Editor's note:

This version (v0.96) is currently awaiting approval by the SAI Steering Committee. The official version of the protocol (v1.0) will be uploaded in the next few days.

The Spine Atlas Initiative (SAI): Mapping spinal care services and practice variation across countries

Version 0.96; 19 September 2024

Contents

1 Executive Summary

The primary goal of the Spine Atlas Initiative (SAI) is to establish an approach for mapping spinal care services and variations in treatments of spinal pathologies across borders. The approach shall enable individual surgeons, hospitals, spinal registries and national societies (participants) worldwide to participate in future international calls for epidemiological data, map their spine care service, benchmark them, and run epidemiological studies.

The first data call 2025 is dedicated to the epidemiology of lumbar degenerative spondylolisthesis (LDS). The initiative aims to collect 10 mandatory and 7 optional data parameters for surgically treated lumbar degenerative spondylolisthesis from each participating country for three months.

The data will be submitted by the participants of the initiative and combined for analysis by the SAI team. For data submission, participants may use a simple provided Excel template, the Spine Tango platform, or another existing registry. The data to be submitted will be required to follow specific definitions and format. The collected data will be analysed, interpreted, and published by a large European network of hospitals and experts.

Each participant will benefit from group authorship (2 authors per participant), the visibility of their services, the network of spine experts and leading spine units, as well as from understanding the variation in LDS pathologies and its surgical treatment.

The initiative is supported by EANS, EUROSPINE and several national registries.

2 Problem definition and proposed solution

Spinal surgery is one of the medical disciplines that evolves rapidly, but the degree of heterogeneity of treatments is systematically increasing. The key reasons for this include:

- A rapidly growing list of available implants, which differ across regions (for example due to regulatory and health policy protocols)
- Different clinical schools, clinical guidelines in different countries, and differences in practice across specialities (neurosurgery, orthopaedic surgery, and spine surgery)
- Differences in local health care systems, health insurance, and health political regulations
- Different healthcare structures
- Varying wealth across regions and financial abilities of the patients as well as differing patient expectations.

At the same time, the degree of heterogeneity has not been systematically explored, as there is no specific evidence or figures available on the number and types of performed treatments and treated pathologies across multiple European countries.

Currently, there is no systematic border-crossing epidemiology and research on spinal treatments. Only a few very valuable stand-alone studies have been published based on combined data from countries. These studies analysed data from 2011-2013 from the national spine registries in the three relatively homogeneous Nordic countries (Denmark, Norway and Sweden) and have shown significant

differences among them in baseline patient characteristics for degenerative disc disease[1], lumbar spinal stenosis[2], and for sciatica with disc herniation including (unadjusted) treatment choices[3].

Any cross-institutional or cross-country research needs a common data frame and definitions. With Spine Tango, EUROSPINE offers a registry platform for its international members. Currently, there are institutions and individuals from about 30 countries around the world that contributed data and shaped Spine Tango data definitions. However, the data collected by the platform is not complete and, thus, not enough to enable representative cross-country analysis, a comprehensive overview of the state of the art of spine treatments, their variation etc.

Registries play a key role in harmonising definitions and conformity and advancing research. In recent years the International Working Group of International Spine Registries (ISR) championed the harmonisation of spine treatment registration. One of the first outputs of this working group was the identification of a core dataset that will be recommended to be part of each spine registry.

In the next step, the availability and practicability of the use of this core dataset in the existing registries shall be tested. A low-barrier approach is required for the collection and combination of data from different countries for epidemiological and research purposes. Such an approach shall offer participating individual hospitals and existing registries as well as the wide community of stakeholders a strong value.

The authors propose the Spine Atlas Initiative (SAI) as a collaborative approach to test the availability and practicability of the use of the core dataset in epidemiological studies as well as to collect and combine data on spinal pathologies and treatments from different countries.

3 Rationale for documenting numbers and types of performed treatments and treated pathologies across countries

This epidemiological and healthcare provision perspective is necessary to make informed (i.e. correct or better) decisions for problems that do not relate to individual cases, but that affect entire populations.

Epidemiological domain

To describe the patient population and to understand the distribution of spinal pathologies that are (surgically) treated across countries.

Health policy domain

[1] Andersen MØ, Fritzell P, Eiskjaer SP, Lagerbäck T, Hägg O, Nordvall D, Lönne G, Solberg T, Jacobs W, van Hooff M, Gerdhem P, Gehrchen M. Surgical Treatment of Degenerative Disk Disease in Three Scandinavian Countries: An International Register Study Based on Three Merged National Spine Registers. Global Spine J. 2019 Dec;9(8):850-858. doi: 10.1177/2192568219838535.

[2] Lønne G, Fritzell P, Hägg O, Nordvall D, Gerdhem P, Lagerbäck T, Andersen M, Eiskjaer S, Gehrchen M, Jacobs W, van Hooff ML, Solberg TK. Lumbar spinal stenosis: comparison of surgical practice variation and clinical outcome in three national spine registries. Spine J. 2019 Jan;19(1):41-49. doi: 10.1016/j.spinee.2018.05.028.

