UNIVERSITY OF TROMSØ UIT

DEPARTMENT OF NEUROSURGERY
FACULTY OF MEDICINE
INSTITUTE OF CLINICAL MEDICINE

# Ensuring valid and reliable data for quality control and research from a clinical registry for spine surgery

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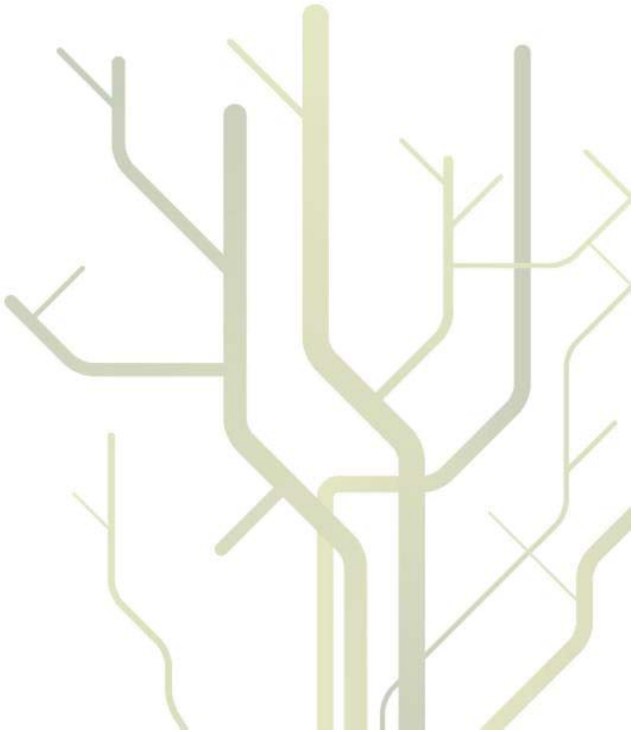

# *Contents*

# 1. Acknowledgements

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## 2. Norwegian abstract - Norsk sammendrag

**Bakgrunn**

Behovet for å kvalitetssikre kirurgisk behandling av rygglidelser og utvikle kliniske retningslinjer er veldokumentert. Derfor ble Nasjonalt kvalitetsregister for ryggkirurgi opprettet. Metodene som brukes må være valide og reliable. Hensikten med avhandlingen var å evaluere målemetodene og å vise hvordan registerdata kan brukes til kvalitetssikring og forskning, slik at pasientbehandlingen kan bli tryggere og mer effektiv**.**

**Metode**

1325 pasienter ble operert og fulgt i ett til to år (n= 633). Omfattende informasjon om pasientene, diagnose og behandling ble samlet inn sammen med pasient rapporterte resultatmål (PROM), det vil si endring av smerte, fysisk funksjonsnivå, livskvalitet og yrkesdeltakelse. I hvor stor grad utvalgte PROM var valide og reliable, beheftet med systematiske målefeil og om de kunne brukes til å skille de med gode og dårlige operasjonsresultat, ble vurdert. Spesielt ble det fokusert på de som ble verre etter kirurgi og hvilke kliniske retningslinjer som bør gjelde for å forhindre forverring.

**Resultat**

Instrumentet EuroQol 5D ga valide og reliable evalueringer av helserelatert livskvalitet og bør kunne benyttes til kostnad/nytte analyser, men var mindre sensitivt og spesifikt i evalueringer av undergrupper av pasientene sammenliknet med sykdomsspesifikke mål som Oswestry Disability Index og numerisk skala for bensmerte. Bedring av PROM var ikke forskjellig hos de som ikke svarte på rutinemessig postoperativ kontroll sammenliknet med de som svarte. Fire prosent av pasientene som ble operert med mikrokirurgisk fjerning av skiveprolaps opplevde at de ble verre etter kirurgi, God fysisk funksjon og langvarig sykemelding før operasjon økte risikoen for å bli verre.

**Konklusjon**

Registeret som samler data fra den daglige driften i de kliniske avdelingene kan gi valid og reliabel informasjon som kan benyttes både til kvalitetssikring og forskning. Dette kan gi ny kunnskap, for eksempel om risikofaktorer, noe som kan bidra til å gjøre behandlingen tryggere og mer effektiv.

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Biveileder: Professor Jan Abel Olsen, ISM, UiT

## 3. List of papers

I. Solberg TK, Olsen JA, Ingebrigtsen T, Hofoss D, Nygaard OP (2005) Health-related quality of life assessment by the EuroQol-5D can provide cost-utility data in the field of low-back surgery. European Spine Journal 14:1000-1007

II. Solberg TK, Sorlie A, Sjaavik K, Nygaard OP, Ingebrigtsen T (2011) Would loss to follow-up bias the outcome evaluation of patients operated for degenerative disorders of the lumbar spine? Acta Orthopaedica 82 (1): 56-63

III. Solberg TK, Johnsen LG, Nygaard ØP, Grotle M (2013) Can we define success criteria for lumbar disc surgery? Estimates for a substantial amount of improvement in core outcome measures. Acta Orthopaedica 84 (2): 196-201

IV. Solberg TK, Nygaard OP, Sjaavik K, Hofoss D, Ingebrigtsen T (2005) The risk of "getting worse" after lumbar microdiscectomy. European Spine Journal 14:49-54

The papers will be referred by their Roman numerals in the text.

# 4. Abbreviations

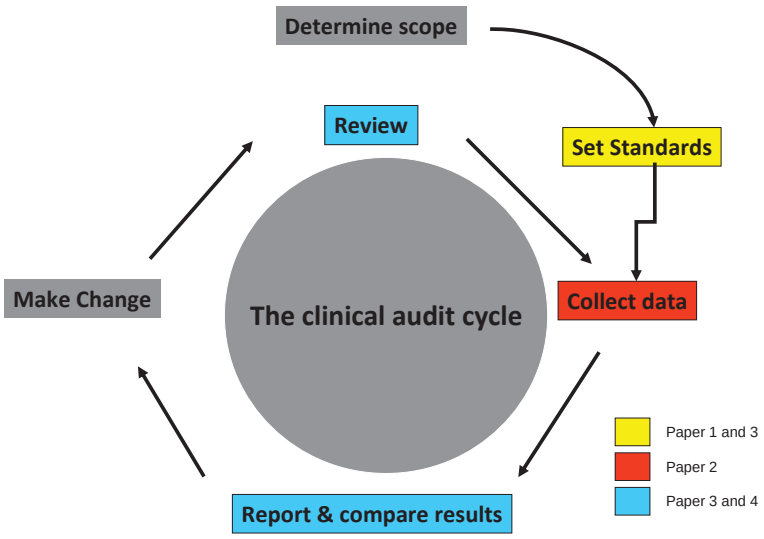
| | |
|---|---|
| ANCOVA | Analysis of covariance |
| ANF | Arctic neurosurgical society |
| ANOVA | Analyses of variance |
| AUC | The area under the curve |
| CI | Confidence interval |
| EQ-5D | EuroQol 5D |
| ES | Effect size |
| HN RHF | Northern Norway regional health authority |
| HN-IKT | IT organization of the Regional health authority of North Norway |
| HRQoL | Health-related quality of life |
| ICC | Intraclass correlation coefficient |
| NORspine | Norwegian registry for spine surgery |
| NRS | Numerical rating scale |
| ODI | Oswestry disability index |
| PROM | Patient reported outcome measure |
| QALY | Quality adjusted life year |
| RCT | Randomized controlled trial |
| ROC | Receiver operating characteristic |
| SKDE | Centre of clinical documentation and evaluation |
| Swespine | Swedish spine register |
| UNN | University hospital of northern Norway |

# 5. Introduction

## *5.1 What is the thesis about?*

This thesis is a result of more than ten years work with a clinical registry for surgical treatment of degenerative disorders in the lumbar spine. The articles mark different key steps in the process of establishing the Norwegian registry for spine surgery (NORspine). The aim is to give the reader an introduction to some basic scientific concepts and methods in the process of collecting registry data, reporting results and developing clinical guidelines. Thus, the articles illustrate some crucial steps in the "clinical audit circle"; which is aimed at reviewing clinical practice so that it can be improved if advocated (Figure 1) [1, 2]. Hopefully, this evidence based framework for continuous clinical audit will contribute to a safer and more effective health service for the patients. The registry data can also give clinicians opportunity to do clinical research, as close to their patients and "real life" as possible. This lies at the heart of evidence based medicine.

**Figure 1: The clinical audit cycle**




The figure is modified after Redfern and Norman, King's College, London 1996.

### *5.2 What is a clinical registry?*

The Scandinavian countries, especially Sweden and Denmark, have been at the forefront of developing clinical registries. According to the definition of the Danish ministry of health: "A clinical registry contains selected, quantifiable variables which can assess parts of or the full quality of a certain treatment, by documenting treatment results for a limited group of patients based on individual lines of treatment" (my translation) [3]. Norway has been lagging behind Denmark and Sweden in this field. An exception is the orthopedic registries, and especially the Norwegian arthroplasty register, which started post marketing surveillance of total hip replacements in 1987 [4], and has earned high national and international recognition. The most developed and successful registry for spine surgery in the world is probably the Swedish spine register (Swespine), which has existed for more than 20 years [5, 6].

# 6. Background/rationale for clinical registries

## *6.1 Evidence based medicine*

According to Sacett et. al, “evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research” [7]. The argument that “everyone already do” falls before striking evidence of variations in use of health services, treatment strategies and follow-up [8-13].

Evidence can be obtained from the basic sciences of medicine, and especially clinical research, and not only from randomised controlled trials (RCTs) [14-18]. Previously accepted knowledge can be invalidated and treatments can become more targeted, powerful and safe [19-22]. Without using current best evidence, clinical practice risks to be rapidly outdated and its quality will lapse.

## *6.2 Quality*

Quality in health care as been defined by the American Institute of Medicine as: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." [23] This statement links quality to evidence based medicine and the clinical perspective, namely that indicators of quality should be linked to patients outcomes [24-26].

## *6.3 Quality indicators and patient reported outcome measures (PROMs)*

Lack of reliable and relevant information has been a major obstacle for improvement of health care across the world [27, 28].Traditionally, monetary issues like hospital activity and budget spending have been used for setting goals and priorities in the health services.

Administrative databases were developed to facilitate and monitor the structure (e.g. numbers of hospital staff and beds) and process of delivering the health care (e.g. patients' access to the services and numbers of procedures performed). Quality indicators were defined on the basis of such readily accessible information, for two main reasons: (1) Structure and process are easy to monitor (2) and to modify [25]. However, most of this information represent indirect measures (proxies) for quality and are mainly cross sectional [25, 29, 30]. In the clinical community quality has traditionally been linked to what comes out of the health service, rather than what is put into it. During the last decades also policy makers and administrators have realized that quality assessment requires use of outcome measures [19], with main focus on treatment effectiveness and safety for the patients [23, 27, 28, 31-33]. Accordingly, new supporting electronic information systems to collect a broader spectrum of data that were relevant, timely, and informative to the clinical teams, were requested [19, 28, 31, 34-39].

This paved the way for clinical registries and the use of patient reported outcome measures (PROMs). PROMs are multidimensional and provide insight into how the impact of diseases and treatments are perceived by the patients, e.g. in terms of pain, disability and health-related quality of life (HRQoL) [33]. Combining information about the structure and process of health care delivery with PROM data can bring about new and relevant knowledge both for patients and health care providers. This approach to quality might help to give answers to some crucial questions, of concern to any doctor involved in clinical practice:

- Is what we think happens to our patients true?
- What works, and what does not work?
- Is our treatment effective according to current standards?
- Which risk factors for unfavourable outcomes should we be aware of?
- Is the treatment safe?

### *6.4 Safety and unfavourable outcomes*

Safety concerns are not new. The origin of the phrase “Primum non nocere”, "first, do no harm" is believed to be from the Hippocratic Oath which was written late 5th century BC [40]. It is still one of the principal precepts of medical ethics around the world. However, even today monitoring and detection of error and harm seems to have been neglected in healthcare organisations [28].

An adverse event is unintended harm to the patient caused by an act of commission or omission, rather than underlying disease [41]. Adverse events during hospital admission affect nearly one out of ten patients, 40-50 % are related to surgical procedures and 5-7 % are lethal [42-45]. It is important to differentiate between a medical error and an adverse event. Not all adverse events (e.g. surgical complications) are preventable or the result of medical errors, which are failures in the process of care [41] [30]. Of all the adverse events, more than half are preventable [42, 45-48]. Their consequences are probably so costly that strong efforts to improve the quality probably would be cost effective [49]. Despite increased focus on patient safety the last decade, the harm resulting from medical care remains high [28, 36, 37, 50, 51]. According to the National Health Plan for Norway, “Systems shall be established to learn from mistakes, so that they are not repeated, and these systems shall support the development of the health service as a learning organization. It is important for the service’s legitimacy that there is openness about errors and improving quality” [31].

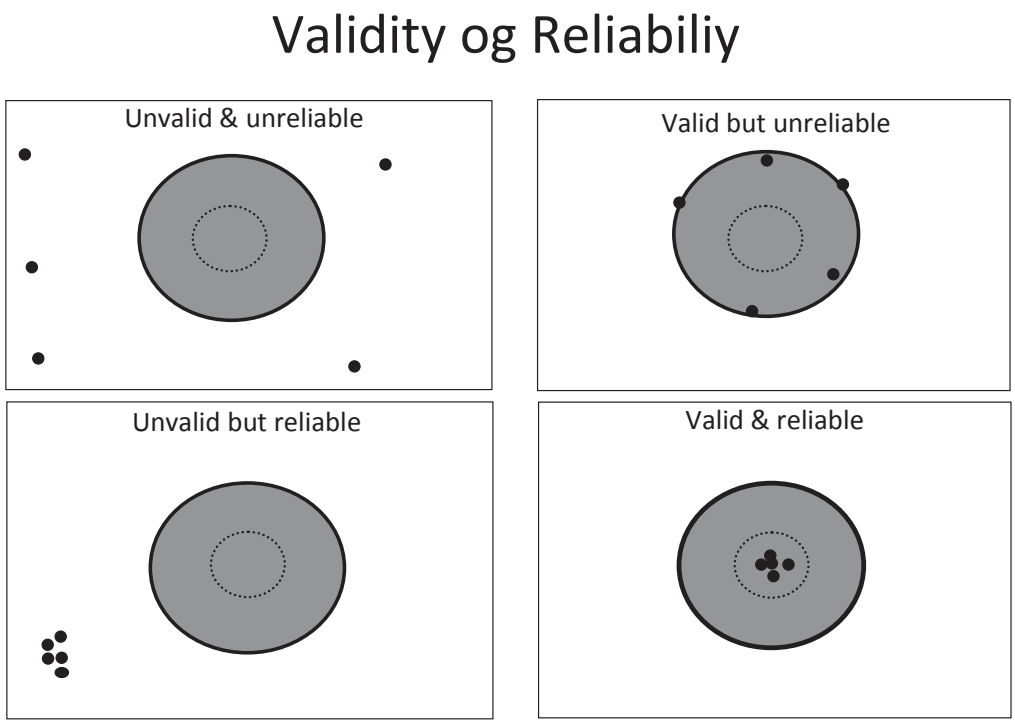
A clinical registry can provide timely and relevant data on safety issues, i.e. integrated information about risk factors (e.g. co-morbidity), process data (e.g. use of antibiotic prophylaxis), adverse events (e.g. complications) and the actual outcome (e.g. disability) [27,36, 52]. A short term follow up can identify immediate effects related to the treatment

whereas a long term follow-up can evaluate if they persist. Prospectively collected PROMs can assess treatment effectiveness [26, 34, 38, 50]. Lack of effectiveness is also a safety issue. Because risk is inherent in any procedure, reducing the number of unnecessary and inefficient operations is important. From a population perspective, this may have a greater impact on complication rates than improving the technical quality of surgery [15].

### *6.5 Validity and reliability of outcome measures*

Validity is concerned with the crucial relationship between concept and indicator; i.e. does the instrument "hit the right target", does it measure what it purports to measure? (Figure 2). Reliability quantifies how stable and consistently a measurement is in "keeping the target", i.e. does measurement of the same phenomenon gives the same result, when repeated either in sequence (test-retest or inter-observer reliability) or by different observers (inter-observer reliability)? (Figure 2). Random error is inherent in any measurement and has a strong impact on reliability.

