

SPINE TANGO Code of Conduct

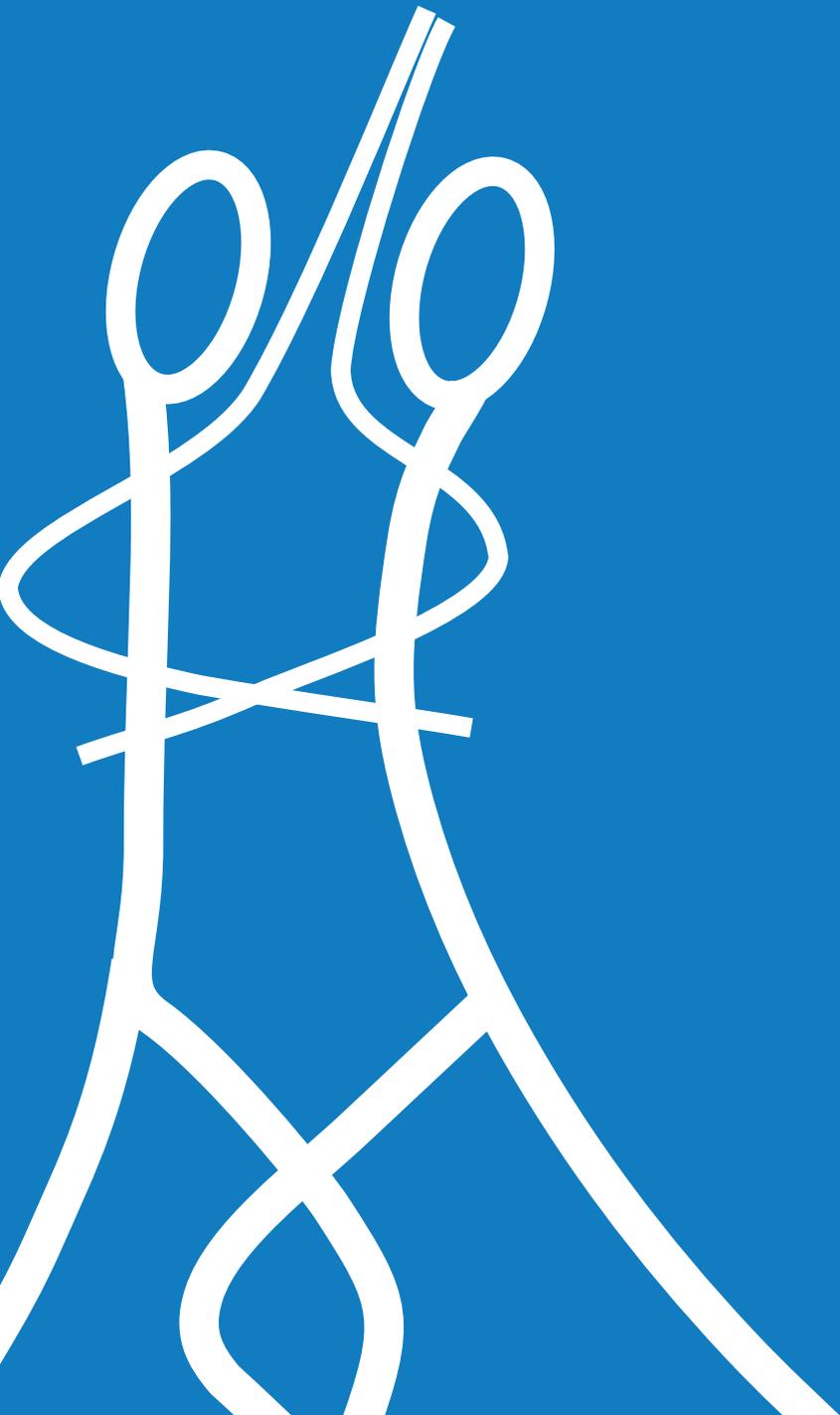


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Code of Conduct

for Participation in the Spine Tango Registry

I. Mission Statement

- a) The registry should facilitate the collection of high quality data describing the outcome of spine surgery.
- b) The data should be collected honestly and as completely as possible.
- c) The means of data collection and the methods of auditing that are put in place to ensure the validity of the data should be transparent to all involved.