[3] Lagerbäck T, Fritzell P, Hägg O, Nordvall D, Lønne G, Solberg TK, Andersen MØ, Eiskjær S, Gehrchen M, Jacobs WC, van Hooff ML, Gerdhem P. Effectiveness of surgery for sciatica with disc herniation is not substantially affected by differences in surgical incidences among three countries: results from the Danish, Swedish and Norwegian spine registries. Eur Spine J. 2019 Nov;28(11):2562-2571. doi: 10.1007/s00586-018-5768-9.

To understand the burden of pathologies within and between countries, and to plan and facilitate the development of health care structures, education, and other related topic in the individual countries and beyond.

Clinical domain

To foster harmonisation of spinal treatment for which the big picture is required first. Surgical practice can vary greatly for spine conditions, even within the same geographical region and among colleagues at the same institution.

Research domain

To document the baseline status before initiating new projects or changing clinical practice aiming to elicit changes.

Pathology and therapy registration

To further develop and improve the registration of spinal pathologies and therapies across European countries.

Spine registries

Data extraction will support the harmonisation of the data structure within registries. This initiative follows the outcome of the 2nd meeting of Spinal Registries in Frankfurt 2023 that a standardised core dataset should be collected in every spine registry.

4 Lumbar degenerative spondylolisthesis

To ensure a smooth implementation of the proposed initiative, a focus should be chosen. One of the controversially discussed questions in spine surgery in the last decade was whether to fuse or not to fuse lumbar degenerative spondylolisthesis (LDS). LDS is a well-known lumbar spinal pathology that presents a common problem in daily spinal practice. It is characterised by displacement of one vertebral body over another due to disc degeneration and facet arthropathy, most commonly in combination with various degrees of spinal canal stenosis and/or foraminal stenosis at the affected level.[4] The symptoms are usually a combination of stenotic-type radiating buttock and leg pain and mechanical low back pain. Conservative management is usually tried first, but if unsuccessful, surgery can be advocated for and has demonstrated repeatedly good results in various studies.[5,6] Although good quality randomised controlled trials (RCTs) are almost unanimous in demonstrating that fusion has no benefit over a decompression only, some trials and meta-analyses still show contradictory results and conclusions[7,8]. In any case, it is not known to what extent current clinical practice varies in terms of the treatment provided.

[4] Kleinstueck et al. To fuse or not to fuse in lumbar degenerative spondylolisthesis: do baseline symptoms help provide the answer? Eur Spine J. 2012 Feb; 21(2): 268–275. doi: 10.1007/s00586-011-1896-1.

[5] Pearson et al. Spine patient outcomes research trial: radiographic predictors of clinical outcomes after operative or nonoperative treatment of degenerative spondylolisthesis. Spine (Phila Pa 1976) 2008;33:2759–2766. doi: 10.1097/BRS.0b013e31818e2d8b

[6] Weinstein et al. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. *J Bone Joint Surg Am.* 2009;91:1295–1304. doi: 10.2106/JBJS.H.00913

[7] Kaiser et al. Decompression alone versus decompression with instrumented fusion in the treatment of lumbar degenerative spondylolisthesis: a systematic review and meta-analysis of randomised trials. Neurol Neurosurg Psychiatry 2023;94:657–666. doi:10.1136/jnnp-2022-330158

[8] Arimbawa et al. Comparison between Decompression Alone and with Additional Fusion for Degenerative Lumbar Spondylolisthesis: A Systematic Review and Meta-Analysis. Spine Surg Relat Res 2023; 7(1): 42-51 dx.doi.org/10.22603/ssrr.2022-0011

5 Goal of the Spine Atlas Initiative

The goal of the initiative is to test the availability and practicability of the use of a core dataset in epidemiological studies as well as to collect and combine data on spinal pathologies and treatments from different countries.

6 Specific aims for the data call 2025

With the data call 2025, we aim to describe the spinal services and practice variation in spinal care for LDS while testing the proposed approach for data collection and submission.

With the lessons learnt, we will further develop the SAI protocol for future data calls, reassess and further develop the standardised definitions, and design a roadmap (process) to collect and implement ideas and requests for collaborations for epidemiological surveillance in spinal care.

7 Data to be submitted

We aim to collect details on the data collection from participants, a core dataset with some optional data, while keeping future expansions in mind.

7.1 Details on the data collection from participants

Each participant will be surveyed using a set of general questions. The purpose of this set of questions is to estimate the coverage of the participants and potential biases in the data. A draft can be found in Appendix 3 and will be reviewed and agreed upon by the steering committee.

- Institution/organisation/participant name, incl. abbreviation used in submission files.
- Country
- Participant type (surgeon, department, hospital, regional/national spine registry, national association for spine/orthopaedics/neurosurgery, research group)
- In case of data containing multiple institutions and <100% national coverage: a list of institutions
- Estimated national coverage of spine surgeries by the participant
- Estimated annual number of cases treated total/ spine related / LDS
- Health system - questions
- (Potential) biases in the data – questions (regarding bias in patient selection, completeness etc.)