**Figure 2**




### *6.6 Bias, confounding and causation*

Non-random, or systematic measurement error, can lead to biased conclusions about causality between an exposition and an observed effect, and can invalidate the results, even though correct statistical methods are used [53].

There are two main types of systematic measurement error; information and selection bias. To avoid information bias, instruments used for measurements have to be valid (Paper I and III). Loss to follow-up is an important potential source for selection bias if patients who fail to respond have different outcomes from those who do not (Paper II).

An association or correlation between two variables is necessary for causation, but does not automatically imply that one causes the other. Criteria such as the strength, coherence and consistency of an association, plausibility, temporal sequence and evidence of a dose-

response effect, lend support to a causal relationship [54]. Lack of causation may be due to confounding; i.e. there may be known or unknown factors, other than the exposition, that are responsible for the effect. This may lead to biased conclusions. This bias can however be corrected for, provided that confounding was anticipated and the requisite information gathered from the start of a study [55]. The effect of confounding can be evaluated in multivariate analyses (Paper II and IV).

### *6.7 Chance and significance testing*

Information, selection and confounding bias can cause highly statistically significant but incorrect results. If none of these factors seems to be present, chance may be another source for false results.

A p-value is not an arbiter of validity or casual relationship, it only evaluates whether a difference is found by chance or not. The frequently used p-value threshold of 0.05 has no basis in medicine, but stems from experiments in agriculture and industry, and does not give strong evidence against the null hypothesis in clinical research [55, 56].The p-value indicates the likelihood of a false-positive result; a difference was found in the study, although it does not exist in a broader population (type I error). A smaller p-value (e.g. < 0.001) decreases the likelihood of a type I error [57]. A false-negative result (type II error) is often due to lack of statistical power to discover an association that could exist in a broader population. The large numbers of patients handled in clinical registries will give high statistical power and the risk for committing both type I and II errors in analyses will be reduced. However, even small and irrelevant effect sizes will reach statistical significance, and use of p-values will often be meaningless. It is therefore important to define clinically meaningful effect sizes, before the hypotheses testing starts (paper III). In contrast to p- values, confidence intervals (CIs) show

the strength, direction, and plausible range of a difference as well as the likelihood of chance occurrence. Presenting CIs is therefore more informative, especially when focus is placed on the clinical importance of the range of values in the interval [57].

### *6.8 The role of registry data in clinical research*

The explanatory randomized controlled trial (RCTs) is regarded as the gold standard in clinical research for evaluating *efficacy* of a new treatment [20, 58]; i.e. does it work under ideal circumstances? This question should be answered before any new treatment is implemented. The goal of the thorough recruitment and randomization process of an RCT is to eliminate threats to its internal validity, namely confounding and selection bias. Even though the internal validity of a well conducted and unbiased RCT is high, concerns about the external validity often remains: Does the new treatment work when it is used in a wide range of practices for a broader mix of patients? [59]. An increasing interest for more pragmatic trials and has therefore emerged [60-62]. The goal of registry studies is to not to evaluate efficacy, but *effectiveness*: To understand how treatments work in daily clinical practice, when physicians and patients add their own preferences and perceptions to the decision-making process [63]. Therefore, selection bias is inevitable. As a consequence, using observational cohort studies to compare effectiveness of different treatments by adjusting for baseline covariates (to compensate for lack of randomization) is controversial and often not advisable [22, 64-66], but may be the only option e.g. for studying the effects of adverse events such as complications [67]. However, if similar conditions are treated consistently different but at two centres, the relative effectiveness of the methods can be studied in matched populations. Registry data can also aid in generating hypothesis and sample size calculations for RCTs. Moreover, in some instances RCTs are impracticable or unlikely to be

performed, i.e. in evaluation of treatments for rare conditions and complex interventions [68-70]. Non patentable medical technology or drugs are rarely evaluated in explanatory RCTs [15, 66]. In these cases clinicians will have to rely on the best evidence available from other sources. *Efficiency* describes whether an intervention is worth its costs to patients or society, in cost-effectiveness or cost-utility analyses [71] by use of generic HRQoL instruments like the EuroQol 5D (EQ-5D). Also in this domain registries can play an important role. Apart from translational research (phase V studies), registries can ensure post-marketing surveillance of new surgical devices and techniques being introduced (phase IV studies). In contrast to registry studies, the RCT design is often not applicable to evaluate risk factors. For instance, it is unethical to randomize patients to risk behaviour such as smoking or alcohol abuse.

The main advantage with clinical registry cohorts is that they can utilize the confounders eliminated in an RCT (e.g. co-morbidity and life style issues.) for risk factor analyses. [72] [73]. These risk factors are often frequent in the "true" population of daily clinical practice, where registry data are collected. Clinical guidelines based on carefully conducted analyses on prognostic factors from well maintained registry cohorts will have the highest possible scientific evidence level [74-76] (Table 1, upper right corner). Identifying modifiable risk factors for adverse outcomes is obviously important, but detecting subgroups of patient who benefit most from certain procedures is also valuable [15].

In summary, well designed and well-conducted registry studies can provide essential information with high level of evidence about risk factors, safety and outcomes, when new treatments are transferred from the ideal setting of an RCT into routine medical practice [77].

**Table 1: Levels of evidence by type of study**

| Level | Therapy/Aetiology | Prognosis/risk factors |
|---|---|---|
| 1a | Systematic review (with homogeneity) of RCTs | Systematic review (with homogeneity) of inception cohort studies; Clinical Decision Rule validated in different populations |
| 1b | Individual RCT (with narrow Confidence Interval) | Individual inception cohort study with ≥ 80% follow-up; Clinical Decision Rule validated in a single population |
| 1c | All or none | All or none case-series |
| 2a | Systematic review (with homogeneity) of cohort studies | Systematic review (with homogeneity) of either retrospective cohort studies or untreated control groups in RCTs |
| 2b | Individual cohort study (including low quality RCT; e.g., <80% follow-up) | Retrospective cohort study or follow-up of untreated control patients in an RCT |
| 2c | "Outcomes" Research | "Outcomes" Research |
| 3a | Systematic reviews (with homogeneity) of case-control studies | |
| 3b | Individual Case-Control Study | |
| 4 | Case-series (and poor quality cohort and case-control studies) | Case-series (and poor quality prognostic cohort studies) |
| 5 | Expert opinion without explicit critical appraisal, or based on physiology, bench research | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" |

The table is modified after: Phillips B et al., Oxford centre for evidence-based medicine (May 2001). Available from: http://www.cebm.net/index.aspx?o=1025

### *6.9 Why a registry for spine surgery?*

Patients with degenerative disorders in the lumbar spine often have chronic low back pain and/or radiating leg pain, with or without neurological deficits. The consequences are disability, reduced HRQoL as well as reduced working capability. In western societies, lumbar-spine disorders account for higher costs resulting from disability and absenteeism from work than any other somatic disease category [78, 79]. Lumbar disc herniation is one of the most common indications for surgery performed in US hospitals [80, 81]. In Norway, 5832 operations for degenerative disorders in the lumbar spine were performed in 2011

[82]. The clinical syndromes are associated with radiological signs of “spondylosis” with disc and facet joint degeneration, bony spurs, thickening of ligaments and inflammation. These degenerative changes can cause disc herniation, spinal stenosis, instability and deformity. Patients with lumbar spondylosis report surprisingly low HRQoL, in fact worse than patients with osteoarthritis of hip and knee, rheumatoid arthritis, peripheral vascular disease, prostate cancer, diabetes mellitus, chronic obstructive lung disease, heart failure and renal failure [83] [84]. In most cases the indication for surgery is relative to the subjective complaints of the patients. A decision has to be based on a trade-off between possible benefits and risks of the treatment.

Decompression of impinged neural structures to relieve radiating pain is the most common indication for surgery. The operative technique used for similar conditions can vary between institutions and surgeons, depending on their education, experience, equipment and preferences [85]. Different surgical procedures are used, ranging from microsurgery to more extensive “open techniques” such as laminectomies, sometimes combined with fusion surgery for instability. The results are variable, and the key to a successful outcome is to use the right indication for surgery for the right patients. If carefully selected, these patients can experience an improvement at the level of those operated with hip and knee replacement [83] [86], which are regarded to be some of the most successful operations in terms of improvement in HRQoL and cost-effectiveness [87, 88].

For those operated for chronic low back pain without instability or spinal stenosis, the results are more disappointing [87]. Comprehensive surgery is often used, e.g. instrumented fusion or disc prosthesis. Still, there is little evidence in the literature to support one treatment strategy instead of the other [89-92], or either of them instead of multidisciplinary rehabilitation programmes [93-95]. Moreover, the correlation between

radiological findings and the clinical diagnosis is low [96-98], and overuse especially of MRI leads to problems with interpretability and increasing costs [99]. The development of new treatments are mainly industry driven, and new surgical instrumentation methods are often introduced without sufficient evidence for efficacy or effectiveness [100, 101]. Some of these procedures can put the patients at higher risks for complications, morbidity and even death [102].

Few areas of clinical medicine are as controversial as the surgical treatment of some of the conditions related to spondylosis, as evidenced by large variations in surgical rates between and presumable similar populations [13, 101, 103, 104].

Carefully planned RCTs in this field have been troubled with issues of blinding (for patients and physicians and investigators), willingness to consent to randomization and post-randomization treatment crossover, limiting their practicality and validity [63, 105]. As a consequence, treatment recommendations are often made with much ambiguity [101, 106], and will have to rely upon other types of studies.

Several authors have argued that clinical registries can contribute to clinical guideline development, which is strongly warranted in this field [15, 16, 18, 81, 107].

### *6.10 A short history of the NORspine*

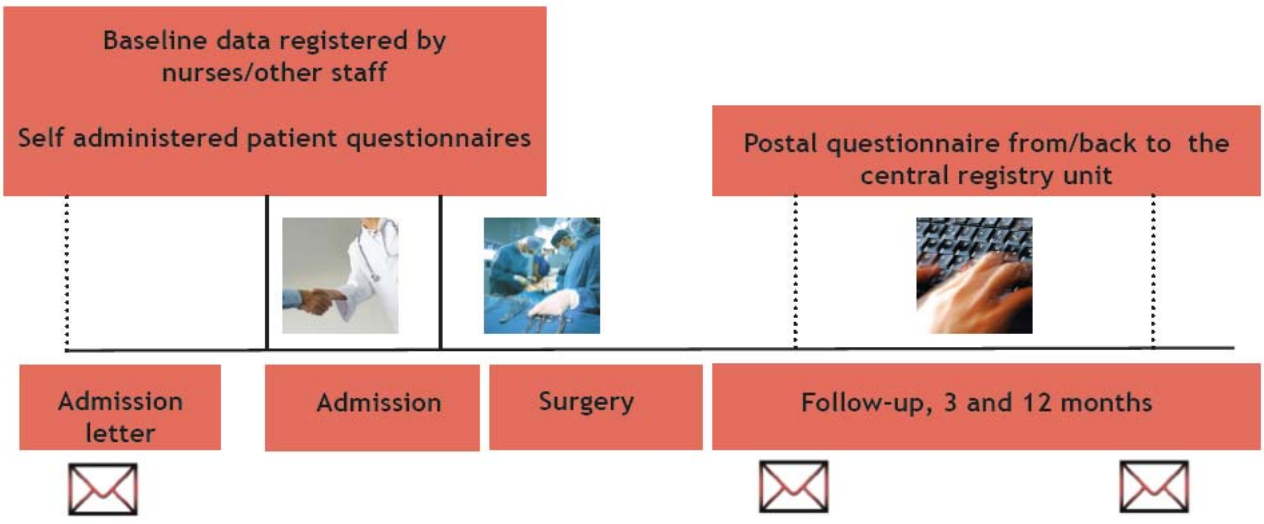
In 2000 we established a local clinical registry for quality control and research for all patients operated for degenerative disorders in the lumbar spine at the Department of Neurosurgery at the UNN. The questionnaires used up to 2004 (paper I, II and IV) are shown in Appendix A. To reduce the work load for the doctors, collection and registration and follow-up involved the whole staff at the department as part of their daily routines. An independent observer at follow-up (research nurse) was used. This ensured good data quality. A large cohort of

patients recruited from daily clinical practice was created with follow-up at 3, 12 and 24 months after surgery. Follow-up visits at the outpatient clinic were replaced by administration of postal questionnaires at 24 months from 2005 and at 12 months from 2006.

The concept of our registry and the first results were presented at a meeting in The Norwegian Society for Spine Surgeons in 2001, which asked us to initiate a Norwegian national registry, based on the methods we had developed at UNN. A formal mandate provided by the Norwegian directory of health to the HN RHF, initiated my work at SKDE in 2005. Despite very strict Norwegian legislation and lack of IT-infrastructure, solutions were fond for routing encrypted sensitive information form all surgical units through the national "safe highway" on the internet (The Norwegian health network) to a common server placed behind the electronic "firewall" of UNN. Simultaneously the first secure, central platform and database for this purpose in Norway (www.helseregister.no) had been developed by HN-IKT. In 2006 the Norwegian data protection authorities approved the protocol and data management so that the local registry could be expanded to the NORspine. A steering group, consisting of both orthopaedic and neurosurgeons, representing all five (later four) regional health authorities in Norway, was established. This group was supported by the three relevant surgical societies, namely the Norwegian Society of orthopaedic surgeons, Norwegian society of neurosurgeons and Norwegian society of spine surgeons [82]. Online registration of data was available from October 2006 (appendix B). The registry database was linked to the National Population Registry of Norway by the national 11-digit personal identification number. In this way, we obtained continuously updated information about changes of home address and dates of death in the study population. In 2009 results from the registry were made available to the surgical units in the first interactive online reports. In

September 2009, version 2.0 of the NORspine was launched. The most important changes were that all follow-ups (at 3 and 12 months) from then were managed by the central registry unit, distributing questionnaires directly to and from patients, without involving the hospitals (Figure 3). Further details concerning the design of the registry, registration procedures and reporting are available in Norwegian at http://www.unn.no/nasjonalt-kvalitetsregister-for-ryggkirurgi/category5972.html ("Registerbeskrivelse", Praktisk veileder", "Brukermanual"). The national coverage rate has increased steadily over the year, and currently 80.5 % of all the surgical units report to the NORspine. In 2010 we developed an algorithm for merging data form the NORspine and the National Patient Registry of Norway [82].At the individual level the coverage increases every year, and in 2012 approximately 60% of the patients for the target conditions operated in Norway were included in the registry (unpublished data). In comparison: The coverage of the Swespine was 75% [6].

**Figure 3: Current data collection in the NORspine.**



# 7. Aims, rationale and methods

The aim of the thesis was to provide a scientific basis for some key methods used in the NORspine; for assessing, reporting and comparing outcomes after surgery for degenerative disorders of the lumbar spine. Thus, the articles illustrate some crucial steps in the "clinical audit circle" [2] (Figure 1); namely to gather valid and reliable data, set valid standards and benchmark criteria for comparing and reviewing results, so that guidelines can be developed and clinical practice can be changed .

## *7.1 Rationale, study population and main methods of each paper*

### 7.1.1 Paper I:

Health-related quality of life assessment by the EuroQol-5D can provide cost-utility data in the field of low-back surgery.

*Rationale*

Generic and preference-weighted measures of health-related quality, like the EQ-5D, can provide clinical data for cost-utility analyses across different diseases and treatments. Disease specific HRQoL instruments are of no value for such purposes. On the other hand, generic questionnaires are regarded to be less responsive than disease-specific instruments and might be to general to assess specific conditions. The EQ-5D was not validated for use in the field of low back surgery when the local registry at UNN was established. To avoid information bias, it was crucial to validate the questionnaire, especially before expanding into a national registry.

*Study population*

A cohort of 326 patients were operated for degenerative disorders in the lumbar spine at the Neurosurgical Department, UNN between 1st of January 2000 and 1st of June 2003 and were followed for one year.

*Main methods*

The EQ-5D was validated against the disease specific ODI and other outcome measures. Patients who were admitted for elective surgery or who were evaluated at follow-up during October and November 2001 completed an extra set of the EQ-5D questionnaire for test–retest reliability assessments.