II. Definitions

Spine Tango Registry

Spine Tango Registry is an internet based documentation and register system dedicated to quality assurance and outcome assessment in the field of spinal care.

Database

The database is the result of the collection of independently gathered data through the Spine Tango Registry, arranged in a systematic or methodical way and individually accessible.

IEFM

Institute for Evaluative Research in Medicine.

Participants

Participants are defined as individuals or groups of individuals complying with the Code described herein.

A "Participant" can be either an individual or a group of individuals constituting a unit or department. An individual should be a member of Eurospine-SSE (in any one of the approved membership categories). Participants practicing outside Europe should be member of another recognized scientific society, or a corresponding member of Eurospine.

For groups, at least one person in the group should be a member of Eurospine-SSE or another recognized society. For participants practicing in Europe, Eurospine-SSE membership should be obtained within 12 months of acceptance of the agreement on Code of Conduct.

Spine Tango Registry Dictionary of Terms

Refers to documents published on each ST module front page.

COMI

Core Outcome Measures Index. Refers to:

Deyo RA, Battie M, Beurskens AJHM, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korf M, Waddell G. Outcome Measures for Low Back Pain Research: A Proposal for Standardized Use. *Spine*. 1998;23(18):2003-2013.

Mannion AF, Elfering A, Staerke R, Junge A, Grob D, Semmer NK, Jacobshagen N, Dvorak J, Boos N. Outcome assessment in low back pain: how low can you go? *Eur Spine J*. 2005;14(10):1014-1026. Spine Tango Registry

Mannion AF, Porchet F, Kleinstueck FS, Lattig F, Jeszenszky D, Bartanusz V, Dvorak J, Grob D (2009) The quality of spine surgery from the patient's perspective. Part 1: The Core Outcome Measures Index in clinical practice. *Eur Spine J* 18 (Suppl 3): 367-73

Mannion AF, Porchet F, Kleinstueck FS, Lattig F, Jeszenszky D, Bartanusz V, Dvorak J, Grob D (2009) The quality of spine surgery from the patient's perspective: Part 2. Minimal clinically important difference for improvement and deterioration as measured with the Core Outcome Measures Index. *Eur Spine J* 18 (Suppl 3): 374-9

III. Spine Tango Registry

III.A. Background

In the late 1990s Prof. Dieter Grob was asked by the cantonal government of Zurich, Switzerland, to conduct an outcome study of the results of surgical interventions on the spine. The investigation was completed and the data provided to the sponsor. There was no further feedback or consequences as a result of this study.

This triggered the idea of conducting similar projects with a specialist society like Eurospine, the Spine Society of Europe and keep full control of the data.

In 2000, Prof. Max Aebi took over the direction of MEM-CED, the Maurice E. Müller Center for Education and Documentation. This institute, which had a research focus on medical registries, multicenter studies and outcomes research, was later integrated into the University of Berne as the Institute for Evaluative Research in Medicine (IEFM).

In cooperation with experts from Eurospine, the Spine Tango content and technology was developed at the IEFM, where its database and administrative center is located.

III.B. Instruments

Being initially a purely surgical registry, Spine Tango has been developed around one core questionnaire for primary and revision surgeries. It is accompanied by a second and very similar questionnaire for staged surgery and a short follow-up questionnaire.

All instruments are available in a scannable paper and online format and follow the three golden rules for medical registries: simplicity, simplicity, simplicity. The forms can be completed in a minute or less and are suitable for documentation of all spinal pathologies, levels, accesses and surgical techniques.