The survey will also be used to record the agreement to participate in the SAI. SAI participants are asked to confirm by ticking the respective box, that permission is granted to use the material submitted for the purposes stated in this proposal, and that patient consent was retrieved -unless not required by local law, i.e. for anonymised data from national registries. Participants can be assured that the submitted data will not be used for purposes other than those outlined above without the explicit permission of the individual participant.

7.2 Data on patients

The exact data definitions are outlined in the Codebook, Appendix 2. The list of variables is based on the harmonisation work and output of the ISR working group and was further developed during the review rounds of the SAI proposal by the SAI steering committee, the Spine Tango Committee, the EUROSPINE Research Committee, the ISR and other involved individuals.

The selection was based on the criteria to have a core mandatory dataset, which contains the most important information to describe the patient populations, type of LDS and surgical intervention.

The optional parameters were also kept minimal and contain predictors of surgical outcome as described previously in literature and three additional questions on pathology and surgery. Outcomes are not included in the variable list.

In short, the mandatory parameters are:

1. Patient age at surgery date (in whole years)*
2. Patient gender
3. Surgery date
4. Primary spine surgery at the same or adjacent level
5. Type of spinal stenosis (central or lateral, foraminal)
6. Grade of LDS (a) by Meyerding (b) OR in mm
7. Surgical measures
    - (if any) (a1) Decompression type and (a2) level
    - (if any) (b1) Fusion type and (b2) level
    - (if any) (c1) Stabilisation rigid type and (c2) level
    - (if any) (d1) Dynamic stabilisation and (d2) level
    - (if any) (e1) Other surgical treatment (e2) level

The optional parameters are:

8. Additional spinal pathology
9. ASA status
10. Number of previous spine surgeries at the same or adjacent level
11. Duration of symptoms
12. (a) Height and (b) weight (c) OR alternatively BMI
13. Current smoker status
14. (if any) (a) Data on the implant manufacturer and (b) article number

*Age may be permitted to be sent in age groups if required by local data protection law. Please contact the SAI team (spineatlas@eurospine.org).

8 Study design, observation period and inclusion criteria

The study design is an international cross-sectional study. The data will be visualised for all participants' data combined and for each one of the individual countries with representative data.

All surgeries for LDS performed between 1 February and 30 April 2025 are to be included in the observation.

Patients to be included must be 18 years of age or older.

Participants (primarily those who already collect data) are invited to provide additional data from before and after this study period if available and possible, to allow for the assessment of the quality, comparability, and completeness of the data submissions.

9 Communication plan and Recruitment of participants

A detailed communication strategy for the recruitment of participants was developed by the SAI team and the plan for the continued information to SAI participants and the dissemination of the SAI results will be established during the course of the project.

An official letter will announce recruitment and start of registration by the end of September 2024. The communication will be made via different channels including social media to have high dissemination and reach out to existing spine registries, national societies, EUROSPINE and EANS members, as well as individual hospitals.

10 Representativeness of the data

Although all hospitals, spine registries and national specialist societies will be invited to contribute their data, we expect that only selected institutions and organisations will submit data leading to an incomplete coverage of data. To assess the representativeness of the submitted data, all participants contributing data will be requested to answer a few questions on the representativeness of their data (see 7.1). The steering committee will determine if the representativeness of a country can be considered sufficient. If sufficient, the country will be shown in the country-wise study results. In any case, all available data from all participants will be used in pooled data analyses.

If data for the same participant is delivered more than once by different means, i.e. as a participant of Spine Tango and simultaneously a participant of a national registry, we will report back to the participants on the congruency of their data and use the result of that analysis as an indicator for coverage.

11 Methods

11.1 SAI organisation

The initiative will be led by **Christian Herrmann**, PhD, from EUROSPINE as the principal investigator (PI).

The PI will be supported by a **steering committee** consisting of

- **Pierre Côté**, PhD (Epidemiology, Methodology)
  Professor Ontario Tech University Research Excellence
  Director, Institute for Disability and Rehabilitation Research, Ontario, Canada
- **Jarkko Halme**, MD (Spine registries)
  Orthopaedic spinal surgeon at the Kuopion yliopistollinen sairaala KYS, Kyopio, Finland
  Representative of the International Spine Registries working group
  Board member of the Finnish Spine Registry (FinSpine)

Chair-elect of the European Spine Society Advisory Board (EuSSAB)

- **Emin Aghayev**, MD MSc (Spine registries)
  Head Research Development at Research Campus of the Lindenhof Hospital Group, Switzerland
  Senior Advisor Spine Tango at EUROSPINE
  Project Manager of the Swiss Spine Implant Registry SIRIS
- **Florian Ringel**, PhD MD (Neurosurgery)
  Director of the Department of Neurosurgery, University Medical Centre Mainz
  Representative from the European Association of Neurosurgical Societies (EANS)
  Chairman of the EANS Spine Section
  President-elect of the German Spine Society
- **Sabrina Donzelli**, MD MSc (Clinical research)
  Research Director National Scoliosis Center, Fairfax, Virginia, US
  Chair of the Spine Tango Committee
  President of the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)
- **Sashin Ahuja**, MD MSc (Spine registries)
  Orthopaedic spinal surgeon at the University Hospital of Wales, Cardiff, UK
  Representative of the International Spine Registries working group
  Committee member of the British Spine Registry (BSR)

The PI and the steering committee will be responsible for steering the initiative.