### 7.1.2 Paper II:

Would loss to follow-up bias the outcome evaluation of patients operated for degenerative disorders of the lumbar spine?

*Rationale*

In limited clinical trials one can make vigorous attempts to trace and retain cohort members. Such efforts are too expensive and resource-demanding to be feasible in large clinical registries like the NORspine, which tries to recruit all patients operated in Norway. Researchers who use registry data will therefore have to deal with higher numbers of non-respondents at follow-up. Different outcomes of non-respondents will lead to selection bias, and biased research conclusions.

*Study population*

A cohort of 633 patients operated with low back surgery from 1st of January 2000 through 31st December 2003 at UNN.

Main methods

Patients not responding at two years of follow-up were traced for a standardized telephone interview, performed by one dedicated doctor.

### 7.1.3 Paper III:

Can we define success criteria for lumbar disc surgery? Estimates for a substantial amount of improvement in core outcome measures.

*Rationale*

In order to monitor surgical outcomes and compare results from different institutions, it is mandatory to develop validated benchmark for “success” criteria based on core outcome measures of the NORspine.

*Study population*

Multicenter cohort of the first 692 consecutive patients were operated for lumbar disc herniation at 16 different surgical units and reported to the NORspine between October 2006 and March 2008, and followed for one year.

*Main methods*

The global perceived scale of change was used as an external criterion, and success was defined as those who reported that they were “completely recovered” or “much better”. (Table 2)

### 7.1.4 Paper IV:

The risk of "getting worse" after lumbar microdiscectomy.

*Rationale*

A frequent concern among the patients is the risk of “getting worse” after the operation. Risk factors for deterioration of functional status and HRQoL after lumbar microdiscectomy had not been reported previously.

*Study population*

A cohort of 180 consecutive patients were operated with microdiscectomy for lumbar disc herniation at UNN from 1st of January 2000 to 1st of June 2003 and followed for one year.

*Main methods*

Deterioration was defined as an increase in ODI score (more disability) at follow up. Risk factors for deterioration were assessed in multivariate analyses.

## *7.2 Research questions of the thesis*

### 7.2.1 Avoiding information and selection bias (Paper I, II and III)

1. Is EQ-5D a valid, reliable and responsive instrument for measuring HRQoL compared to a widely used and validated disease specific instrument, the ODI?
2. Can EQ-5D be used to define a successful outcome after surgery?
3. How many patients do not respond at long term follow up?
4. Will loss to follow-up bias outcome assessments?
5. What are the risk factors for not responding?

### 7.2.2 Creating benchmark criteria for standardized reporting (Paper III and IV)

1. Can we define success criteria for lumbar disc surgery?
2. Which of the core instruments are most valuable to use for defining success?
3. What is a reasonable definition of failed surgery?

### 7.2.3 Using registry data for risk assessment and clinical guideline development (Paper IV)

1. What is the risk of "getting worse" after lumbar microdiscectomy?
2. Which risk factors are important?

## *7.3 General features concerning patients and methods*

### 7.3.1 Patients

The patient population described in paper in paper II was consecutively included at the at the neurosurgical department at UNN. This cohort was established as a research population preceding the national registry. The populations of paper I and IV were sub-cohorts of the larger cohort of paper II.

Paper III evaluated a multicenter cohort from the NORspine, comprising the first patients included during implementation period of the registry.

### 7.3.2 Inclusion criteria

All consecutive patients operated for degenerative disorders in the lumbar spine.

*Definition of degenerative disorders:*

Disc herniation, degenerative disc disease, spinal stenosis, isthmic or degenerative spondylolisthesis / degenerative scoliosis, synovial cysts, spondylarthrosis /spondylosis. "segmental instability" or other non neoplastic disorders which can cause pain, with or without signs of instability

### 7.3.3 Exclusion criteria

• Patients unable to give informed consent due to cognitive deficits or reduced consciousness

• Children < 16 years

• Patients with serious drug abuse or severe psychiatric disorders

• Patients with fractures, primary infections or malignant conditions in the spine

• Patients unable to respond to the declaration of consent and/or the questionnaires due to language barriers.

### 7.3.4 Data collection, general features

All questionnaires used for outcome assessments were self-administered and identical at admission for surgery (baseline) and follow-up. The baseline questionnaire included additional questions about demographics and lifestyle issues.

During the hospital stay, the surgeon recorded data concerning diagnosis, treatment, co morbidity, employment status, duration of symptoms and complications according to a standard registration form.

Finally, all forms were collected and checked for completeness and registered to the database by a dedicated research nurse.

### 7.3.5 Follow-up

*At 3 and 12 months*

A dedicated, trained hospital nurse collected the questionnaires at follow up and interviewed the patients about employment status and complications using a standard registration form at an outpatient clinic.

Paper III (exception): At 12 months after surgery, a questionnaire was distributed by regular post, completed at home by the patients, and returned in the same way.

*At 24 months (only Paper II):*

Patients operated in 2000 and 2001 were summoned for visits at the outpatient clinic. Patients operated in 2002 and 2003 received questionnaires by ordinary postal mail. Non-respondents were traced and interviewed by telephone.

### 7.3.6 Questionnaires (Appendix A-B)

For each case, approximately 350 different variables were recorded at baseline and follow-up in local registry at UNN and later in the NORspine database. They can be divided in three main categories:

*Patient specific data at baseline:* Demographics (age, sex, body mass index, socioeconomic data (e.g. marital status, educational level, employment status), other known risk factors which might affect the outcome after surgery (e.g. duration of symptoms, previous operations, co morbidity, smoking habits)

*Process data:* E.g. diagnosis (clinical and radiological), treatment (type of operation), duration of surgery and of hospital stay, use of prophylactic antibiotic treatment, completed by doctor or nurse.

*Patient reported outcome measures (PROM)* [26]:

A set of validated instruments which are recommended in the literature were used [108]:

Oswestry Disability index (ODI):

Physical function in daily living and disease specific HRQoL (range 0 -100, 0= no disability) [109-112].

EuroQol 5D (EQ-5D):

Generic measure of HRQoL (range -0.540 – 1, 1= best HRQoL). Suitable for estimating quality adjusted life years (QALY) in economic evaluations [113-115].

Leg and back pain

Likert scale for pain in back/leg last week (Range 1-7, no – worst conceivable pain), until January 2004

Visual analogue scales (VAS, range 0-100, 0= no pain) [116,117]until October 2006

Numeric rating scales (NRS, range 1-10, 0= no pain) [118,119], from October 2006

*General health:*

VAS, range 0-100, (100= perfect health) [115].

*Employment status* [120,121].

*Global effects*

*Perceived benefit of operation:* Global perceived change scale (Table 2) [122]:

Five point scale until October 2006

Seven point scale from October 2006 (Table 2)

*Complications, reported by doctor or nurse* [123,125].

### *7.4 Ethical considerations*

Informed consent was obtained from all participants. The registry protocol was approved by the Norwegian data protection authorities. The protocol of the first study from 2005 (Paper IV) was formally presented to our regional ethical committee for medical research, which concluded that the study was a quality control project, and consequently not in need of their approval. They had no objections to the data collection, since this had been approved by the Norwegian data protection authorities. The rest of the study protocols were therefore only

discussed with the ethical committee. The conclusion, at that time, was that also these studies could be classified as clinical audit studies.

In accordance with Norwegian rules and legislations, there has been a tradition for involving the regional ethical committee in studies concerned with new treatments or merging of data from different sources, but not in studies aimed at quality control of standard clinical practice. However, more recently there has been an increasing awareness that the distinction between research and quality control is unclear. It is obvious that analyses of data from clinical registries require the use of research methods and that new knowledge is provided. Most of the study protocols involved in clinical audit will therefore have to be presented to regional ethical committees for medical research in the future [126].

### *7.5 Statistical analyses*

Baseline characteristics and differences in outcome between groups were assessed with one-way analyses of variance (ANOVA) or analysis of covariance with adjustment for baseline scores (ANCOVA, general linear model), independent-samples t-test, Mann-Whitney U-test, or Chi-square test. Within-group change scores changes were evaluated with paired t-test or Wilcoxon's matched-pairs signed rank test depending on the distribution of the data. Central tendency was presented as mean when normally distributed, and as median when skewed. Normal distribution was assessed by the Kolmogorov-Smirnov test. Confidence intervals (CIs) for medians were calculated according to McKean and Schrader [127]. Effect size (ES) was estimated according to the method of Kazis et al. [128]. We assessed risk factors first in univariate, and then multivariate analyses using linear and logistic regression models. To determine the optimal cut-offs for the benchmark criteria on the outcome scores, we used receiver operating characteristic (ROC) curve analyses, looking

at the sensitivity and specificity for various cut-off values and the percentage of misclassification. The area under the curve (AUC), was calculated to evaluate how accurate the instruments could differentiate according to the benchmark criteria. Test–retest reliability was assessed by the intraclass correlation coefficient (ICC) [129], and internal consistency of the EQ-5D was measured by calculating Cronbachs' alpha [130]. SPSS for Windows version 11.0 and 14.0 was used for all analyses.

# 8. Main Results

## *8.1 Avoiding information and selection bias (Paper I, II and III)*

The EQ-5D showed good reliability, with respect to test-retest accuracy (ICC = 0.82 at baseline and 0.87 at follow-up) and internal consistency (Chronbachs alpha= 0.69 at baseline and 0.76 at follow-up) .The validity of the EQ-5D and ODI in the assessments of pain, functional status, health state and employment status were equal. The overall ES was somewhat larger for the ODI (EQ-5D=1.3 and ODI=1.5), but the ranges of the ES between those who reported from "no" to "very much" benefit of the operation were almost equal (EQ-5D=2.1 and ODI=2.0).

The ROC curve showed that the ODI performed better in identifying clinically important improvements (Paper I and Paper III). Among patients operated for lumbar disc herniation (paper III) the sensitivity/specificity values for the ODI and leg pain were acceptable, whereas they were low for the EQ-5D. The EQ-5D performed better in identifying patients with unfavourable outcomes (Paper I), as indicated by the larger negative ES of the EQ-5D in the group of patients who had no benefits of the operation as compared to the ODI.

In paper II we did not find different outcomes among non-respondents as compared to the respondents. However non-respondents were younger and had fewer complications. Forgetfulness seemed to be the main reason for not responding.

## *8.2 Creating benchmark criteria for standardized reporting (Paper III and IV)*

The definition of successful outcome is illustrated in table 2. The cutoff values for success for the mean change scores were 20 (ODI), 2.5 (NRS back), 3.5 (NRS leg). According to the cutoff

estimates, the proportions of successful outcomes were 66% for the ODI and 67% for the NRS leg pain scale

Of the patients 4% had got worse one year after lumbar microdiscectomy, as measured by an increase in ODI score. When adding them with patients who, had an unfavourable ODI raw score (> 39) at follow-up and those who were reoperated, the failure rate increased to 9 and then to 12%.

### *8.3 Using registry data for risk assessment and clinical guideline development (Paper IV)*

Of the patients 4% got worse. Only (43%) out of the patients who had a deterioration in ODI score also had a “poor” ODI raw score (> 39) at follow-up. Independent risk factors of deterioration were long duration of sick leave and relatively small health problems (disability and lower HRQoL) before the operation.

# 9. Discussion

The principle finding of this thesis is that a clinical registry for spine surgery, integrated in the daily workflow of a busy surgical department, can provide valid and reliable data for quality control and research.

## *9.1 Avoiding information and selection bias*

*Patient populations*

The patients included in paper I and IV were sub-cohorts of the population in paper II. Only 1.5% of the patients operated were not included in the registry (Figure 4). The surprisingly high inclusion rate was reached because quality control had been given the highest priority at the Neurosurgical Department at UNN, and the whole staff by was involved. Especially the strong dedication of the research nurses was important. It is not difficult to argue, that the populations in paper I, II and IV are representative, ensuring no selection bias. Biased reporting at follow-up is also less likely, since the consultations were performed by presumably independent observers (trained nurses), and not the surgeons themselves. The one year loss to follow up in paper I was 16 % and 14 % in paper II.

**Figure 4**

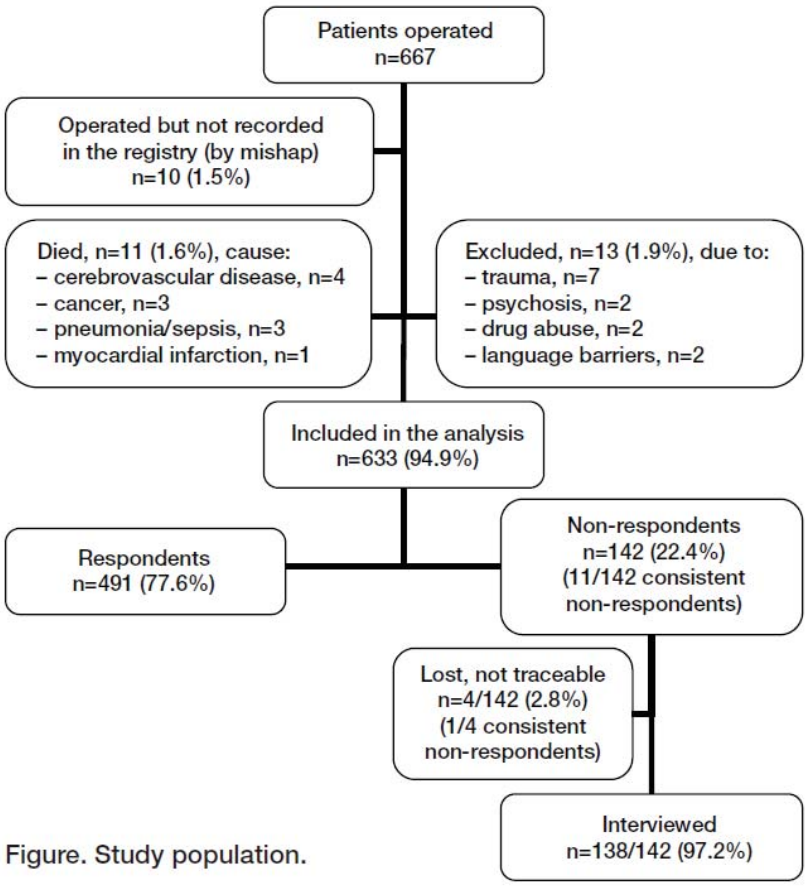



Figure. Study population.

In paper III, which is based on national registry data, we did not know the exact inclusion rate at each hospital and the loss to follow-up rate was 23%. In case of selective inclusion at some hospitals, our results on the amount of patients considered to have a successful outcome may be inaccurate. However, the aim of the study was to define cut-offs for success over a range of outcomes, rather than assessing the effectiveness of the treatment. Furthermore, paper II indicates that we could treat the non-respondents as if they were missing at random in the analyses. It is therefore unlikely that selective reporting at follow-up would influence the cut-off estimates for success. The improvement we found of the ODI,

and back and leg pain after surgery for disc herniation were also similar to those reported from the Swedish spine registry [6]

A major asset was that we finally were able to obtain responses from 97% of the patient population. Since the non-respondents did not return the postal questionnaires (paper II), there was no other option than to use telephone interview. However, this may have replaced a potential selection bias with an information bias, if patients would respond differently to interviews. Moreover, the patients were interviewed with a twelve months mean delay with respect to the two years follow up. Even though outcomes seem to be stable over many years [6, 131, 132], we can not exclude that a memory problems (recall bias) might be present. Non-respondents were younger and had experienced fewer complications than the respondents. The CI for the association between having experienced a complication and responding was wide, but the association at the lower level of the interval was very strong, while the p-value only showed borderline significance (p= 0.07). This indicates that a type II error might be present. Consequently these findings should be reassessed in a larger population. Importantly, we found no evidence indicating that not responding was due to more adverse outcomes or other health problems.