There has been a significant shift in political and consumer requirements for validated surgical outcomes. With this in mind the Core Outcome Measures Index (COMI), originally proposed by R. Deyo et al. (1998), was developed by a group at the Schulthess Klinik and at Balgrist Hospital,

Zurich (AF Mannion, D Grob, N Boos et al.) for back and neck pain (two separate instruments) and is now officially recommended as the outcome instrument of choice for the Spine Tango community. Similar to the physician-based documentation, the COMI is short, comprehensive and easy for patients to fill in.

Since the superiority of surgical versus conservative treatment is still unclear for many spinal disorders, a working group has developed the “Spine Tango conservative form”, a documentation form for the most important non-surgical treatment options (Kessler JT et al, ESJ 2011 Mar;20(3):369-79). This will enlarge the potential user base of Tango, making it a diagnostic endeavor with possibilities to compare surgical and non-surgical treatments and their outcomes using one and the same registry.

IV. Parties

This agreement is established between Eurospine, The Spine Society of Europe, the Participants of the Spine Tango Registry and IEFM.

V. General Code of participation

All “Participants” in the Spine Tango Registry shall adhere to the Participant Agreement.

All participants shall provide a signed agreement to the conditions and standards set out herein. All participants shall be responsible in ensuring that all necessary agreements are obtained from their institution (and produced on demand) in respect to any local laws, guidelines, “best practices”, ethical requirements, infrastructure etc.

The underlying rationale for each requirement (highlighting how it is intended to promote/advance the overall quality of the registry) are, after the statement of each rule, indicated in square brackets.

V.A. Requirements for Participants

All participants shall irrevocably and for an indefinite period provide their data to Spine Tango. For the avoidance of doubt each participant hereby agrees by their participation to accept that data cannot be withdrawn/removed at a later date, irrespective of that Participant withdrawing for any reason from Spine Tango. Only data entered and subsequently found to be “fraudulent” will be removed from the data pool. If such data has already been used in existing publications, and have markedly influenced those published findings, this shall be addressed as an addendum in the relevant journal or publication. [The reason for insisting on the retention of all data in the registry is that any scientific papers that have been published, based on a given data set, must be readily accessible and available should inspection be requested by the publishing journal. Although an electronic copy of the specific dataset will be stored separately in the database, the original data must be traceable within the registry at all times.]

All Participants must agree to a common language for completion of the Spine Tango forms in accordance with the definitions given in the Spine Tango Registry Dictionary of Terms. Constructive comments and feedback on the dictionary is encouraged and welcomed, especially if Participants encounter any inconsistencies or ambiguities. [Adherence to the Spine Tango Dictionary of Terms is important to ensure consistent and systematic data collection, and to avoid any wording/

phrasing from being interpreted differently by different users.]

If it is available in their native language, all Participants are strongly encouraged to use the Core Outcome Measures Index (COMI) as their patient-orientated outcome instrument. This instrument has been validated in many languages, and is short and practical for use in daily clinical practice. [We recommend the consistent use of this instrument for all Participants because it is a practical and valid tool and its use will facilitate benchmarking between centers.]

All Participants shall be required to indicate the methodology and means (e.g Clinic Information System, Operating Room report, personal agenda, billing procedure) by which they will verify the number of cases they have operated upon or treated in a given year at their personal convenience. The data source selected shall be a matter for the Participant subject to that source being considered “legitimate” by the Spine Tango Registry. [The annual number of cases will permit calculation of compliance with submitted documentation of each user, to give them a key performance indicator for future improvement and/or to form the basis of their application to ultimately become an Accredited Spine Tango Participant]

Participants shall be required to accept and agree to on-site auditing by an independent party contracted by the EuroSpine-SSE Spine Tango Committee. Such independent auditor will be bound to medical confidentiality. [Auditing of the Spine Tango registry data, to include verification of the proportion of all cases submitted and the accuracy of the specific data entered, is essential to ensure that the data is trustworthy. Auditing is a prerequisite of any high quality registry.]