The **SAI team** is funded and based at EUROSPINE. It consists of Christian Herrmann (PI), Emin Aghayev (steering committee), Sandy Sutter and Sylvia Hartog. The SAI team will organise and administrate the initiative. Statistical analyses will be led by Christian Herrmann.

In the future, the steering committee will be expanded by participants who wish to be included more actively in the initiative and subsequent iterations. In the future, sub-committees to deal with specific tasks and data calls will be introduced on a need base.

11.2 Data submission

The data submission will be accompanied by a survey for metadata, coverage and potential biases.

No patient-identifiable data will be allowed, processed or used in the study, except optional numerical patient IDs. Other patient-identifiable data are not part of the requested data parameters to submit. If submitted, they will be rejected and deleted immediately.

Hospital-level data will not be disclosed in the study except hospital reports, which will only be shared with the involved hospital.

The data definitions will follow the protocol, a code book is available in Appendix 2. Data delivery will be done in two ways: as a dataset (a, c) or online via case report form.

a) Established spine registries that routinely collect data will be invited to share their collected dataset of the requested parameters with the SAI team.
   They will be provided with data requirements and codebook documentation, detailing how to name and format rows and columns, and which code values to use with the definitions provided. They are asked to consult with the SAI team if difficulties arise with recoding variables from their definitions to the study definitions.
   The data file format shall be in a corruption-free readable table-like format. Character

encoding must be UTF-8. Please consult with the SAI team, if this is not possible. Preferred file formats are Tab-separated Text format from Excel and Rdata. Upon request, we may also allow XLSX, SAS, Stata or SPSS.
The file name must include the country and institution/organisation abbreviation as specified in the accompanying survey.
Data transmission must be done over secure, encrypted services, preferably certified services for the transfer of health data. At least one option for secured data transmission will be offered to participants.

b) The hospitals that are already participating in the Spine Tango registry will be informed about this initiative and supported in their data collection online in the Spine Tango platform as far as possible. Spine Tango registry Terms and Conditions will apply to the Spine Tango participants in the SAI.
c) The hospitals that are not yet taking part in a registry are eligible to use a trial version of the Spine Tango platform for the data collection.
d) Participants who are not part of an existing registry and do not want to use the Spine Tango platform may submit data in the same form as described for the established spine registries (a).

Hospitals and participants falling under subparagraphs c) and d) will be required to agree to the "Terms and Conditions" attached hereto as Appendix 1, on the survey, see **Error! Reference source not found.**. Hospitals and participants wishing to obtain full access to the Spine Tango registry for a limited trial subscription will be required, in addition to signing Appendix 1, to "click and accept" the limited trial subscription link in Section 4 of Appendix 1.

All data will be combined by the SAI team with the support of NEC Software Solutions as the IT and statistical service provider of EUROSPINE. Any non-anonymous data will be rejected as described above. Numerical Patient IDs may be submitted by participants for validation purposes of their numbers by the participant. IDs are not required for the statistical analyses. Age in years and gender of the patient as well as hospital and country of the hospital will be required and used in the analysis.

Each data submission will go through a basic validity check. The SAI team will confer with the submitter if problems arise. Summary statistics for each submission are produced and sent to the respective study participant.

For the rare occurrence of double submissions, i.e. simultaneous users of a national register and Spine Tango with different levels of detail, we will create comparison statistics, and the steering committee will decide how to incorporate the data.

The data will be reported by country if deemed representative of the related country. The SAI steering committee will decide for each country if the coverage and representativeness of the data are sufficient to produce comparable single-country statistics for them.

The metadata survey answers and the decision on representativeness will be included in the study database.

11.3 Data retention/ Data security

The received and processed data will be kept separate from normal operations in the SAI team it will be stored without personal data -that was removed at data collection- on a Swiss-based secure server with access control. Access will be only granted to direct SAI personnel (CH, EA, SS).

Data will be kept for a period of 15 years after completion of the study.

11.4 Estimated efforts of participants

Estimated efforts are a combination of the time required 1) to set up the procedure for the data documentation, 2) to fill in the survey on the metadata, and time 3) to document and submit data.

1) Time should be reserved for the one-off setting up of the procedure for the data documentation (e.g. information of the involved personnel, watching a tutorial video, ensuring the availability of the required data etc.).

2) The survey on metadata may require between 5-10 minutes to fill in, depending on the knowledge of representativeness, potential bias and similar.