Being summoned for follow-up visits at the outpatient clinic obviously created a commitment among the patients, since the likelihood for responding increased (paper III). Due to high cost and administrative burden, registry participants will still have to be contacted at home. Forgetfulness especially among the younger people appeared to be an important cause, but may be an excuse for indifference. In our modern society, people are repeatedly contacted through postal mail and social media by commercial companies and other organizations. Many of them are conducting surveys. This may cause a kind of fatigue and/or indifference which we were unable to classify correctly. Since there was no

previously validated questionnaire for classifying reasons for not responding available, we had to rely on the "expert opinion" of our study group. It can not be ruled out that these factors might represent a source for information bias.

### *9.2 Outcome measures and benchmarking*

We found that the reliability of the EQ-5D was acceptable. Acceptable accuracy has also been reported for the other PROMs we have used; e.g. in a study from the Swespine (for leg and back pain) and a Norwegian survey (for the ODI) [133, 134].

In large clinical registries like the NORspine, it is important that generic questionnaires are short enough to secure a high inclusion rate. The EQ-5D is brief, efficient to administer and highly acceptable to respondents and investigators. It can be used across conditions and treatments and for assessing cost per quality adjusted life years (QALYs). In paper I, we concluded that this instrument could be suitable for such purposes. However, recent studies indicate EQ-5D may be too short, and a new 5-level version of the EQ-5D has now been developed to improve the instrument's sensitivity and to reduce ceiling effects [135, 136]. A weakness of the methods used in paper I was that we did not assess the measurement error extensively enough by calculating the minimal detectable change (MDC). Based entirely on the distribution of the data, the MDC quantifies the smallest amount of change that is possible to detect beyond the underlying measurement error. For an instrument like EQ-5D, MDC should ideally be greater than the minimum clinically important difference (MCID) [137, 138], which also was omitted from the analyses. In retrospect, the statement "It was also impossible to calculate minimally clinical important difference MCID from our data set", is probably incorrect. Moreover, we could have evaluated the sensitivity and specificity values of the EQ-5D for detecting a clinical meaningful improvement, which we found to be insufficient in paper III. Consequently, the EQ-5D should not be used for estimation of MCID

or for sample size calculations. According to the developers of the EQ-5D, it should be supplemented by a disease-specific questionnaire especially in studies focusing on disease specific problems, and not only overall treatment effects [139].

A problem with the ODI is lack of a clear distinction between pain and disability. The mix of different constructs makes it difficult to know what it measures, and reflects shortcomings in its theoretical foundation, i.e. content and construct validity. Moreover, even the disease specific ODI, covering ten different items (activities of daily living), could fail to address issues that are important to patients. Individuals might also weight the importance of each item differently according to preferences. How the effect of an operation is perceived will also depend on the expectations the patient had in advance [140, 141], but both expectations and preferences are too complex concepts to be monitored in a clinical registry. We therefore used a global effect scale (Likert scale) for outcome evaluations and for defining success criteria [122]; "How much benefit have you had from the operation?" An answer will most probably reflect both preferences and expectations, but in retrospect. One study showed that global change scale ratings are strongly influenced by the current health status of the patient and that accuracy may decrease as transition time increases [122]. Some authors argue that the criteria should be defined prior to treatment, by letting the patients quantify, e.g. on a pain scale, how great the improvement should be to be important [142]. However, no such alternative external anchors for self-reported questionnaires exist. A problem with the five point Likert scale for patient perceived benefit of the operation in paper I and II was imbalanced response alternatives: ''Very much'', ''Quite a lot'', ''Some'', ''No'' or ''Uncertain''. No categories for deterioration were used (Appendix A). In paper I we dichotomized the variable into substantial improvement (''Very much'' and ''Quite a lot'' benefit) or not. The results from the ROC curve analyses in paper I should

therefore be valid, but the argument that the EQ-5D could be more capable than the ODI to identify patients who have deteriorated, lacks sufficient evidence. In paper III we used a balanced seven point scale (Table 2).

**Table 2**

Global perceived change scale

"How much benefit have you had of the operation ?"

| | | |
|---|---|---|
| ☐ | **Completely recovered** | **Cut-off for "success"** ↓ |
| ☐ | **Much improved** | |
| ☐ | **Slightly improved** | |
| ☐ | **No change** | |
| ☐ | **Slightly worsened** | |
| ☐ | **Much worsened** | |
| ☐ | **Worse than ever** | |

In large cohorts of many thousand patients, even small effects which are clinically irrelevant may reach statistical significance. Valid (optimal) cut-offs for success, failure and MICD are therefore warranted, to secure that reporting and sample size calculations are unbiased.

In paper IV we discussed why rates of unfavourable outcomes should include both patients who deteriorate (increase in ODI score) and those who have persistent severe disability (ODI raw score > 39) at follow-up. We stated that patients who were re-operated within the study period could be defined as failures. This assumption has some limitations. Most of the

patients who are operated for recurrent disc herniation within one year after the index operation have favourable final outcomes [82, 143, 144]. The distinction between failure and unfavourable outcomes is therefore difficult. Consequently, it would be wise to report unfavourable outcomes and reoperations separately.

Those who got worse had a greater change than the MCID of 10 [93]. If disability is severe and for instance drops from 80 to 70 on the ODI score (12.5% improvement) after treatment, this would probably not be as clinically significant compared to a drop from 40 to 30 (25% improvement). Therefore, the ODI score change can be regarded as an ordinal scale, making risk factor analyses based on linear regression models more difficult. This represents a weakness in the part of the multivariate analyses of paper IV were linearity was presumed. Use of logistic regression requires a categorical dependent variable. Dichotomous outcomes based on optimal cut-offs (paper II and III) has some advantages. The problem with skewed data related to the dependent variable is reduced, and risk estimates that can be expressed in odds ratios (OR). An OR is an easier concept to explain and discuss with the patient and present to the public than the regression coefficient beta (ß). From odds (O) it is also possible to calculate a probability (p) (p = O/1+O), which is even more comprehendible for doctors and patients in clinical decision making. The results of the binary logistic analyses in Paper IV could have been more enlightening if we had reported the strength of the association between predictor and outcome by OR and not ß, like in paper II. The main problem with dichotomization of continuous variables is that they do not make full use of information in the response scale, resulting in loss of statistical power and problems with evaluating dose-response effects. [145].

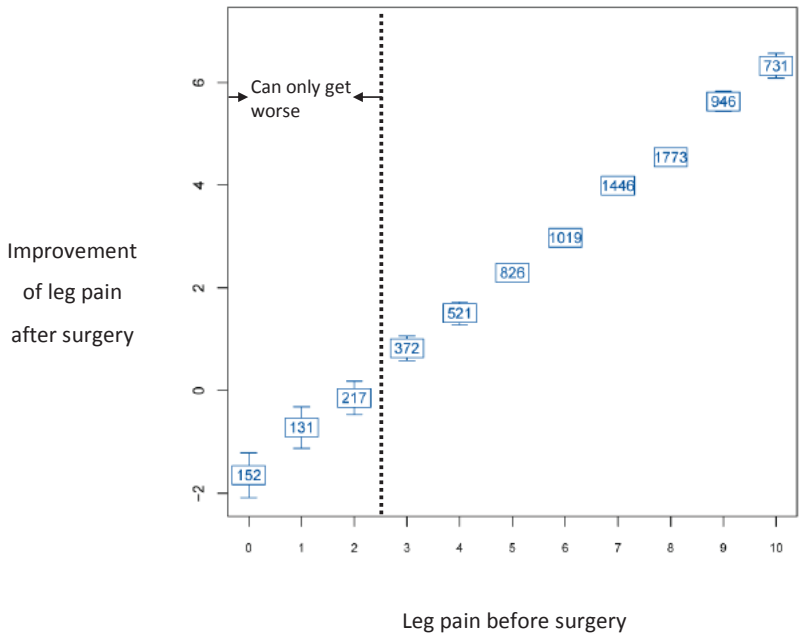
### *9.3 Using registry data for risk assessment and clinical guideline development*

Defining and reporting risk factors for unfavourable outcomes is not straight forward. A potential weakness of the registry design is that psychosocial factors, which can account for a significant proportion of the variation in the outcome measures [146], only are evaluated as part of the EQ-5D (last item: about anxiety and/or depression). Since psychosocial factors might be important confounders, there is an ongoing discussion in the board of the NORspine if a more specific instrument should be included in the next version of the questionnaires. However, a recent paper showed that psychological disturbance can be the consequence of longstanding pain and disability, rather than a cause for patients reporting poor outcomes. The Psychological disturbance seems to improve when symptoms resolve after successful surgery [147].

Stepwise regression analysis uses p-value (chance) related criteria for building a statistical model, but the best strategy for selecting variables is to use clinical judgment. It is therefore crucial for confounding adjustment that only clinically relevant variables are included in the regression model, and that they are checked for interactions and inter-correlations. When our registry was designed, known factors (e.g. among baseline characteristics) that were judged to be clinically relevant to outcome were included with the purpose of performing risk factors analyses [148-159]. The predictors assessed in paper IV and II were chosen based on their clinical relevance to the research questions. It is therefore unlikely that we identified independent risk factor by chance, due to multiple testing. However, the creation of the regression models could have been described more thoroughly. The patient population was relative small (n= 180) in paper IV, and risk factors analyses were linked to a small proportion of them (4 %). We might therefore have failed to identify other relevant

risk factors (type II error). In study II and IV we included the pre-treatment score as independent in the multivariate analyses. Whether this method is appropriate is still controversial, and discussed in the literature [160]. The relationship between the preoperative score and its improvement at follow-up has not only statistical relevance. Recent results from a much greater population included in the NORspine confirms that weak indications for surgery (less disability prior to surgery) is a strong predictor for deterioration and no or clinically insignificant improvement after surgery. Conversely, severe disability predicts a large amount of improvement. This applies for all outcome measures including leg pain (Figure 5).

**Figure 5: The impact of the intensity of preoperative leg pain (numerical rating scale) on its improvement after surgery (NORspine 2011, n= 8.239)**



# 10. Future perspectives

To secure sufficient data quality in this new field of clinical research, validation of the methodology will be a continuous process. Data have to be collected before being validated, and methods have to be tested and revised while the registry cohort expands and goes forward. By signing the declaration of consent of the NORspine, the patients approve to no time limit for use of the data, that they can be contacted again by researchers, and that merging data with several other registries and cohorts can be done. This makes extensive research linked to the NORspine possible. (Appendix C)

Comparing results of a strict multi-centre RCT with “real life” outcome data from routine practice can be possible if a RCT is performed within framework of the registry, using the same questionnaires. New treatments often are introduced simultaneously in both settings, and this approach could contribute to better understanding of both efficacy and effectiveness of interventions, and the external validity of the RCT can then be assessed. Long term outcome evaluations, e.g. after ten years, can be accomplished if advocated. Combining information about adverse events and patient centred outcomes can provide a at least a crude measure of hazards and consequences (risk score) which can be compared and reported over time and across the surgical units [19, 28]. Involvement of patients in reporting adverse events has been recommended [29, 44, 161]. Most complications become evident after discharge [125, 162-164], and are usually not documented in hospital records [29, 30, 164]. Although patients tend to report more complications than clinicians, the agreement seems to be moderate to strong [123, 165]. Mail responses from patients could in fact be less biased than those obtained in the hospital setting. A Swedish study by Öhrn et al. showed that surgical site infections after spine surgery was under-reported in the SWEspine, which prompted the SWEspine to start using patient reported complications

[124]. The method was adopted by the NORspine in 2009, but it needs further validation in future studies. Benchmark criteria for adverse outcomes have to be defined so that we can find modifiable risk factors for prevention.

To secure implementation of guidelines, new knowledge needs to be fed back to health workers and patients in a timely, relevant, understandable manner, utilizing the new social media. Shared decision making between doctors and patients can be facilitated if understandable registry reports about risks and outcomes are communicated to the patients, but efficient and valid methods have yet to be developed and tested. It is also important to find ways to ensure that guidelines are implemented and followed by the clinical teams. If reduction of loss to follow-up can be achieved by contacting patients by SMS or via the internet, as suggested in paper II, needs to be investigated.

Merging data from the NORspine and the Norwegian patient registry for health services research has already been accomplished. At least between some regions, there are large differences in the use of lumbar spine surgery (population rates) [15, 166], and overuse of surgery may be a problem. Relating outcome to volume of surgery at hospitals and different surgical rates in populations may become important aspects of quality improvement, especially for repeat surgery. How social inequity affects patients' access to treatments, especially in private health services, is also be an important issue for the future.

# 11. Main conclusions

- The EQ-5D is valid and reliable for assessing patients undergoing low back surgery for degenerative disorders, and could be used to evaluate overall treatment effects. Hence, this instrument would provide data for cost-utility analyses. The sensitivity/specificity values were too low to be used for sample size calculations and for defining cut-offs for success or MCID.

- The ODI and the NRS leg pain scale showed the best ability to discriminate between success or lack of success in patients who had been operated for lumbar disc herniation. We recommend that a change score of at least 20 points in the ODI and of at least 3.5 in NRS leg pain should be achieved to ensure a successful outcome after surgery. These cut-offs can enhance interpretation of outcomes across different surgical units and monitoring effectiveness. To calculate an accurate rate of unfavourable outcomes, both changes in disability scores and the actual raw score at follow-up should be evaluated.

- A loss to follow-up of 22% would not bias conclusions about overall treatment effects and, importantly, there were no indications of worse outcomes among non-respondents. Younger patients and those not experiencing complications were less likely to respond, and forgetfulness may be an important cause.

- The risk for deterioration is after lumbar microdiscectomy is small (4%), but larger if the patient has been unable to work despite relatively small health problems. For these patients, the indication for surgery could be stricter. These matters should be discussed with patients prior to surgery.

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# 13. Papers and appendices

### *13.1 Papers I-IV*

## *13.2 Appendices A-C*

### 13.2.1 Appendix A

**Questionnaires used until 2004 (paper I, II and IV).**
**Norwegian version**

**Baseline data:**

**Ia Patient questionnaire**
**IIa Surgeon/staff questionnaire**

**Follow-up:**

**Ib Patient questionnaire**
**IIb Nurse questionnaire**

Løpenummer: RiTø ☐☐☐

**SKJEMA Ia: PASIENTOPPLYSNINGER PREOPERATIVT**
(Hvite ark, fylles ut av pasienten før operasjonen)

# SPØRRESKJEMA FOR PASIENTER SOM SKAL OPERERES I RYGGEN

| **Pasientdata** | |
|---|---|
| Navn | ..... |
| Fødselsnummer (11 siffer) | ☐☐☐☐☐☐ ☐☐☐☐☐ |
| Adresse | ..... |
| Alder (år) | ☐☐ |
| Kjønn | ☐ Mann ☐ Kvinne |

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og å vurdere effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fire deler. Første del omhandler ulike sider ved din utdanning og familie samt dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet. Den siste delen er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

| **Dato for utfylling** | ☐☐ ☐☐ ☐☐<br>År Mnd Dag | |
|---|---|---|
| **Utfylt** | ☐ Før operasjon | ☐ Ved etterkontroll |

**Høyde og vekt**

1. Hvor mye veier du? ☐☐☐ (kg)
2. Hvor høy er du? ☐☐☐ (cm)

**Røyker du?**

☐ Nei
☐ Ja

**Utdanning og yrke**

1. Hva er din høyeste fullførte utdanning? (sett ett kryss)
   - ☐ Grunnskole 7-10 år, framhaldsskole eller folkehøyskole
   - ☐ Yrkesfaglig videregående skole, yrkesskole eller realskole
   - ☐ Allmenfaglig videregående skole eller gymnas
   - ☐ Høyskole eller universitet (mindre enn 4 år)
   - ☐ Høyskole eller universitet (4 år eller mer)

2. Hvilke yrke har du, eller hadde du tidligere
   (før du eventuelt ble arbeidsledig, permittert, trygdet eller pensjonert)
   .....

**Familie og barn**

1. Sivilstatus (sett ett kryss)
   - ☐ Gift
   - ☐ Samboende
   - ☐ Enslig
2. Hvor mange barn har du? ☐☐
3. Hvor mange av barna er under 8 år? ☐☐

**Hvor langt klarer du å gå?** (sett ett kryss)

- ☐ <0.5 km
- ☐ 0.5 – 1.0 km
- ☐ 1 – 5 km
- ☐ >5 km

**Hvor mye smerte har du hatt i rygg/ben den siste uken?** (sett ett kryss)

- ☐ Ingen smerte
- ☐ Ubetydelig smerte
- ☐ Litt smerte
- ☐ Ganske mye smerte
- ☐ Mye smerte
- ☐ Svært mye smerte
- ☐ Uutholdelig smerte

**Hvor sterke smerter har du nå?**

De vannrette linjene nedenfor viser en skala fra 0 til 100 for smertestyrke. Den begrenses på venstre side av ingen smerte (0) og på høyre side av uutholdelige smerter (100). Sett en strek på tvers av linjene svarende til din største smerte nå for tiden (den siste uken).