In the case of proven fraudulent behavior the Participant’s entire data set will be removed from the registry and their current and previous participation terminated forthwith. Their name will be deleted from the published list of Participants, for all years. This step will only be taken after an investigation by the Eurospine –SSE Executive Committee. The investigation shall take such form as the Executive Committee shall in its absolute discretion determine. It will be a positive duty for all Participants, if so requested, to assist the Executive Committee in the investigation of such matters. [Honesty, truthfulness and integrity is expected and demanded of all Participants. However to retain external credibility and accountability, it is essential that decisive action is taken where such conditions are breached. Strict adherence to and enforcement of this rule is essential in order to ensure the integrity of the dataset, and its value to other Participants and the Society.]

Participants and their administrative assistants should agree to share their expertise and know-how about Spine Tango with other Participants/ administrators. [Fostering an atmosphere of open exchange, support and assistance from other users is expected to benefit the whole Spine Tango community.]

The Participants are free to cease participation at any time. His/her name will remain on the year-list of Participants and accredited Participants published on the website for the years corresponding to the periods of their Participation.

On-site start-up assistance and online assistance

On-site start-up assistance will be provided in terms of setting-up and training in the use of the system. Based on circumstances (e.g. travel distance, time involved, accommodation, etc) charges for this may apply.

Electronic assistance is available to all Participants upon request.

V.B. Specific requirements for Accredited Participants

A Participant will be acknowledged by the Eurospine-SSE and IEFM as an “Accredited Spine Tango Participant” if they comply with the completion rates for data input described below. The final de-

cision for recognition as an “Accredited Spine Tango Participant” will be made by the Spine Tango Committee based on the data completion compliance.

Accredited Participants must obtain the following compliance rates:

Minimum 80% case documentation rate. A “case” is defined as a preoperative COMI form, the surgical intervention form, and at least one postoperative COMI and physician follow-up form at an interval of 3 months after surgery or later. For the non-surgical participants, a “case” is defined as a pre-treatment COMI form, the conservative treatment form and an end of treatment assessment with a COMI form.

Where Accredited Participants already have a system in place that relies on other established outcome questionnaires (e.g. Oswestry, RMDQ, etc.) they will not be compelled to change to the COMI; however, where feasible, they will be encouraged to use the COMI in addition to their own chosen outcome instrument(s) and must as a minimum include two 0-10 pain scales for axial pain and referred pain. [Having at least one instrument in common between all centers (pain scale) will facilitate comparison. It may also allow some sort of “calibration” of the data collected using outcome instruments other than the COMI.]

Participants may proactively apply to become accredited after a minimum of 12 months’ participation in the Spine Tango Registry. If they believe that they have reached the necessary standards and that these can be maintained in the long term, a document (e.g. hospital’s or department’s annual report) credibly indicating the annual surgical or treatment volume and an informal application letter must be sent to the ST committee head. If compliance is deemed inadequate, assistance will be offered in an attempt to remedy the shortcoming.

Accreditation will be affirmed on an annual basis.

VI. Benefits for all Participants in the Spine Tango Registry

Consistent and accurate in-house data collection

The Participant has a personal database of their own activity for inter alia, quality assurance, outcome research or implant postmarket surveillance, for example. Furthermore, they will have the satisfaction of knowing that their work in contributing to the Spine Tango data pool will be useful to the wider community even if of limited or no value to the Participant.

Online statistics, Benchmarking

Basic online descriptive statistics regarding ones own performance and comparison with the anonymous data pool (“benchmarking”) of all other Participants can be obtained using the Spine Tango online statistics tool, without the need for any statistical software or data handling knowledge.

Raw data exports

The Spine Tango Registry database permits the exporting of a Participant’s own raw data at any time, allowing the Participant to perform further statistical analyses beyond those offered by the online statistics.