3) The time to document and submit the data will depend on the type of participation in the data call:

a) Established spine registries
If requested data is routinely collected, the registry will be required to export the data and, if necessary, map it to the expected data structure, perform a plausibility and quality check, and share it with the SAI team.

b) The participants who are already taking part in the Spine Tango registry
For all Spine Tango participants, there will be no additional efforts. The SAI team will extract the required data from the anonymised data pool based on the current Spine Tango Terms and Conditions and the consent of the respective participants.

c) The participants that are not yet taking part in a registry, who will use the minimal surgery form version of Spine Tango
Same as for (b), while considering that new users were not registering data so far and will therefore need to establish the procedure first and reserve sufficient time to register cases. Estimated efforts for new participants in Spine Tango who will be using the minimal surgery form: entry of the data may require about 5-10 minutes per case. The time for the data entry for one single patient should be multiplied by the number of patients. For a department with 10 cases of the required pathology per month, about 2 hours per month will be required.

d) Participants who are not part of an existing registry and do not want to use the Spine Tango platform may submit data in the same form as described for the established spine registries (a).
Estimated efforts may be similar as described in (c), entry of the data for 5-19 parameters in an Excel file may require up to 5-10 minutes per case. This is due to Spine Tango automatically coding selected text options into categorized values. The coding has to be done manually in case (d) and requires more time for the same number of variables collected.

11.5 Statistical methods

For the first goal, we will describe the pool of study participants, the estimated coverage and representativeness by country. We will describe the number and completeness of the data submitted and which method of data collection was used.

As mentioned in 7.1, the representativeness of submitted data for a country will be assessed by the steering committee using the data from the participant survey (see **Error! Reference source not found.**, Appendix 3). Indicators include the sum of coverage percent of all country contributors,

plausible-completeness index (data volume times 4 being approximately equal to stated annual numbers of LDS surgeries), self-reported completeness, number and distribution of answers to "similarity to national average". Representativeness will be assessed separately for single variables if indicated by participants with incomplete data parameters.

With the mandatory parameters, we will describe the characteristics of the treated patient population (age and gender distribution), and the distribution of LDS types and grades and performed treatments (type and involved levels). Descriptive statistics of the patient population overall and by country for countries considered to have representative data will be produced. Besides producing a map with the observed values, we also want to understand if there are country-wise trends in treating LDS patients. For this, we will only include countries with representative data and categorise patients into different diagnosis and treatment combinations. We want to answer the questions:

- Is the distribution of age and gender the same among countries and regions, or do statistically different patterns arise?
- Does the distribution of diagnosis and treatment combinations differ among countries or regions (after standardisation by age and gender)?
- What is the within-country variability of treatment patterns?

For the non-mandatory variables, we will re-assess if the representativeness of a country is still given. Those variables will be used to further describe the patient population and to adjust the treatment patterns further. By comparing the distribution of mandatory variables among the submissions with optional data and those without, we will estimate if the participants with the additional data may be significantly different to those without or if the additional data may be assumed to be representative of all participants. We will investigate the questions (all age and gender standardised):

- Are the distributions of the ASA status, the number of previous spine surgeries, the duration of symptoms, the BMI, and the smoker status the same among countries and regions, or do statistically different patterns arise?
- Are there patient clusters regarding the patient characteristics?
- Does the distribution of diagnosis and treatment combinations differ among countries or regions when corrected for age, gender, ASA status, previous spine surgeries, symptom duration, BMI and smoker status (each only if being a significant factor)?
- What is the variability of implants used?

To describe practice variation, we will use descriptive statistics to describe the distribution of treatment types per country and point estimates with 95% Confidence Intervals, or any other appropriate test to assess between-country variation. We will use logistic regressions or other appropriate models to identify predictors for each type of surgery and test if the country /region of treatment is a significant factor.

12 Data call 2025 phases

Here are the proposed phases and their schedule.

- Implementation of communication plan and materials — July-September 2024
- Recruitment of participants — September-January 2024
- Preparation (incl. trainings, ethical approval) — September-January 2024
- Observation period — February-April 2025

- Data submission deadline — 31. Mai 2025
- Data evaluation — June-August 2025
- Presentation of the results — starting from August 2025
- Publication of the results — August-December 2025

13 Funding

No specific funding is available. The SAI organisation and implementation are funded by EUROSPINE.

The data collection efforts require primarily personnel resources. They will have to be provided by the individual hospitals and/or established registries.

The data evaluation, presentation to the hospitals, and publication will be covered by the available Spine Tango's budget of EUROSPINE.

Seeking out funding for potential meetings and maybe a PhD student will be considered in future SAI data calls.

14 Ethical concerns

EUROSPINE will submit the protocol to the responsible Swiss cantonal ethics committee and seek approval. The responsible ethics committee of Eastern Switzerland declared for a similar project that no ethics approval is required for the study itself, but that laws for data and privacy protection apply. (BASEC Nr. 2024-01252 EKOS 24/133).

Anonymous data collection and usage for grouped summary statistics is allowed in most countries if the patients are duly informed and consented to it. See section 15. Participants need to follow local regulations and may consult with their local ethics committee or institutional review board about the data calls.

To support participants in case they need to seek formal ethical approval, the SAI team seeks additional index ethical approval from the local ethics committee of Eastern Switzerland for the collection and submission of SAI data. This will be made available on the website. Please contact the SAI team for more details about security if needed.