0 Smerter i rygg og hofte 100

Ingen Uutholdelig

0 Smerter i bein (lår, legg og fot) 100

Ingen Uutholdelig

**Hvor stor nytte tror du at du vil ha av operasjon?** (sett ett kryss)

- ☐ Meget stor nytte
- ☐ Stor nytte
- ☐ Litt nytte
- ☐ Ingen nytte
- ☐ Vet ikke

**Funksjonsscore (Oswestry)**

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun ett kryss for hver dimensjon) i de rutene som passer best for deg.

1. Smerte

- ☐ Jeg kan tolerere smerten uten å bruke smertestillende midler
- ☐ Jeg har store smerter, men klarer meg uten smertestillende midler
- ☐ Smertestillende midler gjør meg helt smertefri
- ☐ Smertestillende midler gjør meg delvis smertefri
- ☐ Smertestillende midler hjelper nesten ingen ting
- ☐ Smertestillende midler hjelper ikke på smertene, og jeg bruker ingenting

2. Personlig stell

- ☐ Jeg kan på vanlig måte stelle meg selv uten at det gir smerter
- ☐ Jeg kan på vanlig måte stelle meg selv, men det gir smerter
- ☐ Det er smertefullt å foreta det personlige stell, men jeg gjør det sakte og forsiktig
- ☐ Jeg trenger litt hjelp, men klarer for det meste mitt personlige stell
- ☐ Jeg trenger hjelp til det meste hver dag ved mitt personlige stell
- ☐ Jeg kler ikke på meg selv, vasker meg med vanskelighet og er sengeliggende

3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få smerter
- ☐ Jeg kan løfte tunge ting, men det øker smerten
- ☐ Smertene hindrer meg i å løfte tunge ting fra gulvet, men jeg klarer det hvis de står gunstig til
- ☐ Smerte hindrer meg i å løfte tunge ting, men jeg klarer lette og middels tunge ting hvis de er gunstig plassert
- ☐ Jeg kan bare løfte svært lette ting
- ☐ Jeg kan ikke løfte eller bære noen ting i det hele tatt

**Funksjonsscore (Oswestry) forts.**

4. Å gå

- ☐ Smerte hindrer meg ikke i å gå
- ☐ Smerte hindrer meg i å gå mer enn 1,5 km
- ☐ Smerte hindrer meg i å gå mer enn 750 m
- ☐ Smerte hindrer meg i å gå mer enn 350 m
- ☐ Jeg kan bare gå hvis jeg bruker stokk eller krykker
- ☐ Jeg er for det meste sengeliggende og må krabbe til toalettet

5. Å sitte

- ☐ Jeg kan sitte i en hvilken som helst stol så lenge jeg vil
- ☐ Jeg kan sitte i min favorittstol så lenge jeg vil
- ☐ Smerte hindrer meg i å sitte mer enn 1 time
- ☐ Smerte hindrer meg i å sitte mer enn ½ time
- ☐ Smerte hindrer meg i å sitte mer enn 10 min.
- ☐ Smerte hindrer meg i å sitte i det hele tatt

6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få smerter
- ☐ Jeg kan stå så lenge jeg vil, men det øker smerten
- ☐ Smerte hindrer meg i å stå mer enn 1 time
- ☐ Smerte hindrer meg i å stå mer enn ½ time
- ☐ Smerte hindrer meg i å stå mer enn 10 min
- ☐ Smerte hindrer meg i å stå i det hele tatt

7. Å sove

- ☐ Smerte hindrer meg ikke i å sove godt
- ☐ Jeg sover bare godt når jeg har tatt medisiner
- ☐ Selv om jeg tar medisiner, sover jeg ikke mer enn 6 timer
- ☐ Selv om jeg tar medisiner, sover jeg ikke mer enn 4 timer
- ☐ Selv om jeg tar medisiner, sover jeg ikke mer enn 2 timer
- ☐ Smerte hindrer meg i å sove i det hele tatt

**Funksjonsscore (Oswestry) forts.**

8. Seksualliv

- ☐ Mitt seksualliv er normalt og gir ikke mer smerte
- ☐ Mitt seksualliv er normalt, men det gir litt mer smerte
- ☐ Mitt seksualliv er nærmest normalt, men det er svært smertefullt
- ☐ Mitt seksualliv er i høy grad hemmet av smerter
- ☐ Smerte hindrer så og si alt seksualliv
- ☐ Smerte hindrer ethvert seksualliv

9. Sosialt liv (omgang med venner og kjente)

- ☐ Mitt sosiale liv er normalt, og gir meg ikke mer smerte
- ☐ Mitt sosiale liv er normalt, men øker smerten
- ☐ Smerte har ikke noen bestemt virkning på mitt sosiale liv, bortsett fra aktive interesser som feks. dansing
- ☐ Smerte har begrenset mitt sosiale liv, og jeg går ikke ofte ut
- ☐ På grunn av smerter er mitt sosiale liv begrenset til hjemmet
- ☐ Jeg har overhodet ikke noe sosialt liv

10. Å reise

- ☐ Jeg kan reise hvor som helst uten å få mer smerte
- ☐ Jeg kan reise hvor som helst, men det gir meg mer smerte
- ☐ Smerten er stor, men jeg klarer å reise i mer enn 2 timer
- ☐ På grunn av smerte klarer jeg ikke å reise i mer enn ½ time
- ☐ På grunn av smerte klarer jeg bare korte nødvendige reiser på under ½ time
- ☐ Smerte hindrer meg i å reise i det hele tatt, bortsett fra til lege og sykehus

**Beskrivelse av helsetilstand (EQ-5D)**

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette ett kryss i en av rutene utenfor hver av dimensjonene nedenfor.

1. Gange
   - ☐ Jeg har ingen problemer med å gå omkring
   - ☐ Jeg har litt problemer med å gå omkring
   - ☐ Jeg er sengeliggende

2. Personlig stell
   - ☐ Jeg har ingen problemer med personlig stell
   - ☐ Jeg har litt problemer med å vaske meg eller kle meg
   - ☐ Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (feks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)
   - ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
   - ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
   - ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag
   - ☐ Jeg har hverken smerte eller ubehag
   - ☐ Jeg har moderat smerte eller ubehag
   - ☐ Jeg har sterk smerte eller ubehag

5. Angst og depresjon
   - ☐ Jeg er hverken engstelig eller deprimert
   - ☐ Jeg er noe engstelig eller deprimert
   - ☐ Jeg er svært engstelig eller deprimert

**Helsetilstand**

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Nåværende helsetilstand

Best tenkelige helsetilstand


Verst tenkelige helsetilstand

**Løpenummer: RiTø** ☐☐☐

**SKJEMA IIa: SYKEPLEIER / LEGEOPPLYSNINGER PREOPERATIVT**
(Røde ark. Følger pasientens journal under innleggelsen. Side 1-4 fylles ut av journalskrivende lege og side 5 av forskningssykepleier)

# REGISTRERINGSSKJEMA FOR PASIENTER SOM SKAL OPERERES I RYGGEN

| **Pasientdata** | |
|---|---|
| Navn | ..... |
| Fødselsnummer (11 siffer) | ☐☐☐☐☐☐ ☐☐☐☐☐ |
| Adresse | ..... |
| Alder (år) | ☐☐ |
| Kjønn | ☐ Mann ☐ Kvinne |

| **Dato for utfylling** | ☐☐ ☐☐ ☐☐<br>År Mnd Dag |
|---|---|

| **Sykehistorie** | | |
|---|---|---|
| 1. Tidligere operert? | ☐ Ja, samme nivå | |
| | ☐ Ja, annet nivå | |
| | ☐ Nei | |
| 2. Arbeidsstatus | ☐ I arbeid | ☐ Sykmeldt |
| | ☐ Hjemmeværende | ☐ Delvis sykmeldt |
| | ☐ Student/skoleelev | ☐ Attføring |
| | ☐ Pensjonist | ☐ Uføretrygdet |
| | ☐ Arbeidsledig | |
| 3. Symptomvarighet | Ryggsmerter | ☐☐ (uker) |
| | Utstrålende smerte | ☐☐ (uker) |
| | Varighet sykmelding og/eller | |
| | attføring pga. disse smertene | ☐☐ (uker) |

| **Ventetider** | |
|---|---|
| Tid fra symptomdebut til spesialistvurdering | ☐☐☐ (uker) |
| Tid fra symptomdebut til operasjon | ☐☐☐ (uker) |

**Smertebehandling preoperativt** (Kryss av for ett av alternativene)

| | |
|---|---|
| ☐ 0 | Ingen medikasjon |
| ☐ 20 | ASA, Paracetamol, NSAID |
| ☐ 40 | Ett eller flere medikamenter under 20 pluss: Paralgin Forte, Nobligane, Gamaquil, Somadril eller andre B-preparater som tilleggsmedikasjon |
| ☐ 60 | Bare Paralgin Forte eller Aporex, eventuelt supplert med Nozinan, Largactil eller andre nevroleptika |
| ☐ 80 | Paralgin Forte eller Aporex med tillegg av andre B-preparater, feks. Gamaquil, Somadril, Nobligane eller sovemedikamenter som Apodorm, Rohypnol osv. |
| ☐ 100 | 10 eller flere Paralgin Forte eller aporex per døgn, event. Fortralin, Temgesic, Ketgogan eller andre A-preparater hovedmedikasjon. |

**Klinisk undersøkelse preoperativt** (Kryss av for ett av alternativene på hvert spørsmål)

| | | |
|---|---|---|
| 1. Columna | ☐ 0 | Ingen avvergescoliose |
| | ☐ 10 | Avvergescoliose ved fleksjon |
| | ☐ 20 | Avvergescoliose i oppresist stilling |
| 2. Laseque | ☐ 0 | Negativ, event. smerteutstråling >60° |
| | ☐ 10 | Smerteutstråling mellom 30 og 60° |
| | ☐ 20 | Smerteutstråling under 30° |
| 3. Muskelatrofi | ☐ 0 | Ingen |
| | ☐ 10 | Lett |
| | ☐ 20 | Betydelig |
| 4. Muskelstyrke | ☐ 0 | Normal |
| | ☐ 10 | Lett nedsatt (grad 4 eller bedre) |
| | ☐ 20 | Betydelig nedsatt (grad 3 eller dårligere) |
| 5. Sensibilitet | ☐ 0 | Normal |
| | ☐ 10 | Lett nedsatt |
| | ☐ 20 | Betydelig nedsatt |

**Livskvalitetsscore (EQ-5D) – beskrivelse av helsetilstand**

Vis hvordan du oppfatter pasientens helsetilstand i dag ved å sette ett kryss i en av rutene utenfor hver av dimensjonene nedenfor. Du skal ikke intervjue pasienten for å få frem hans/hennes oppfatning, men angi hvordan du antar at tilstanden er etter din vanlige anamnese og kliniske undersøkelse.

1. Gange
   - ☐ Pasienten har ingen problemer med å gå omkring
   - ☐ Pasienten har litt problemer med å gå omkring
   - ☐ Pasienten er sengeliggende

2. Personlig stell
   - ☐ Pasienten har ingen problemer med personlig stell
   - ☐ Pasienten har litt problemer med å vaske meg eller kle meg
   - ☐ Pasienten er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (feks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)
   - ☐ Pasienten har ingen problemer med å utføre mine vanlige gjøremål
   - ☐ Pasienten har litt problemer med å utføre mine vanlige gjøremål
   - ☐ Pasienten er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag
   - ☐ Pasienten har hverken smerte eller ubehag
   - ☐ Pasienten har moderat smerte eller ubehag
   - ☐ Pasienten har sterk smerte eller ubehag

5. Angst og depresjon
   - ☐ Pasienten er hverken engstelig eller deprimert
   - ☐ Pasienten er noe engstelig eller deprimert
   - ☐ Pasienten er svært engstelig eller deprimert

**Helsetilstand**

Skalaen ved siden av måler helsetilstand. Den beste helsetilstanden man kan tenke seg er markert med 100 og den værste med 0. Marker hvordan du tror at pasienten ville angi sin helsetilstand i dag på en tilsvarende skala ved å trekke ei linje fra boksen nedenfor til et punkt på skalaen.

Best tenkelige helsetilstand


Verst tenkelige helsetilstand

Nåværende helsetilstand

**Hvor stor nytte mener du at pasienten vil ha av operasjon?** (sett ett kryss)

- ☐ Meget stor nytte
- ☐ Stor nytte
- ☐ Litt nytte
- ☐ Ingen nytte
- ☐ Vet ikke

**Radiologisk vurdering**

(Sammenfatter konklusjonen av både CT, MR og radiculografi. Kryss av for flere alternativer samtidig når det er aktuelt)

1. Undersøkelse
   - ☐ CT
   - ☐ MR
   - ☐ Radiculografi

2. Funn
   - ☐ Normal
   - ☐ Skiveprolaps
   - ☐ Sentral spinalstenose
   - ☐ Recesstenose
   - ☐ Instabilitet

**Operasjonen**

1. Metode
   - ☐ Mikrokirurgi
   - ☐ Laminektomi
   - ☐ Fusjonskirurgi
   - ☐ Chymopapain

2. Operert(e) nivå(er) og side(r) (Sett om nødvendig flere kryss)

| | | |
|---|---|---|
| ☐ L2/3 | ☐ Hø. | ☐ Ve. |
| ☐ L3/4 | ☐ Hø. | ☐ Ve. |
| ☐ L4/5 | ☐ Hø. | ☐ Ve. |
| ☐ L5/S1 | ☐ Hø. | ☐ Ve. |

**Tidsforbruk**

1. Tidsforbruk i forbindelse med inngrepet
   - Medgått tid fra pas. forlot sengeposten til han/hun kom tilbake ☐☐ ☐☐ (timer – min)
   - Medgått tid på operasjonstuen / intervensjonsrommet ☐☐ ☐☐ (klokkeslett)

2. Antall liggedøgn i forbindelse med inngrepet ☐☐ (dager)

**Løpenummer: RiTø** ☐☐☐

**SKJEMA Ib: PASIENTOPPLYSNINGER**
(Gule ark, fylles ut av pasienten *etter* operasjonen ved etterkontroller)

# SPØRRESKJEMA FOR PASIENTER ETTER RYGGOPERASJON

| **Pasientdata** | |
|---|---|
| Navn | ..... |
| Fødselsnummer (11 siffer) | ☐☐☐☐☐☐ ☐☐☐☐☐ |
| Adresse | ..... |
| Alder (år) | ☐☐ |
| Kjønn | ☐ Mann ☐ Kvinne |

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og å vurdere effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fem deler. Første del omhandler dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet, mens den neste er en skala der du skal merke av hvor god eller dårlig din helsetilstand er. Til slutt følger noen spørsmål om hva du tror er viktigst for å forklare din eventuelle bedring etter operasjonen.

| **Dato for utfylling** | ☐☐ ☐☐ ☐☐<br>År Mnd Dag | |
|---|---|---|
| **Utfylt** | ☐ Før operasjon | ☐ Ved etterkontroll |

**Hvor langt klarer du å gå?** (sett ett kryss)

- ☐ <0.5 km
- ☐ 0.5 – 1.0 km
- ☐ 1 – 5 km
- ☐ >5 km

**Hvor mye smerte har du hatt i rygg/ben den siste uken?** (sett ett kryss)

- ☐ Ingen smerte
- ☐ Ubetydelig smerte
- ☐ Litt smerte
- ☐ Ganske mye smerte
- ☐ Mye smerte
- ☐ Svært mye smerte
- ☐ Uutholdelig smerte

**Hvor sterke smerter har du nå?**

De vannrette linjene nedenfor viser en skala fra 0 til 100 for smertestyrke. Den begrenses på venstre side av ingen smerte (0) og på høyre side av uutholdelige smerter (100). Sett en strek på tvers av linjene svarende til din største smerte nå for tiden (den siste uken).

| | 0 | Smerter i rygg og hofte | 100 | |
|---|---|---|---|---|
| Ingen | ⊢ | ——— | ⊣ | Uutholdelig |

| | 0 | Smerter i bein (lår, legg og fot) | 100 | |
|---|---|---|---|---|
| Ingen | ⊢ | ——— | ⊣ | Uutholdelig |

**Hvor stor nytte mener du at du har hatt av operasjon?** (sett ett kryss)

- ☐ Meget stor nytte
- ☐ Stor nytte
- ☐ Litt nytte
- ☐ Ingen nytte
- ☐ Vet ikke

**Funksjonsscore (Oswestry)**

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun ett kryss for hver dimensjon) i de rutene som passer best for deg.

