

How to Tango: a manual for implementing Spine Tango

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Abstract The generic approach of the Spine Tango documentation system, which uses web-based technologies, is a necessity for reaching a maximum number of participants. This, in turn, reduces the potential for customising the Tango according to the individual needs of each user. However, a number of possibilities still exist for tailoring the data collection processes to the user's own hospital workflow. One can choose between a purely paper-based set-up (with in-house scanning, data punching or mailing of forms to the data centre at the University of Bern) and completely paper-free online data entry. Many users work in a hybrid mode with online entry of surgical data and paper-based recording of the patients' perspectives using the Core Outcome Measures Index (COMI)

questionnaires. Preoperatively, patients can complete their questionnaires in the outpatient clinic at the time of taking the decision about surgery or simply at the time of hospitalisation. Postoperative administration of patient data can involve questionnaire completion in the outpatient clinic, the handing over the forms at the time of discharge for their mailing back to the hospital later, sending out of questionnaires by post with a stamped addressed envelope for their return or, in exceptional circumstances, conducting telephone interviews. Eurospine encourages documentation of patient-based information before the hospitalisation period and surgeon-based information both before and during hospitalisation; both patient and surgeon data should be acquired for at least one follow-up, at a minimum of three to six months after surgery. In addition, all complications that occur after discharge, and their consequences should be recorded.

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Introduction

After 8 years of development and over 6 years of data collection Spine Tango has now reached a stage of maturity with respect to content, software and hardware. It has been transformed from a European spine registry into an international registry with users from all parts of the world and with regional national servers located in countries such as the United States, Mexico, Brazil, Germany, Austria and Italy [1]. The format of Spine Tango has been optimised and made more versatile. It is now suitable for routine use by both academic institutions and smaller hospitals. The number of participating institutions per country can be found in Table 1. The data pool is still somewhat

Table 1 Participants per country, non-disclosing list

Country	N (clinics)
Austria	3
Belgium	3
Brazil	1
Finland	2
Germany	11
Italy	2
Mexico	1
UK	1
USA	1
Switzerland	5
Singapore	1

heterogeneous with respect to the case histories: there are 8,687 surgeries documented without any additional information; there are 1,758 surgeries with preoperative patient assessment but without follow-up information; there are 1,347 preoperative patient assessments without surgery forms; there are 1,454 surgery forms with pre- and post-operative patient assessment and there are 3,676 surgery forms with physician-based follow-up documentation.

The primary goal remains the documentation of the full range of spinal pathologies and surgical procedures. The continual appearance of new innovations on the market results in an ever increasing need for documentation to assess the efficiency, safety and cost-effectiveness of the new techniques and technologies. The embedding of a clinical documentation system into a surgeon’s day-to-day workflow is a challenge to which numerous established Spine Tango participants have now risen—a testament to

the feasibility of the system in daily practice. The current article aims to give detailed information about the set-up opportunities, configurations, and workflows of the system, including their latest developments and possible pitfalls. The history and philosophy of Spine Tango have been described previously [2, 3] and a first article about the macro set-up was published in 2005 [4]. The interested reader is referred to these for further background information.

In the current paper we focus on the micro set-up, i.e., participants’ individual workflows and their integration of the Spine Tango system into their clinical practice.

User registration: department versus individual approach

Before starting documentation with the Spine Tango, one must be clear about the desired level of representation. The dataset collected can be used to represent the whole department only if the data are entered using one and the same username/password for all participants. If the individual representation of a surgeon’s activities and outcomes is the goal, each user needs to be registered individually and has to submit his/her cases with their respective username/password. That way, the online statistics tool can be used to query performance of the individual surgeon, department and performance of the Spine Tango community, i.e., the data pool (Fig. 1).

If it is not desired to see the individual online statistics for each user but it is of interest to be able to still link a case to the operating surgeon and/or assisting resident, all

User registration options	
One UN/PW* for all users	Individual user registration
Consequences for online tools	
„Department view“	„Individual view“
<ul style="list-style-type: none"> •Form creator equals form submitter •Pull down menu in surgery form shows one name •Statistics query for „my data“ and „my department data“ will always show same results 	<ul style="list-style-type: none"> •Form creator and form submitter can be different users •Pull down menu in surgery form shows all registered names •Statistics query for „my data“ and „my department data“ can show different results
Consequences for exported data	
NO further user differentiation possible (surgeon/assistant)	Further user differentiation possible (surgeon/assistant)

* username/password

Fig. 1 Spine Tango user registration options and consequences for data management

users need to be registered. Only one username/password is used to submit the cases, but the surgeon and assistant are indicated with the respective pull-down menu in the surgery sub-form, which automatically displays all registered users. In this way, annual statistics about surgeries and/or the assistance given can be created from a data export (Fig. 1).