15 Agreement / Informed patient consent

All SAI participants are required to ensure that patients for whom data is contributed were informed and have consented to their data being collected and used in anonymised form for summary statistics, unless not required by local law. The SAI team won't be able to control the participants' compliance, and therefore the participation in the study will be subject to a statement of compliance, unless not already covered by the participation agreement of Spine Tango users.

Participants who have no own patient consent forms may use the templates provided by Spine Tango.

For existing Spine Tango participants, the use of data and all data and privacy protection issues are already outlined and governed by the Terms and Conditions for using the Spine Tango platform.

For all participants, the accompanying survey and Terms and Conditions (Appendix 1) ask each SAI participant to confirm by ticking the respective box, that permission is granted to use the material submitted for the purposes stated in this proposal and that patient consent was retrieved -unless not required by local law, i.e. for anonymised data from national registries. Participants can be assured that the submitted data will not be used for purposes other than those outlined above without the explicit permission of the individual participant.

16 Authorship of the results

The following authorship positions will be reserved:

- First author: PI
- Contributing authors:
    - Study participants who significantly contributed to the manuscript
    - One statistician
- Senior author: the author who has provided the most substantial intellectual contribution, which will be assessed by the first author and agreed upon by all authors

All other persons including all data contributors and steering committee members, as not included above, will be listed as the Spine Atlas Working Group (SAWG). Max. 2 persons per data contributor/institution will be named, while all other persons assisting in data contributions will be listed in the acknowledgements. For registries, more than 2 persons may be permitted on a case-by-case basis.

17 Use of collected data

The collected data could be used in numerous analyses for the assessment of different hypotheses.

The authorship group as described in section 16 reserves the right to publish the first two main publications, one to describe the infrastructure and collected data, and one with the results of the data call 2025 as described in the study goals described above.

Subsequently, all involved hospitals and countries will have the equal right to use the pooled data for their research and publications. The standing steering committee (see SAI organisation) will review study proposals and control who does what to avoid duplication, maximise the use of the data and ensure high quality of the data usage. The Committee shall invite all interested colleagues from the SAWG to participate, with a priori a maximum of one representative per country. The SAWG must be included as contributing authorship.

18 Benefits from and significance of this study

18.1 Hospitals

The hospitals will join a large network of European hospitals, which may lead to various research projects and collaborations. They can potentially co-author and/or participate in joint research projects, but also analyse and publish the data on their own under certain terms and conditions approved by the Steering Committee.

Each hospital and country will also receive a benchmarking report comparing their data with the pooled data of all other hospitals and countries.

The hospitals joining the Spine Tango platform may benefit from the platform for collecting additional data (physician-based as well as PROMs), receiving benchmarking reports, getting access to pooled international data, and thus, being empowered in quality assurance and research.

18.2 Overarching perspective

EUROSPINE and established Spine Registries advocate for the importance of disease registration in providing the necessary insight for the improvement of treatment strategy and quality insurance.

The collected data will be valuable for the planning and development of health structures as well as research. The data will give an overarching perspective to all key stakeholders on the treated study population and applied treatments, which is essential for their actions.

This data call provides a unique source of comparable treatment data for researchers worldwide. Each subsequent data call will facilitate the understanding of the evolving magnitude and patterns of spine pathologies in different regions/countries. A strict evaluation of the data quality will ensure comparability across different time periods and regions.

The data provides evidence for the origins of variability across regions, may it be due to environmental, behavioural, societal, medical school, guideline, or other reasons, and may show potential for improvement across multiple factors.

19 Contact

SAI team to contact:

The Spine Atlas Initiative (SAI)
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Page reserved for approval confirmation by steering committee members

Appendix 1 Terms and Conditions applicable to the collection and submission of data under the Spine Atlas Initiative

1. Definitions

Spine Atlas Initiative (SAI) Participants are individuals, groups of individuals from academic institutions, or a legal entity primarily engaged in the fields of research, education, prevention and treatment of spinal disorders that have agreed to participate in the Spine Atlas project **that are not currently participating in the Spine Tango registry (the "Registry")**, nor have recently contributed data to the Registry.

The anonymised data to be submitted by the Participant includes all clinical data that will be submitted under the SAI in accordance with the terms and conditions, and excludes all patient-identifiable personal data.

Steering Committee is the Spine Tango Working group approved board that steers the further development of the SAI and that reviews and approves requests for accessing, sharing and publishing the anonymized pooled data of the SAI for quality assurance and research purposes.

NEC Software Solutions ("Host") is the provider of IT, statistical and reporting services for the SAI.

2. Terms and conditions

1) The Participant shall ensure that all necessary agreements and approvals are obtained from their institution (and can be made available on demand) in respect to any local laws, guidelines, "best practices", ethical requirements, etc. In particular, the Participant is explicitly responsible for obtaining and documenting each patient's informed consent for the use of their data for purposes of the SAI;
2) The anonymized collected and pooled data will be provided solely for purposes of the SAI.
3) No patient-identifiable personal data may be collected or released;
4) Hospital-identifiable data may only be released upon prior consent of the releasing hospital;
5) Patient-level data without patient-identifiable personal data may only be collected if a data use agreement or equivalent arrangement is in place between the releasing hospital and Participant;
6) If patient-level data are not released, the Host will extract and analyse the data as specified in the SAI protocol;
7) Authorship shall be determined solely in accordance with the SAI proposal.