1. Smerte
   - ☐ Jeg kan tolerere smerten uten å bruke smertestillende midler
   - ☐ Jeg har store smerter, men klarer meg uten smertestillende midler
   - ☐ Smertestillende midler gjør meg helt smertefri
   - ☐ Smertestillende midler gjør meg delvis smertefri
   - ☐ Smertestillende midler hjelper nesten ingen ting
   - ☐ Smertestillende midler hjelper ikke på smertene, og jeg bruker ingenting

2. Personlig stell
   - ☐ Jeg kan på vanlig måte stelle meg selv uten at det gir smerter
   - ☐ Jeg kan på vanlig måte stelle meg selv, men det gir smerter
   - ☐ Det er smertefullt å foreta det personlige stell, men jeg gjør det sakte og forsiktig
   - ☐ Jeg trenger litt hjelp, men klarer for det meste mitt personlige stell
   - ☐ Jeg trenger hjelp til det meste hver dag ved mitt personlige stell
   - ☐ Jeg kler ikke på meg selv, vasker meg med vanskelighet og er sengeliggende

3. Å løfte
   - ☐ Jeg kan løfte tunge ting uten å få smerter
   - ☐ Jeg kan løfte tunge ting, men det øker smerten
   - ☐ Smertene hindrer meg i å løfte tunge ting fra gulvet, men jeg klarer det hvis de står gunstig til
   - ☐ Smerte hindrer meg i å løfte tunge ting, men jeg klarer lette og middels tunge ting hvis de er gunstig plassert
   - ☐ Jeg kan bare løfte svært lette ting
   - ☐ Jeg kan ikke løfte eller bære noen ting i det hele tatt

**Funksjonsscore (Oswestry) forts.**

4. Å gå

- ☐ Smerte hindrer meg ikke i å gå
- ☐ Smerte hindrer meg i å gå mer enn 1,5 km
- ☐ Smerte hindrer meg i å gå mer enn 750 m
- ☐ Smerte hindrer meg i å gå mer enn 350 m
- ☐ Jeg kan bare gå hvis jeg bruker stokk eller krykker
- ☐ Jeg er for det meste sengeliggende og må krabbe til toalettet

5. Å sitte

- ☐ Jeg kan sitte i en hvilken som helst stol så lenge jeg vil
- ☐ Jeg kan sitte i min favorittstol så lenge jeg vil
- ☐ Smerte hindrer meg i å sitte mer enn 1 time
- ☐ Smerte hindrer meg i å sitte mer enn ½ time
- ☐ Smerte hindrer meg i å sitte mer enn 10 min.
- ☐ Smerte hindrer meg i å sitte i det hele tatt

6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få smerter
- ☐ Jeg kan stå så lenge jeg vil, men det øker smerten
- ☐ Smerte hindrer meg i å stå mer enn 1 time
- ☐ Smerte hindrer meg i å stå mer enn ½ time
- ☐ Smerte hindrer meg i å stå mer enn 10 min
- ☐ Smerte hindrer meg i å stå i det hele tatt

7. Å sove

- ☐ Smerte hindrer meg ikke i å sove godt
- ☐ Jeg sover bare godt når jeg har tatt medisiner
- ☐ Selv om jeg tar medisiner, sover jeg ikke mer enn 6 timer
- ☐ Selv om jeg tar medisiner, sover jeg ikke mer enn 4 timer
- ☐ Selv om jeg tar medisiner, sover jeg ikke mer enn 2 timer
- ☐ Smerte hindrer meg i å sove i det hele tatt

**Funksjonsscore (Oswestry) forts.**

8. Seksualliv

- ☐ Mitt seksualliv er normalt og gir ikke mer smerte
- ☐ Mitt seksualliv er normalt, men det gir litt mer smerte
- ☐ Mitt seksualliv er nærmest normalt, men det er svært smertefullt
- ☐ Mitt seksualliv er i høy grad hemmet av smerter
- ☐ Smerte hindrer så og si alt seksualliv
- ☐ Smerte hindrer ethvert seksualliv

9. Sosialt liv (omgang med venner og kjente)

- ☐ Mitt sosiale liv er normalt, og gir meg ikke mer smerte
- ☐ Mitt sosiale liv er normalt, men øker smerten
- ☐ Smerte har ikke noen bestemt virkning på mitt sosiale liv, bortsett fra aktive interesser som feks. dansing
- ☐ Smerte har begrenset mitt sosiale liv, og jeg går ikke ofte ut
- ☐ På grunn av smerter er mitt sosiale liv begrenset til hjemmet
- ☐ Jeg har overhodet ikke noe sosialt liv

10. Å reise

- ☐ Jeg kan reise hvor som helst uten å få mer smerte
- ☐ Jeg kan reise hvor som helst, men det gir meg mer smerte
- ☐ Smerten er stor, men jeg klarer å reise i mer enn 2 timer
- ☐ På grunn av smerte klarer jeg ikke å reise i mer enn ½ time
- ☐ På grunn av smerte klarer jeg bare korte nødvendige reiser på under ½ time
- ☐ Smerte hindrer meg i å reise i det hele tatt, bortsett fra til lege og sykehus

**Beskrivelse av helsetilstand (EQ-5D)**

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette ett kryss i en av rutene utenfor hver av dimensjonene nedenfor.

1. Gange
   - ☐ Jeg har ingen problemer med å gå omkring
   - ☐ Jeg har litt problemer med å gå omkring
   - ☐ Jeg er sengeliggende

2. Personlig stell
   - ☐ Jeg har ingen problemer med personlig stell
   - ☐ Jeg har litt problemer med å vaske meg eller kle meg
   - ☐ Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (feks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)
   - ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
   - ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
   - ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag
   - ☐ Jeg har hverken smerte eller ubehag
   - ☐ Jeg har moderat smerte eller ubehag
   - ☐ Jeg har sterk smerte eller ubehag

5. Angst og depresjon
   - ☐ Jeg er hverken engstelig eller deprimert
   - ☐ Jeg er noe engstelig eller deprimert
   - ☐ Jeg er svært engstelig eller deprimert

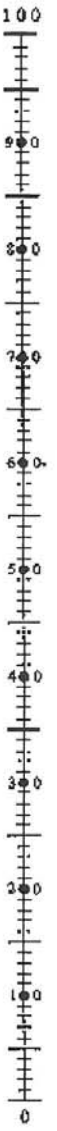
**Helsetilstand**

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Nåværende helsetilstand

Best tenkelige helsetilstand




Verst tenkelige helsetilstand

**Løpenummer: RiTø** ☐☐☐

**SKJEMA IIb: LEGEOPPLYSNINGER POSTOPERATIVT**
(Fylles ut av lege eller forskningssykepleier ved etterkontroll)

# REGISTRERINGSSKJEMA VED KONTROLL ETTER RYGGOPERASJON

| **Pasientdata** | |
|---|---|
| Navn | ..... |
| Fødselsnummer (11 siffer) | ☐☐☐☐☐☐ ☐☐☐☐☐ |
| Adresse | ..... |
| Alder (år) | ☐☐ |
| Kjønn | ☐ Mann ☐ Kvinne |

| | |
|---|---|
| **Etterundersøkelse dato** | ☐☐ ☐☐ ☐☐<br>År Mnd Dag |
| **Tidspunkt etter inngrepet** | ☐☐ (måneder) |

| | | |
|---|---|---|
| **Arbeidsstatus** | ☐ I arbeid | ☐ Sykmeldt |
| | ☐ Hjemmeværende | ☐ Delvis sykmeldt |
| | ☐ Student/skoleelev | ☐ Attføring |
| | ☐ Pensjonist | ☐ Uføretrygdet |
| | ☐ Arbeidsledig | |

| | | |
|---|---|---|
| **Friskmeldt?** | Hvis ja, angi dato | ☐☐ ☐☐ ☐☐<br>År Mnd Dag |

**Komplikasjoner etter inngrepet?**

| | |
|---|---|
| ☐ Infeksjon | ☐ Overfladisk sårinfeksjon |
| | ☐ Dyp sårinfeksjon/diskitt |
| ☐ Blødning (som krever reoperasjon) | |
| ☐ Allergisk reaksjon mot chymopapain | |
| ☐ Liquorlekkasje | |
| ☐ Annet (spesifiser) | ..... |

**Smertebehandling ved kontrolltidspunkt** (Kryss av for ett av alternativene)

| | |
|---|---|
| ☐ 0 | Ingen medikasjon |
| ☐ 20 | ASA, Paracetamol, NSAID |
| ☐ 40 | Ett eller flere medikamenter under 20 pluss: Paralgin Forte, Nobligane, Gamaquil, Somadril eller andre B-preparater som tilleggsmedikasjon |
| ☐ 60 | Bare Paralgin Forte eller Aporex, eventuelt supplert med Nozinan, Largactil eller andre nevroleptika |
| ☐ 80 | Paralgin Forte eller Aporex med tillegg av andre B-preparater, feks. Gamaquil, Somadril, Nobligane eller sovemedikamenter som Apodorm, Rohypnol osv. |
| ☐ 100 | 10 eller flere Paralgin Forte eller aporex per døgn, event. Fortralin, Temgesic, Ketgogan eller andre A-preparater hovedmedikasjon. |

**Klinisk undersøkelse ved kontrolltidspunkt** (Kryss av for ett av alternativene på hvert spørsmål)

| | | |
|---|---|---|
| 1. Columna | ☐ 0 | Ingen avvergescoliose |
| | ☐ 10 | Avvergescoliose ved fleksjon |
| | ☐ 20 | Avvergescoliose i oppresist stilling |
| 2. Laseque | ☐ 0 | Negativ, event. smerteutstråling >60° |
| | ☐ 10 | Smerteutstråling mellom 30 og 60° |
| | ☐ 20 | Smerteutstråling under 30° |
| 3. Muskelatrofi | ☐ 0 | Ingen |
| | ☐ 10 | Lett |
| | ☐ 20 | Betydelig |
| 4. Muskelstyrke | ☐ 0 | Normal |
| | ☐ 10 | Lett nedsatt (grad 4 eller bedre) |
| | ☐ 20 | Betydelig nedsatt (grad 3 eller dårligere) |
| 5. Sensibilitet | ☐ 0 | Normal |
| | ☐ 10 | Lett nedsatt |
| | ☐ 20 | Betydelig nedsatt |

**Livskvalitetsscore (EQ-5D) – beskrivelse av helsetilstand**

Vis hvordan du oppfatter pasientens helsetilstand i dag ved å sette ett kryss i en av rutene utenfor hver av dimensjonene nedenfor. Du skal ikke intervjue pasienten for å få frem hans/hennes oppfatning, men angi hvordan du antar at tilstanden er etter din vanlige anamnese og kliniske undersøkelse.

1. Gange
   - ☐ Pasienten har ingen problemer med å gå omkring
   - ☐ Pasienten har litt problemer med å gå omkring
   - ☐ Pasienten er sengeliggende

2. Personlig stell
   - ☐ Pasienten har ingen problemer med personlig stell
   - ☐ Pasienten har litt problemer med å vaske meg eller kle meg
   - ☐ Pasienten er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (feks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)
   - ☐ Pasienten har ingen problemer med å utføre mine vanlige gjøremål
   - ☐ Pasienten har litt problemer med å utføre mine vanlige gjøremål
   - ☐ Pasienten er ute av stand til å utføre mine vanlige gjøremål

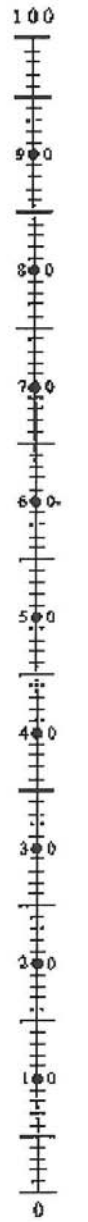
4. Smerte og ubehag
   - ☐ Pasienten har hverken smerte eller ubehag
   - ☐ Pasienten har moderat smerte eller ubehag
   - ☐ Pasienten har sterk smerte eller ubehag

5. Angst og depresjon
   - ☐ Pasienten er hverken engstelig eller deprimert
   - ☐ Pasienten er noe engstelig eller deprimert
   - ☐ Pasienten er svært engstelig eller deprimert

**Helsetilstand**

Skalaen ved siden av måler helsetilstand. Den beste helsetilstanden man kan tenke seg er markert med 100 og den værste med 0. Marker hvordan du tror at pasienten ville angi sin helsetilstand i dag på en tilsvarende skala ved å trekke ei linje fra boksen nedenfor til et punkt på skalaen.

Best tenkelige helsetilstand




Verst tenkelige helsetilstand

Nåværende helsetilstand

**Hvor stor nytte mener du at pasienten har hatt av operasjonen?** (sett ett kryss)

- ☐ Meget stor nytte
- ☐ Stor nytte
- ☐ Litt nytte
- ☐ Ingen nytte
- ☐ Vet ikke

13.2.2 Appendix B

**Questionnaires used in paper III**
**Norwegian version**

**Baseline data:**

**Ia Patient questionnaire**
**IIa Surgeon/staff questionnaire**

**Follow-up:**
**Ib (2) Patient questionnaire**
**IIb Nurse/staff questionnaire used at outpatient clinic visit**

**SKJEMA Ia: PASIENTOPPLYSNINGER PREOPERATIVT**
**(Fylles ut av pasienten før operasjonen)**

# Spørreskjema for pasienter som skal opereres i ryggen

| Pasientdata | |
|---|---|
| Navn | |
| Fødselsnr. (11 siffer) | ☐☐☐☐☐☐ ☐☐☐☐☐ |
| Adresse | |
| Alder (år) | ☐☐ |
| Kjønn | ☐ Mann ☐ Kvinne |

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og å vurdere effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fire deler. Første del omhandler ulike sider ved din utdanning og familie samt dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet. Den siste delen er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

Dato for utfylling ☐☐ Dag ☐☐ Måned ☐☐ År

Røyker du? ☐ Ja ☐ Nei

## Utdanning og yrke

1. **Hva er din høyeste fullførte utdanning? (Sett ett kryss)**

☐ Grunnskole 7-10 år, framhaldsskole eller folkehøyskole

☐ Yrkesfaglig videregående skole, yrkesskole eller realskole

☐ Allmennfaglig videregående skole eller gymnas

☐ Høyskole eller universitet (mindre enn 4 år)

☐ Høyskole eller universitet (4 år eller mer)

2. **Hvilket yrke har du, eller hadde du tidligere (før du eventuelt ble arbeidsledig, permittert, trygdet eller pensjonert)**

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## Familie og barn

| | |
|---|---|
| **1. Sivilstatus (sett ett kryss)** | ☐ Gift |
| | ☐ Samboende |
| | ☐ Enslig |
| **2. Hvor mange barn har du?** | ☐☐ stk |

## Morsmål

☐ Norsk

☐ Samisk

☐ Annet, angi hvilket

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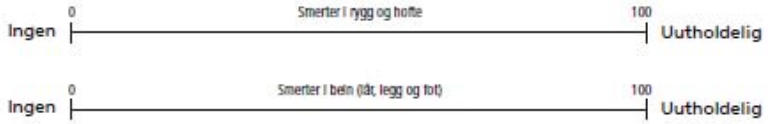
## Hvor sterke smerter har du nå

De vannrette linjene nedenfor viser en skala fra 0 til 100 for smertestyrke. Den begrenses på venstre side av ingen smerte (0) og på høyre side av uutholdelige smerter (100). Sett en strek på tvers av linjene svarende til din største smerte nå for tiden (den siste uken).