Annual report

The data center in Berne provides an individual annual report by email or in the participant’s user account

Statistical/epidemiological services

Members of the Spine Tango community can make use of the statistical/epidemiological and methodological expertise of the IEFM in Berne or other Spine Tango expert members.

Registration of the requested analysis/study at the IEFM will be required. To ensure high quality data analyses and interpretation, and efficient use of the available personnel and resources, a structured and brief study protocol summary will have to be submitted. The template is available on the Spine Tango web page under "Forms"

1)

Accredited participants are treated in a prioritized mode and have exclusive access to the pool of accredited data for an even more valid and high quality benchmark.

Implant capture

Thanks to a sophisticated implant interface, Participants can record their implants by manually adding them to the surgery form, by making use of electronic supplier catalogues, or by using the MEMdoc or GHX barcode scanners. A personal "Implant Notebook" can also be created with the most frequently used implants of the respective user.

Imaging system

The Spine Tango Registry system offers an online imaging interface for uploading, storing and viewing image files.

Promotional material

Participants will receive Spine Tango brochures as promotional material for patients, insurance companies, referring physicians, etc. (informing about the aims of Spine Tango, its accreditation procedure, and the value and kudos associated with your participation).

VI.A. Additional Benefits for Accredited Participant of Spine Tango

Accreditation

Yearly accreditation with a certificate confirming status as "Eurospine, the Spine Society of Europe Spine Tango Accredited Participant".

All accredited Participants will be listed on the Eurospine website and Spine Tango website, on an annual basis and for each year.

Use of logo indicating status of "Eurospine, the Spine Society of Europe Spine Tango Accredited Participant" to be placed on official letterheads, website, etc. of the Participant's/Participants' institution.

Benchmarking

Offline Statistics concerning Participants performance and comparison with the Accredited Pool.

VII. Scientific publication of the Spine Tango data

VII.A. *Participants' rights and duties*

Each user may use their own data as they deem appropriate for the purposes of scientific publication. This also applies for groups of users that wish to use their combined data for inter alia hospital, multicentre, or on a national basis.

Should a Participant have a proposal for a paper that requires/involves data from the whole data pool, a summary of the proposed “study/analysis” shall initially be submitted for approval to the Spine Tango committee.

If approved, the major Participants contributing the data ($\geq 20\%$) for the proposed “study” will be invited to co-author the paper, conditional upon their effective contribution to the work (i.e., the writing of the manuscript).

The first author shall be the judge of “effective contribution” and the subsequent rights of authorship. Should a dispute arise in relation to “effective contribution” the Spine Tango Committee shall be the final arbiter whose decision shall be final and binding upon the parties

The Spine Tango group should be acknowledged as “participating investigators” and reference should be made to the web page where the names of all Accredited Participants are indicated (according to the recommendations of Tornetta P, Siegel J, McKay P, Bhandari M. Authorship and Ethical Considerations in the Conduct of Observational Studies 2009; J Bone Joint Surg Am. 2009;91:61-67.doi:10.2106/JBJS.H.01538).

VII.B. *Third parties (industry, insurance companies, political bodies, societies, etc).*

Should an individual or organization (the above being a non exhaustive list) wish to investigate or pose a question which involves utilizing the whole data pool, they shall initially submit to the Eurospine Spine Tango Committee an outline and/or justification of the enquiry or proposed issue for approval.

If such approval is forthcoming, a report containing the requested information will be provided by the Eurospine Spine Tango Committee. Individual raw data shall under no circumstances be released, and the released data will comprise only a summary addressing the specific enquiry.

The third party using Spine Tango pool data will be invited to make a donation to the project depending on the number of cases that are of use for the respective data analysis.

VIII. User fee

In order to contribute to the upkeep of the registry, as of 1.1. 2014 an annual user fee of EUR 1000 per center and registered surgeon will be introduced. The maximum annual fee per center will be EUR 2500. Accredited participants will receive a 50% reduction. In justified cases (e.g. socio-economically poor countries), a fee reduction or waiver may be granted.