3. Intellectual property rights

The Participant acknowledges and agrees that it shall have no right to any intellectual property rights in the SAI pooled data, reports and results generated by the SAI, or data provided by EUROSPINE's Spine Tango registry or the Host. The foregoing intellectual property rights are protected by copyright laws and treaties around the world. All such rights shall be subject to the terms and conditions described in the SAI proposal, and reserved by the Host, and EUROSPINE.

4. Limited Trial Access to the Spine Tango Registry

The Project Participant shall be entitled to obtain full access subscription to the Spine Tango registry for a limited trial access by clicking and accepting the Spine Tango registry Terms and Conditions here https://www.eurospine.org/fileadmin/Images/Research/Limited_Trial_to_the_Spine_Tango_Registry_General_Terms__Spine_Atlas_.pdf. The trial period should commence upon accepting the Terms and Conditions and end 6 months from acceptance. The Project Participant shall be entitled at any time prior to the expiration of the trial period, to enter into a definitive agreement to participate in the Spine Tango registry.

Appendix 2 Codebook

Type	Nr.	Parameter	Answer value	Answer text
Mandatory	1	Patient age at surgery date	[years]	-
	2	Patient gender	0	female
			1	male
			9	other
			99	unknown
	3	Surgery date	[dd.mm.yyyy]	-
	4	Spinal stenosis	1	central or lateral
			2	foraminal
	5	Primary spine surgery at the same or adjacent level	0	no
			1	yes
			9	unknown
	6a	Grade of LDS (Meyerding)	0	grade 0
			1	grade I
			2	grade II
			3	grade III
			4	grade IV
			5	spondyloptosis (V)
	6b	Grade of LDS (mm)	[mm]	-
	7a1	Decompression type	0	none
			1	discectomy partial/total
			2	sequestrectomy
			3	laminotomy
			4	hemi-laminectomy
			5	laminectomy
			6	foraminotomy
			7	facet joint resection partial
			8	facet joint resection full
			9	other decompression
	7a2	Decompression level	1	L1/2 or L1
			2	L2/3 or L2
			3	L3/4 or L3
			4	L4/5 or L4
			5	L5/S1 or L5
	7b1	Fusion type	0	none
			1	interbody fusion (ALIF)
			2	interbody fusion (OLIF)
			3	interbody fusion (PLIF)
			4	interbody fusion (TLIF)
			5	interbody fusion (XLIF)
			6	other interbody fusion
			7	posterolateral fusion
			8	posterior fusion
			9	other fusion

Type	Nr.	Parameter	Answer value	Answer text
Mandatory	7b2	Fusion level	1	L1/2 or L1
			2	L2/3 or L2
			3	L3/4 or L3
			4	L4/5 or L4
			5	L5/S1 or L5
	7c1	Rigid stabilisation type	1	pedicle screws cemented
			2	pedicle screws uncemented
			3	facet screws
			4	lateral mass screw
			5	laminar screws
			6	iliac screws
			7	laminar hooks
			8	pedicle hooks
			9	sublaminar band/wire
			19	other rigid stabilisation
	7c2	Rigid stabilisation level	1	L1/2 or L1
			2	L2/3 or L2
			3	L3/4 or L3
			4	L4/5 or L4
			5	L5/S1 or L5
	7d1	Dynamic stabilisation	1	disc replacement
			2	Interspinous spacer
			3	other
	7d2	Dynamic stabilisation level	1	L1/2 or L1
			2	L2/3 or L2
			3	L3/4 or L3
			4	L4/5 or L4
			5	L5/S1 or L5
	7e1	Other (surgical treatment)	[free text]	-
	7e2	Other (surgical treatment) level	1	L1/2 or L1
			2	L2/3 or L2
			3	L3/4 or L3
			4	L4/5 or L4
			5	L5/S1 or L5
Optional	8	Additional pathology	0	none
			1	non-degenerative deformity
			2	traumatic fracture
			3	pathological fracture
			4	inflammation
			5	infection
			6	tumour
			7	repeat surgery
	9	ASA status	1	ASA 1 (no disturbance)
			2	ASA 2 (mild/moderate)
			3	ASA 3 (severe)

Type	Nr.	Parameter	Answer value	Answer text
Optional		(ASA status continued)	4	ASA 4 (life threatening)
			5	ASA 5 (moribund)
			6	unknown
	10	Number of previous spine surgeries at the same or adjacent level	0	0
			1	1
			2	2
			3	3
			4	>3
	11	Duration of symptoms	1	<3 months
			2	3-12 months
			3	>12 months
	12a	Height	[cm]	-
	12b	Weight	[kg]	-
	12c	BMI	[kg/m^2]	-
	13	Current smoker status	1	Currently non-smoker
			2	Currently smoker
			3	unknown
	14a	Manufacturer	[full name]	-
	14b	Article number	[full name]	-

Appendix 3 Participants survey

Version 0.4, CH, 16.09.2024

The purpose of this set of questions is to

1) identify the data delivery and country of origin
2) estimate the coverage of a particular country by the participants data
3) identify and take potential biases in the data into account for analyses

The survey can be filled in with the knowledge currently available. The participants will be asked to update their answers, when submitting their data.