## Funksjonsscore (Oswestry)

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun ett kryss for hvert avsnitt) i de rutene som passer best for deg.

### 1. Smerte

- ☐ Jeg har ingen smerter for øyeblikket
- ☐ Smertene er veldig svake for øyeblikket
- ☐ Smertene er moderate for øyeblikket
- ☐ Smertene er temmelig sterke for øyeblikket
- ☐ Smertene er veldig sterke for øyeblikket
- ☐ Smertene er de verste jeg kan tenke meg for øyeblikket

### 2. Personlig stell

- ☐ Jeg kan stelle meg selv på vanlig måte uten at det forårsaker ekstra smerter
- ☐ Jeg kan stelle meg selv på vanlig måte, men det er veldig smertefullt
- ☐ Det er smertefullt å stelle seg selv, og jeg gjør det langsomt og forsiktig
- ☐ Jeg trenger noe hjelp, men klarer det meste av mitt personlige stell
- ☐ Jeg trenger hjelp hver dag til det meste av eget stell
- ☐ Jeg kler ikke på meg, har vanskeligheter med å vaske meg og holder sengen

### 3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få mer smerter
- ☐ Jeg kan løfte tunge ting, men får mer smerter
- ☐ Smertene hindrer meg i å løfte tunge ting opp fra gulvet, men jeg greier det hvis det som skal løftes er gunstig plassert, for eksempel på et bord
- ☐ Smertene hindrer meg i å løfte tunge ting, men jeg klarer lette og middels tunge ting, hvis det er gunstig plassert
- ☐ Jeg kan bare løfte noe som er veldig lett
- ☐ Jeg kan ikke løfte eller bære noe i det hele tatt

### 4. Å gå

- ☐ Smerter hindrer meg ikke i å gå i det hele tatt
- ☐ Smerter hindrer meg i å gå mer enn 1 1/2 km
- ☐ Smerter hindrer meg i å gå mer enn 3/4 km
- ☐ Smerter hindrer meg i å gå mer enn 100 m
- ☐ Jeg kan bare gå med stokk eller krykker
- ☐ Jeg ligger for det meste i sengen, og jeg må krabbe til toalettet

### 5. Å sitte

- ☐ Jeg kan sitte så lenge jeg vil i en hvilken som helst stol
- ☐ Jeg kan sitte så lenge jeg vil i min favorittstol
- ☐ Smerter hindrer meg i å sitte i mer enn en time
- ☐ Smerter hindrer meg i å sitte i mer enn en halv time
- ☐ Smerter hindrer meg i å sitte i mer enn ti minutter
- ☐ Smerter hindrer meg i å sitte i det hele tatt

### 6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få mer smerter
- ☐ Jeg kan stå så lenge jeg vil, men får mer smerter
- ☐ Smerter hindrer meg i å stå i mer enn en time
- ☐ Smerter hindrer meg i å stå i mer enn en halv time
- ☐ Smerter hindrer meg i å stå i mer enn ti minutter
- ☐ Smerter hindrer meg i å stå i det hele tatt

**7. Å sove**

- ☐ Søvnen min forstyrres aldri av smerter
- ☐ Søvnen min forstyrres av og til av smerter
- ☐ På grunn av smerter får jeg mindre enn seks timers søvn
- ☐ På grunn av smerter får jeg mindre enn fire timers søvn
- ☐ På grunn av smerter får jeg mindre enn to timers søvn
- ☐ Smerter hindrer all søvn

**8. Seksualliv**

- ☐ Seksuallivet mitt er normalt og forårsaker ikke mer smerter
- ☐ Seksuallivet mitt er normalt, men forårsaker noe mer smerter
- ☐ Seksuallivet mitt er normalt, men svært smertefullt
- ☐ Seksuallivet mitt er svært begrenset av smerter
- ☐ Seksuallivet mitt er nesten borte på grunn av smerter
- ☐ Smerter forhindrer alt seksualliv

**9. Sosialt liv (omgang med venner og kjente)**

- ☐ Det sosiale livet mitt er normalt og forårsaker ikke mer smerter
- ☐ Det sosiale livet mitt er normalt, men øker graden av smerter
- ☐ Smerter har ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenser mine mer fysisk aktive sider, som sport osv.
- ☐ Smerter har begrenset mitt sosiale liv, og jeg går ikke så ofte ut
- ☐ Smerter har begrenset mitt sosiale liv til hjemmet
- ☐ På grunn av smerter har jeg ikke noe sosialt liv

**10. Å reise**

- ☐ Jeg kan reise hvor som helst uten smerter
- ☐ Jeg kan reise hvor som helst, men det gir mer smerter
- ☐ Smertene er ille, men jeg klarer reiser på to timer
- ☐ Smerter begrenser meg til korte reiser på under en time
- ☐ Smerter begrenser meg til korte, nødvendige reiser på under 30 minutter
- ☐ Smerter forhindrer meg fra å reise, unntatt for å få behandling

## Beskrivelse av helsetilstand (EQ-5D)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette ett kryss i en av rutene for hvert punkt nedenfor.

**1. Gange**

- ☐ Jeg har ingen problemer med å gå omkring
- ☐ Jeg har litt problemer med å gå omkring
- ☐ Jeg er sengeliggende

**2. Personlig stell**

- ☐ Jeg har ingen problemer med personlig stell
- ☐ Jeg har litt problemer med å vaske meg eller kle meg
- ☐ Jeg er ute av stand til å vaske meg eller kle meg

**3. Vanlige gjøremål** (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)

- ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
- ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

**4. Smerte og ubehag**

- ☐ Jeg har hverken smerte eller ubehag
- ☐ Jeg har moderat smerte eller ubehag
- ☐ Jeg har sterk smerte eller ubehag

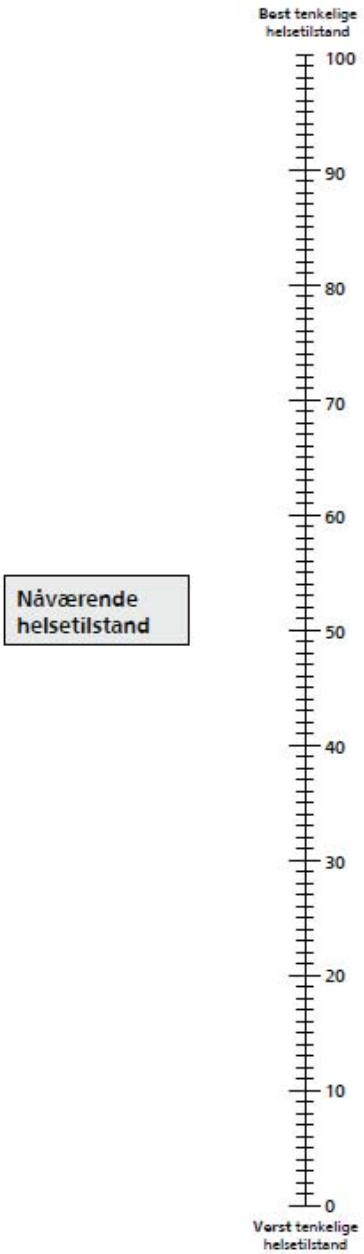
**5. Angst og depresjon**

- ☐ Jeg er hverken engstelig eller deprimert
- ☐ Jeg er noe engstelig eller deprimert
- ☐ Jeg er svært engstelig eller deprimert

## Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.




## Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine rygg- og/eller beinsmerter?

- ☐ Ja
- ☐ Nei

Hvis du har svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett ett kryss)

- ☐ Sjeldnere enn hver måned
- ☐ Hver måned
- ☐ Hver uke
- ☐ Daglig
- ☐ Flere ganger daglig

## Har du søkt om uføretrygd?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

## Har du søkt om erstatning fra forsikringsselskap eller folketrygden (evt. yrkesskadeerstatning)?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

**SKJEMA IIa:**
**SYKEPLEIER/LEGEOPPLYSNINGER PREOPERATIVT**
(Følger pasientens journal under innleggelsen.
Fylles ut av lege/sykepleier)

# Registreringsskjema for pasienter som opereres i ryggen


**Nasjonalt Kvalitetsregister for Ryggkirurgi**
Senter for Klinisk Dokumentasjon og Evaluering - Helse Nord RHF
E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no


Dato for utfylling ☐☐ ☐☐ ☐☐
Dag Måned År

## Pasientdata (Barkode)

Navn

Fødselsnr. (11 siffer) ☐☐☐☐☐ ☐☐☐☐☐

Adresse

Alder (år) ☐☐ Kjønn ☐ Mann ☐ Kvinne

## Høyde og vekt

Vekt ☐☐☐ (kg) Høyde ☐☐☐ (cm)

## Sykehistorie

**Tidligere operert?**

☐ Ja, samme nivå

☐ Ja, annet nivå

☐ Nei

- Pasienten har vært operert ..... ganger tidligere i LS-kolumna
(Fylles kun ut ved reoperasjon)

### Arbeidsstatus

☐ I arbeid
☐ Hjemmeværende, ulønnet
☐ Student/skoleelev
☐ Alderspensjonist
☐ Arbeidsledig
☐ Sykemeldt
☐ Aktivt sykemeldt
☐ Delvis sykemeldt
_____ % sykemeldt
☐ Attføring/rehabilitering
☐ Uføretrygdet
evt. _____ % uføretrygdet

### Andre relevante sykdommer, skader eller plager

☐ Nei

☐ Ja, spesifiser:

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## Symptomvarighet

Varighet av nåværende rygg-/hoftesmerter:

☐ Pasienten har ingen rygg-/hoftesmerter
☐ Mindre enn 3 måneder
☐ 3 til 12 måneder
☐ 1 til 2 år
☐ Mer enn 2 år

Varighet av nåværende utstrålende smerter:

☐ Pasienten har ingen utstrålende smerter
☐ Mindre enn 3 måneder
☐ 3 til 12 måneder
☐ 1 til 2 år
☐ Mer enn 2 år

Varighet sykemelding/attføring/rehabilitering pga aktuelle plager ☐☐☐ (uker)

## Radiologisk vurdering (Sett evt. flere kryss)

**1. Undersøkelse**

☐ CT
☐ MR
☐ Radikulografi
☐ Diskografi
☐ Diagnostisk blokade
☐ Røntgen LS-columna
☐ Med fleksjon/ekstensjon

**2. Funn**

☐ Normal
☐ Skiveprolaps
☐ Sentral spinalstenose
☐ Recesstenose
☐ "Degenerativ rygg" uten prolaps, spinal stenose eller spondylolistese
☐ Spondylolistese
  ☐ Istmisk spondylolistese
  ☐ Degenerativ spondylolistese
☐ Degenerativ skoliose
☐ Annet, spesifiser

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SNU

**Operasjonsindikasjon (Sett evt. flere kryss)**

- ☐ Smerter
  - ☐ Rygg-/hoftesmerter
  - ☐ Bensmerter
  - ☐ Begge deler
- ☐ Parese, Grad (0-5): ..... Se evt. rettledning
- ☐ Cauda equina syndrom
- ☐ Annet, spesifiser ----------

**Operasjonsdato** ☐☐ (Dag) ☐☐ (Måned) ☐☐ (År)

**Operasjonskategori**

☐ Elektiv ☐ Øyeblikkelig hjelp ☐ 1/2 øyeblikkelig hjelp

**Dagkirurgi**

☐ Ja ☐ Nei

**ASA-klassifisering**

| | |
|---|---|
| ☐ I | Ingen organisk, fysiologisk, biokjemisk eller psykisk forstyrrelse. Den aktuelle lidelsen er lokalisert og gir ikke generelle systemforstyrrelser |
| ☐ II | Moderat sykdom eller forstyrrelse som ikke forårsaker funksjonelle begrensninger |
| ☐ III | Alvorlig sykdom eller forstyrrelse som gir definerte funksjonelle begrensninger |
| ☐ IV | Livstruende organisk sykdom som ikke behøver å være knyttet til den aktuelle kirurgiske lidelse eller som ikke bedres ved det planlagte kirurgiske inngrepet |
| ☐ V | Døende pasient som ikke forventes å overleve 24 timer uten kirurgi |

**Operasjonsmetode (Sett evt. flere kryss)**

**Har operatøren brukt mikroskop eller lupebriller?**

☐ Ja ☐ Nei

**Prolapsekstirpasjon?**

- ☐ Nei
- ☐ Ja, med tømming av skive (diskektomi)
- ☐ Ja, uten tømming av skive

**Kirurgisk dekompresjon**

- ☐ Dekompresjon uten laminektomi — ☐ Unilateral ☐ Bilateral
- ☐ Laminektomi
- ☐ Fasettektomi i ett eller flere nivåer — ☐ Unilateral ☐ Bilateral

**Andre operasjonsmetoder**

- ☐ Endoskopi
- ☐ Ekspanderende interspinøst implantat
- ☐ Skiveprotese
- ☐ Fusjonskirurgi (se nedenfor)

Annet, spesifiser: ----------

**Type fusjonskirurgi (Sett evt. flere kryss)**

- ☐ Bakre
  - ☐ Instrumentell
  - ☐ Ikke instrumentell
- ☐ Fremre
  - ☐ Instrumentell
  - ☐ Ikke instrumentell

Annet, spesifiser ----------

**Operert(e) nivå(er) og side(r) (Sett evt. flere kryss)**

| | | | |
|---|---|---|---|
| ☐ L2/3 | ☐ Hø. | ☐ Ve. |
| ☐ L3/4 | ☐ Hø. | ☐ Ve. |
| ☐ L4/5 | ☐ Hø. | ☐ Ve. |
| ☐ L5/S1 | ☐ Hø. | ☐ Ve. |

Annet, spesifiser ----------

**Tidsforbruk**

**1. Tidsforbruk i forbindelse med inngrepet**

Medgått tid fra pasienten forlot sengeposten til han/hun kom tilbake ☐☐ ☐☐ (timer/min)

Knivtid (hud til hud) ☐☐ ☐☐ (timer/min)

**2. Antall liggedøgn i forbindelse med inngrepet**

☐☐☐ (dager)

**Antibiotikaprofylakse**

☐ Ja ☐ Nei

**SKJEMA Ib(2): PASIENTOPPLYSNINGER**
(Fylles ut av pasienten etter operasjonen.
Skjemaet punches som 1b og 2b i databasen)
**BESVARES PER BREV AV PASIENTEN.**


**Nasjonalt Kvalitetsregister for Ryggkirurgi**

Senter for Klinisk Dokumentasjon og Evaluering - Helse Nord RHF

E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no


# Spørreskjema for pasienter etter ryggoperasjon

| Pasientdata (Barkode) | |
|---|---|
| Navn | |
| Fødselsnr. (11 siffer) | |
| Adresse | |
| Alder (år) | |
| Kjønn | ☐ Mann ☐ Kvinne |

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager å vurdere effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fem deler. Første del omhandler dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet, mens den neste er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

Dato for utfylling ☐☐ Dag ☐☐ Måned ☐☐ År

Tidspunkt etter operasjon ☐☐ (måneder)

**Hvilken nytte mener du at du har hatt av operasjon?**

**(Sett ett kryss)**

- ☐ Jeg er helt bra
- ☐ Jeg er mye bedre
- ☐ Jeg er litt bedre
- ☐ Ingen forandring
- ☐ Jeg er litt verre
- ☐ Jeg er mye verre
- ☐ Jeg er verre enn noen gang før

**Hvor fornøyd er du med behandlingen du har fått på sykehuset?**

**(Sett ett kryss)**

- ☐ Fornøyd
- ☐ Litt fornøyd
- ☐ Hverken fornøyd eller misfornøyd
- ☐ Litt misfornøyd
- ☐ Misfornøyd

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## Hvor sterke smerter har du hatt siste uke?

Hvordan vil du gradere smertene du har hatt i rygg/hofte i løpet av den siste uken? Sett ring rundt ett tall.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

Hvordan vil du gradere de smertene du har hatt i benet (ett eller begge) i løpet av den siste uken? Sett ring rundt ett tall.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

## Funksjonsscore (Oswestry)

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun ett kryss for hvert avsnitt) i de rutene som passer best for deg.

