicate that cases lost to follow-up are missing at random, implying loss to follow-up does not cause attrition bias if the variables associated with loss to follow-up are controlled for [61].

weakness that follow-up beyond 12 months (e.g. after 2 or 15 years), is possible only for projects with external funding to pay for the use of NORspine's infrastructure.

In contrast, Spine Tango recently compared 3-month outcomes of 12-month respondents with 12-month non-respondents [64]. They found that 12-month non-respondents had significantly worse early outcomes than respondents, and concluded that loss to follow-up as low as 11–14% may cause overestimation of the treatment effect. The authors speculated that re-catch studies introduce a social desirability bias. On the other hand, it is not obvious that 3-month data are an unbiased predictor of 12-month outcome. Also, Parai et al. [65] used regression models based on baseline characteristics of respondents to predict outcomes for non-respondents in Swespine. They predicted statistically significantly worse outcomes for non-respondents, but the differences were small.

It is a strength that public funding of NORspine prohibits influence from commercial stakeholders such as industry, which could increase the risk for publication bias.

Information bias

Use of predictors and validated and responsive PROMs recommended by ICHOM ensure accurate, relevant and comparable data, and is a strength [16, 25–27]. Indirectly, NORspine's methods have also been validated through numerous peer-reviewed publications. However, continuous evaluation of data quality is mandated for any clinical registry to maintain legitimacy and financial support.

Even though the NORspine includes nearly all known predictors for outcome, residual confounding will exist. The PROMs have not been validated with qualitative studies for patients undergoing spine surgery, and they may not cover all aspects considered important by patients [66].

NORspine records early reoperations as a complication. Studies analysing administrative register data (NPR), assessing reoperation rates, comorbidity and complication rates [4, 22] found identical reoperations rates within 90 days, less comorbidity and lower complication rates in NPR compared to NORspine [23]. This indicates that reoperation rates are accurately reported, but comorbidity and complications seem to be underreported in administrative databases compared to NORspine [23]. Still, other studies indicate that complications and comorbidity tend to be underreported in registries, including NORspine, when compared to the EHR [52, 67]. In NORspine, surgeons record *relevant comorbidity*. They probably under-report because no clear definition of a *relevant* comorbidity exists. Quigley et al. recently reviewed comorbidity recorded in spine registries, including the completeness of such data, and how they are collected [68]. They reported significant methodological variation, and difficulties in assessing the completeness of the data. NORspine was one of few which collect comorbidity data

directly from surgeons. Other registers collected such data from patients, the EHR or administrative databases.

Operational stability

Proper funding is mandatory to ensure sufficient staffing and sustainability. Due to limited funding, NORspine relies on a strong personal commitment from its staff. Especially, increased statistician support is warranted due to increasing demands for reporting, safe data management and delivery, and continuous data quality assessment.

Future perspectives

In 2023, NORspine launch a new register for cases operated for non-degenerative spine deformities and a register for spinal fractures might be a further expansion.

Register data are not readily available in everyday clinical practice. However, an innovation project which integrates NORspine and the EHR is in progress with piloting scheduled in 2024. This integration will aid in structuring the EHR, and availability of register data in the clinician's regular user interface is expected to boost the capture rate. The project also integrates presurgical prognostic modelling of individuals' probability for different surgical outcomes, by the use of artificial intelligence. The intention is to support shared decision-making at surgical outpatient clinics and to facilitate personalised health care and patient selection prior to surgery.

Currently, it is beyond of NORspine's scope to record patients undergoing conservative treatment. Accordingly, we cannot assess whether surgery is offered to those who will benefit most. There could be undetected under- or oversupply in different regions, hospitals or sub-populations. Detecting unwarranted variation would require an expansion to capture all patients evaluated for surgery. A collaboration with the Norwegian Neck and Back Registry, a national clinical quality registry for non-surgical treatment at physical medicine and rehabilitation outpatient clinics, could potentially be a way forward. Spine Tango is, to our knowledge, the only surgical spine registry that also includes conservatively treated cases [57].

Generalisability

The NORspine is located in a country where access to health services is relatively uniform and government funded, and where the public trust to government is high. Some of these premises are unique for the Nordic countries. This limits the generalizability of health services research to countries with other health care systems.

Conclusion

NORspine is a well-designed population-based comprehensive national clinical quality registry. The register's methods ensure appropriate data for quality surveillance and improvement, and research. Maintaining high data quality is a continuous and resource-demanding processes.

Declarations

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