General questions (grey fields are already asked at registration)	
Name of participant in English	Name of organisation/institution/individual for which data will be delivered
Name of contact person	<text field>
Email-address of participant	Enter the email-address that should be used for main communication, either institutional or from representative
Other contact persons and email-addresses	Enter a list of persons that should receive information. Use format: "Name1" <email1>, "Name2" <email2> etc.
Country (participants spanning multiple countries: please submit data and the survey for each country separately)	Select out of a list of Countries, stored as ISO 3166-1 alpha-2 codes
Type of participant	Choose: - Health care professional - Surgeon - Department - Hospital - Region - National spine registry - National association for spine - National association for orthopaedics - National association for neurosurgery - Other national association - Research group - Other
Are you a current participant in a spine registry?	Choose: - No - Australian Spine Registry - Belgian Spine Registry - British Spine Registry - Danish Spine Registry - Finish Spine Registry - Norwegian Spine Registry

	- Swiss Implant Registry SIRIS - Spine Tango - Swedish Spine Registry - Other --> please specify
- Please specify if other:	<text field>
Which method of data collection and submission would you use?	Choose: - SAI Excel template, secure file transfer - Database format, following the SAI data definitions, secure file transfer - Spine Tango registry platform (existing user) - Spine Tango registry platform (new user) - unsure
Name of Author 1	<text field>
Affiliation of Author 1	<text field>
Email-of Author 1	<text field>
Name of Author 2	<text field>
Affiliation of Author 2	<text field>
Email-of Author 2	<text field>
Other authors (to be considered in a rotation system)	Enter a list of persons, affiliations and emails. Add a paragraph with instructions. Use format: "Name1", "Affiliation1", <email1> "Name2", "Affiliation2", <email2> etc.
Estimated annual average number of spine related surgeries performed by the participant	<text field>
Estimated annual number of lumbar degenerative spondylolisthesis (LDS) treated surgically by the participant	<text field>
Estimated percent coverage of country (in case of data containing multiple institutions and <100% national coverage please provide the SAI team spineatlas@eurospine.org with a list of institutions)	Please estimate how many LDS surgeries are performed by the participant in relation to the whole country. You may additionally state what percent of spinal surgeries are performed as a rough approximation.
Questions regarding potential bias in the data	
May there be certain legislation, healthcare guidelines or practice recommendations in your country that might lead to different patient selection or treatment characteristics of patients with LDS than in other countries (like the recommendation to avoid fusion if possible)	Yes, No, Unknown
- If yes, please explain	<text field>
Do you estimate your patient demographics to be similar to the national average (consider age, gender, health status, affluence, insurance status)	Yes, Somewhat similar, No, Unknown
- Please explain if you believe that your patients may be different to the national	<text field>

average and some groups may be underrepresented	
Please explain, if and what data is missing, or you expect to be missing for certain patient groups	<text field>
Please estimate the proportion of submitted cases versus overall surgically treated cases for LDS in the reported period for the participant (please count patients without no informed patient consent as missing)	Please choose: - 95-100% completeness - 90-94% - 75-89% - 50-74% - less than 50% submitted
Please state the level of completeness within the data parameters and how correctness was ensured	Please select all applicable to your submission: ☐ Validity check by more than 1 person and/or audit and/or quality assurance ☐ Data entry and validity check by one person only ☐ Missing parameters were followed up and completed as much as possible ☐ Mandatory data parameters complete ☐ Mandatory data parameters incomplete ☐ No optional data parameters submitted ☐ Some optional data parameters submitted ☐ All optional data parameters submitted ☐ Unsure
- Please specify for which variables it was difficult/ impossible to collect data and submit	☐ Patient age at surgery date ☐ Patient gender ☐ Surgery date ☐ Spinal stenosis ☐ Grade of LDS ☐ Decompression type and level ☐ Fusion type and level ☐ Stabilisation rigid type and level ☐ Additional pathology ☐ ASA status ☐ Number of previous spine surgeries at the same or adjacent level ☐ Duration of symptoms ☐ Height and weight/ BMI ☐ Current smoker status ☐ Data on the implant manufacturer and article number - Please specify: <text field>
Agreement	
Do you grant the SAI team permission to use the submitted data for the purposes stated in the SAI proposal, and that patient consent was retrieved -unless not required by local law. Appendix 1 Participants can be assured that the submitted data will not be used for purposes other than	Yes / No

those outlined above without the explicit permission of the individual participant.	
-for non-Spine-Tango participants only- Do you agree to the Terms and Conditions below / in Appendix 1 of the SAI protocol?	Yes / No / Not applicable

To be included: Terms and Conditions for Non-Spine Tango users, Links to patient consent forms and Spine Tango terms and conditions