### 1. Smerte

- ☐ Jeg har ingen smerter for øyeblikket
- ☐ Smertene er veldig svake for øyeblikket
- ☐ Smertene er moderate for øyeblikket
- ☐ Smertene er temmelig sterke for øyeblikket
- ☐ Smertene er veldig sterke for øyeblikket
- ☐ Smertene er de verste jeg kan tenke meg for øyeblikket

### 2. Personlig stell

- ☐ Jeg kan stelle meg selv på vanlig måte uten at det forårsaker ekstra smerter
- ☐ Jeg kan stelle meg selv på vanlig måte, men det er veldig smertefullt
- ☐ Det er smertefullt å stelle seg selv, og jeg gjør det langsomt og forsiktig
- ☐ Jeg trenger noe hjelp, men klarer det meste av mitt personlige stell
- ☐ Jeg trenger hjelp hver dag til det meste av eget stell
- ☐ Jeg kler ikke på meg, har vanskeligheter med å vaske meg og holder sengen

### 3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få mer smerter
- ☐ Jeg kan løfte tunge ting, men får mer smerter
- ☐ Smertene hindrer meg i å løfte tunge ting opp fra gulvet, men jeg greier det hvis det som skal løftes er gunstig plassert, for eksempel på et bord
- ☐ Smertene hindrer meg i å løfte tunge ting, men jeg klarer lette og middels tunge ting, hvis det er gunstig plassert
- ☐ Jeg kan bare løfte noe som er veldig lett
- ☐ Jeg kan ikke løfte eller bære noe i det hele tatt

### 4. Å gå

- ☐ Smerter hindrer meg ikke i å gå i det hele tatt
- ☐ Smerter hindrer meg i å gå mer enn 1 1/2 km
- ☐ Smerter hindrer meg i å gå mer enn 3/4 km
- ☐ Smerter hindrer meg i å gå mer enn 100 m
- ☐ Jeg kan bare gå med stokk eller krykker
- ☐ Jeg ligger for det meste i sengen, og jeg må krabbe til toalettet

### 5. Å sitte

- ☐ Jeg kan sitte så lenge jeg vil i en hvilken som helst stol
- ☐ Jeg kan sitte så lenge jeg vil i min favorittstol
- ☐ Smerter hindrer meg i å sitte i mer enn en time
- ☐ Smerter hindrer meg i å sitte i mer enn en halv time
- ☐ Smerter hindrer meg i å sitte i mer enn ti minutter
- ☐ Smerter hindrer meg i å sitte i det hele tatt

### 6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få mer smerter
- ☐ Jeg kan stå så lenge jeg vil, men får mer smerter
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**7. Å sove**

- ☐ Søvnen min forstyrres aldri av smerter
- ☐ Søvnen min forstyrres av og til av smerter
- ☐ På grunn av smerter får jeg mindre enn seks timers søvn
- ☐ På grunn av smerter får jeg mindre enn fire timers søvn
- ☐ På grunn av smerter får jeg mindre enn to timers søvn
- ☐ Smerter hindrer all søvn

**8. Seksualliv**

- ☐ Seksuallivet mitt er normalt og forårsaker ikke mer smerter
- ☐ Seksuallivet mitt er normalt, men forårsaker noe mer smerter
- ☐ Seksuallivet mitt er normalt, men svært smertefullt
- ☐ Seksuallivet mitt er svært begrenset av smerter
- ☐ Seksuallivet mitt er nesten borte på grunn av smerter
- ☐ Smerter forhindrer alt seksualliv

**9. Sosialt liv (omgang med venner og kjente)**

- ☐ Det sosiale livet mitt er normalt og forårsaker ikke mer smerter
- ☐ Det sosiale livet mitt er normalt, men øker graden av smerter
- ☐ Smerter har ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenser mine mer fysisk aktive sider, som sport osv.
- ☐ Smerter har begrenset mitt sosiale liv, og jeg går ikke så ofte ut
- ☐ Smerter har begrenset mitt sosiale liv til hjemmet
- ☐ På grunn av smerter har jeg ikke noe sosialt liv

**10. Å reise**

- ☐ Jeg kan reise hvor som helst uten smerter
- ☐ Jeg kan reise hvor som helst, men det gir mer smerter
- ☐ Smertene er ille, men jeg klarer reiser på to timer
- ☐ Smerter begrenser meg til korte reiser på under en time
- ☐ Smerter begrenser meg til korte, nødvendige reiser på under 30 minutter
- ☐ Smerter forhindrer meg fra å reise, unntatt for å få behandling

## Beskrivelse av helsetilstand (EQ-5D)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette ett kryss i en av rutene for hvert punkt nedenfor.

**1. Gange**

- ☐ Jeg har ingen problemer med å gå omkring
- ☐ Jeg har litt problemer med å gå omkring
- ☐ Jeg er sengeliggende

**2. Personlig stell**

- ☐ Jeg har ingen problemer med personlig stell
- ☐ Jeg har litt problemer med å vaske meg eller kle meg
- ☐ Jeg er ute av stand til å vaske meg eller kle meg

**3. Vanlige gjøremål** (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)

- ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
- ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

**4. Smerte og ubehag**

- ☐ Jeg har hverken smerte eller ubehag
- ☐ Jeg har moderat smerte eller ubehag
- ☐ Jeg har sterk smerte eller ubehag

**5. Angst og depresjon**

- ☐ Jeg er hverken engstelig eller deprimert
- ☐ Jeg er noe engstelig eller deprimert
- ☐ Jeg er svært engstelig eller deprimert

## Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine rygg- og/eller beinsmerter?

☐ Ja ☐ Nei

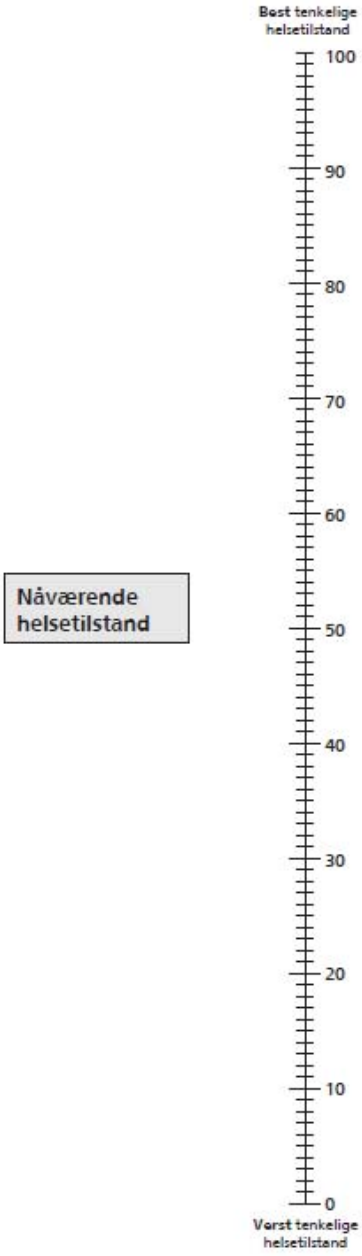
Hvis du har svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett ett kryss)

- ☐ Sjeldnere enn hver måned
- ☐ Hver måned
- ☐ Hver uke
- ☐ Daglig
- ☐ Flere ganger daglig

## Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.




## Arbeidsstatus

- ☐ I arbeid
- ☐ Aktivt sykemeldt
- ☐ Hjemmeværende, ulønnet
- ☐ Delvis sykemeldt
- ☐ Student/skoleelev _____ % sykemeldt
- ☐ Alderspensjonist
- ☐ Attføring/rehabilitering
- ☐ Arbeidsledig
- ☐ Uføretrygdet
- ☐ Sykemeldt evt. _____ % uføretrygdet

## Friskmeldt?

**Hvis ja, angi dato** ☐☐ ☐☐ ☐☐
Dag Måned År

**Varighet av sykemelding etter operasjon** ☐☐☐ (uker)

## Komplikasjoner til inngrepet?

- ☐ Uventet skade (spesifiser) _____
- ☐ Blødning
- ☐ Infeksjon i operasjonssåret
- ☐ Allergisk reaksjon
- ☐ Annet (spesifiser)

_____

## Har du søkt om uføretrygd?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

## Har du søkt om erstatning fra forsikringsselskap eller folketrygden (evt. yrkesskadeerstatning)?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

**SKJEMA IIb:**
**SYKEPLEIER/LEGEOPPLYSNINGER POSTOPERATIVT**
**(Fylles ut av sykepleier/lege ved etterkontroll)**

**Nasjonalt Kvalitetsregister for Ryggkirurgi**
Senter for Klinisk Dokumentasjon og Evaluering - Helse Nord RHF
E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no

# Registreringsskjema ved kontroll etter ryggoperasjon

## Pasientdata (Barkode)

Navn

Fødselsnr. (11 siffer) ☐☐☐☐☐☐ ☐☐☐☐☐

Adresse

Alder (år) ☐☐

Kjønn ☐ Mann ☐ Kvinne

**Etterundersøkelse dato** ☐☐ ☐☐ ☐☐
Dag Måned År

**Tidspunkt etter inngrepet** ☐☐ (måneder)

## Arbeidsstatus

- ☐ I arbeid
- ☐ Aktivt sykemeldt
- ☐ Hjemmeværende, ulønnet
- ☐ Delvis sykemeldt
- ☐ Student/skoleelev ---------- % sykemeldt
- ☐ Alderspensjonist
- ☐ Attføring/rehabilitering
- ☐ Arbeidsledig
- ☐ Uføretrygdet
- ☐ Sykemeldt evt ---------- % uføretrygdet

## Friskmeldt?

**Hvis ja, angi dato** ☐☐ ☐☐ ☐☐
Dag Måned År

**Varighet av sykemelding etter operasjon** ☐☐☐ (uker)

## Komplikasjoner til inngrepet?

- ☐ Nerveskade, spesifiser
- ☐ Blødning
- ☐ Infeksjon
- ☐ Overfladisk sårinfeksjon
- ☐ Allergisk reaksjon
- ☐ Dyp sårinfeksjon/diskitt/spondylitt
- ☐ Liquorlekkasje
- ☐ Annet (spesifiser)
- ☐ Reoperert innen 3 måneder etter operasjon

## Har pasienten fortsatt?

- ☐ Parese, Grad (0-5) ☐
- ☐ Cauda equina utfall
- ☐ Annet, spesifiser:

## Andre relevante sykdommer, skader eller plager

- ☐ Nei
- ☐ Ja, spesifiser:

LUNDBLAD MEDIA AS TROMSØ - 01001001

13.2.3 Appendix C

**Declaration of consent, NORspine.**

| Pasientdata (Barkode) |
| --- |
| Navn: |
| Fødselsdato: |

Nasjonalt Kvalitetsregister for Ryggkirurgi
Degenerativ rygg

E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no

# Samtykkeerklæring

**Til deg som skal opereres i ryggen**
På oppdrag fra Helsedirektoratet har Helse Nord RHF opprettet Nasjonalt Kvalitetsregister for Ryggkirurgi. Hensikten med registeret er å forbedre kvaliteten på behandlingen som blir tilbudt på de ulike sykehus i Norge. Administrerende direktør ved Universitetssykehuset Nord-Norge HF (UNN) er databehandlingsansvarlig.

**Hva skal registreres?**
Ditt personnummer og navn, opplysninger om diagnose, samt opplysninger som beskriver plagene dine, grad av funksjonshemning og yrkesstatus. I tillegg registreres vanlige journalopplysninger som sykehistorie, røntgenfunn og opplysninger knyttet til behandlingen, blant annet hvilken type ryggoperasjon som er utført.

**Hvordan samles opplysningene inn?**
Opplysninger samles inn både før og etter operasjonen. Før operasjonen registreres spørreskjemaet som vi nå ber deg fylle ut, samt opplysninger fra legen som behandler deg. Nasjonalt Kvalitetsregister for Ryggkirurgi vil i tillegg sende deg et kodet spørreskjema (uten gjenkjennbare personopplysninger) 3 og 12 måneder etter operasjonen.

**Hvem kan få tilgang til opplysningene?**
Det er ønskelig at de som har behandlet deg (leger og andre helsearbeidere) får kjennskap til sine behandlingsresultater. De kan da vurdere effekten av behandlingen de tilbyr på en systematisk måte. Samtlige opplysninger som samles inn gjøres derfor tilgjengelig for den sykehusavdeling eller institusjon som behandlet deg, og det er kun de som får tilgang til dine personidentifiserbare opplysninger. Opplysningene behandles konfidensielt og de som har tilgang til dem har taushetsplikt. Opplysningene vil også bli sammenstilt med opplysninger fra Norsk pasientregister for å kunne beregne registerets dekningsgrad.

**Forskning**
Forskere vil kunne bruke registeret til å evaluere blant annet hva som har betydning for gode eller dårlige operasjonsresultat, hvilken betydning behandlingen har i relasjon til trygde-, og sosialmedisinske forhold og i forhold til helseøkonomi. For spesielle forskningsprosjekter kan det være aktuelt å sammenstille informasjon fra registeret med relevante opplysninger knyttet til dine ryggplager fra din pasientjournal, eller med andre offentlige registre (se oversikt på baksiden av dette arket). Dersom du godtar at dine opplysninger lagres i registeret, samtykker du også til at du kan kontaktes på nytt utenom kontrollene (3 og 12 måneder etter operasjonen) enten per brev, SMS eller e-post, eventuelt mange år frem i tid. Sammenstilling av data krever forhåndsgodkjenning av de offentlige instanser loven krever. Forskningsprosjekter skal godkjennes av Regional komité for medisinsk forskningsetikk. Registrerte pasienter kan også bli invitert til å delta i spesielle forskningsstudier som er relatert til formålet med registeret. Forskningsresultatene kan komme fremtidige pasienter til nytte og vil bli publisert i medisinske tidsskrifter i inn- og utland.

**Lagring av data og dine rettigheter**
Spørreskjemaene oppbevares i et arkiv ved sykehuset. De vil bli makulert senest etter to år. Opplysningene i skjemaet lagres også elektronisk i en database som er godkjent av Datatilsynet. Opplysninger i databasen lagres på en trygg måte som ivaretar personvernet. De vil bli lagret uten tidsbegrensning. Alle data vil bli slettet dersom konsesjonen opphører.

Å bidra med opplysninger til registeret er frivillig. Hvis du velger å ikke skrive under på samtykkeerklæringen vil det ikke få noen konsekvenser for behandlingen du får nå eller i fremtiden. Du har rett til å få vite hva som står om deg i registeret, og du har rett til å kreve at eventuelle feil blir korrigert eller at opplysninger blir slettet fra registeret.

Med vennlig hilsen

Tore Solberg
Styringsgruppeleder, Nasjonalt Kvalitetsregister for Ryggkirurgi

Snu arket!

Det kan være aktuelt å koble sammen informasjon fra Nasjonalt Kvalitetsregister for Ryggkirurgi med følgende offentlige registre og befolkningsundersøkelser:

- Nasjonalt Kvalitetsregister for Nakke- og Rygglidelser,
- Registre i NAV,
- Dødsårsaksregisteret,
- Medisinsk Fødselsregister,
- Norsk Pasientregister,
- Kreftregisteret,
- Reseptregisteret,
- Registeret i Statistisk sentralbyrå,
- Nasjonalt register for leddproteser,
- Befolkningsundersøkelsene som inngår i Conor (Cohort of Norway),
- Befolkningsundersøkelsene som inngikk i Statens Helseundersøkelser (SHuS),
- Skattedirektoratets databaser.

Det vil også kunne bli aktuelt å sammenstille avidentifiserte opplysninger fra nasjonalt Kvalitetsregister for Ryggkirurgi med
tilsvarende opplysninger fra Ryggregistret (Swespine) i Sverige. For en nærmere beskrivelse av disse registrene og
befolkningsundersøkelsene se oversikt på www.ryggregisteret.no

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Jeg har lest gjennom informasjonen ovenfor og samtykker til at nevnte opplysningene registreres og gjøres tilgjengelig for kvalitetssikring og forskning.

Sted: _____ Dato: _____

Underskrift: _____

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