“Tricking” the default system set-up

Some hospitals do not want to see surgeon-specific online statistics, and do not wish to share their data, i.e., allow it to be viewed on the departmental level, which is the default setting for the application. If surgeons within a department wish to avoid others seeing their individual cases (a statistical overview of another surgeon’s performance with the online statistics tool is only possible if his username/password is used), each surgeon can be registered as his/her own hospital (e.g. Galeazzi Orthopaedic Institute Orthopaedic department 1, Galeazzi Orthopaedic Institute Orthopaedic department 2, Galeazzi Orthopaedic Institute Orthopaedic department 3, and so on). The only drawback of this “back door” solution is that it precludes the shared use of the SEDICO scanner for automated implant tracking in the operating theatre [5] (see below) since the scanner can only belong to one department and can hence only be assigned to one of the surgeons or his virtual “hospital”. Also, such a system would prevent the use of online statistical queries at the departmental level, since each surgeon would represent a different hospital and department.

Data proprietary and blinding

Several levels of data ownership prevail. An individual surgeon is the owner of his own cases and can use them freely for analysis and publication. However, Eurospine owns the anonymised data pool, which can be stratified down to the country or hospital level for analysis. If less than three hospitals are active within a country, it is not included in such country stratification, since this would

come close to revealing the results of an individual participating hospital. The results of individual hospitals or users can never be used or revealed in a non-anonymised way, but may be looked like “Hospital 1”, “Hospital 2”, “Hospital 3” and so on, i.e., by means of an anonymised stratification at the hospital level. As can be seen in Fig. 1, the national modules convert surgeon and assistant names into codes that are stored in the central database. The same applies for the hospital identities. In this way, it is not possible to identify participants in the central pool unless permission is given to link the central pool dataset with the module dataset containing the surgeon and hospital identifiers. The Spine Tango data pool also does not contain any patient-related information—only the country where the data comes from, i.e., the national module and the patient sex and age (derived from year of birth). All other personalized patient information reside in the national modules and are not transmitted to the central database [4]. If a user wants to initiate an analysis of data from the Spine Tango international data pool, he must submit a written application to the Spine Tango committee via the Eurospine head office (info@eurospine.org). All employees handling data at the Institute for Evaluative Research in Orthopaedic Surgery (IEFO), University of Bern are obliged to exercise professional discretion.

The forms

The Spine Tango questionnaire battery has been consolidated into a final set of five forms: one surgery form, one form for staged surgical procedures, one physician-based follow-up form, and two patient forms containing the Core Outcome Measures Index (COMI) for cervical and lumbar spinal pathologies [7] plus additional questions (post-surgery) about global outcome, satisfaction, complications, and repeat surgery. All of these are available in an online and paper-based format. The language versions and their current status of validation for patient-based assessment (COMI) are displayed in Table 2. Recently, a minimal format of the surgical form has been implemented, which

Table 2 Language versions of the Spine Tango forms

	EN	DE	ES	FR	IT	PT	TR	PL	CS	NO	HU	GR	JA	SL	DU
COMI back	Y	Y	Y	Y	V	Y	D	D	D	V	V	V	D	D	D
COMI neck	Y	Y	Y	Y	V	Y	D	D	D	V	V	V	D	D	D
FU physician	Y	Y	Y	P	Y	P	V	V	V						
SSE surgery	Y	Y	Y	P	Y	P	V	V	V						
SSE staged	Y	Y	Y	P	Y	P	V	V	V						

EN English, DE German, ES Spanish, FR French, IT Italian, PT Portuguese, TR Turkish, PL Polish, CS Czech, NO Norwegian, HU Hungarian, GR Greek, JA Japanese, SL Slovenian, DU Dutch

Y existing, P in programming, V undergoing validation, D in development

can be completed in less than one minute. It is not an extra form; instead, the essential items belonging to this minimal set are colour-coded on the regular surgery sheet. A few questions in the admission and surgery sub-forms have been made optional, i.e., their completion is no longer compulsory, and the complete discharge sub-form can now be left empty if desired. This sub-form is a critical step in the organization of many hospitals because it cannot be completed directly after surgery, but only after patient discharge. Consequently, this last part of the form becomes the responsibility of the ward staff (Fig. 2). On many occasions the data center in Bern was confronted with perfectly filled-in forms that had an empty discharge sub-form and were hence rejected by the database. Moreover, some participating hospitals do not want their hospitalisation times calculated and do not want to indicate their complications. For these users, the new minimal format was created. Some institutions have found an internal solution to the problem of the logistics, which involves asking the clinician to indicate in the patient’s discharge letter (written to the referring physician) whether any complications arose. The letter is concluded with a box, entitled “most important details in short”, in which there is an item “complications, y/n”. The letter is to be found within the clinic information system: if there are no complications, the form is completed accordingly by the person scanning the forms into the system; if any complications are indicated, the form must be returned to the surgeon for completion of the details in the “complications” section. Since usually only 1–2% of patients experience complications during their hospitalisation, this represents a feasible amount of extra work for the surgeon to have to deal with.

Methods of data entry

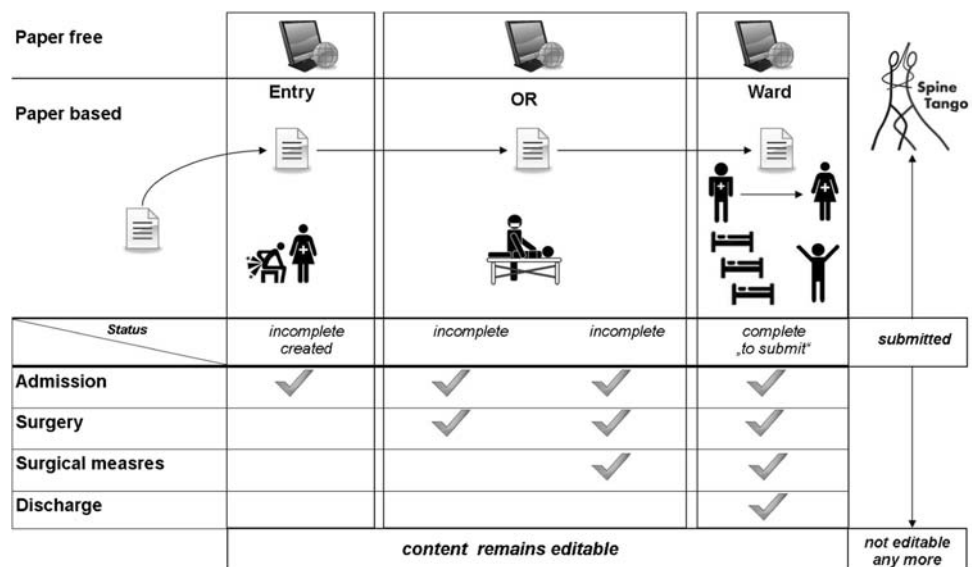
There are currently five possible ways that forms and questionnaires can be transferred to the database (Fig. 3).

1. Online data entry (A)
2. Paper-based data capture with OMR scanner-assisted entry of data (B)
3. Paper-based data capture with data punching using the online interface (C)
4. Paper-based data capture with mailing of the forms to the IEFO or other partner institutions for OMR scanner-assisted entry of data (D)
5. Hybrid method of direct online entry of surgical data (A) and OMR scanner-assisted entry of patient questionnaires (B), or direct online entry of surgical data (A) and delayed online entry of questionnaires that were completed on paper by the patients (C).

Online data entry

The completely paper-free data entry mode is certainly the cheapest way of administrating the Spine Tango for all involved. The hospitals do not need an OMR reader for scanning paper forms, and the high precision print-outs of the Tango questionnaires that are produced in Bern and sent all over the world are not necessary. Nonetheless, an excellent IT infrastructure must be in place, and fast internet access at every site where patient contact and subsequent data entry is possible (ward, OR, outpatient-clinic) is a basic prerequisite. In addition, all staff members involved in data collection must have sufficient knowledge of the application for allowing time efficient navigation

Fig. 2 Micro set-up (workflow—hospital treatment)



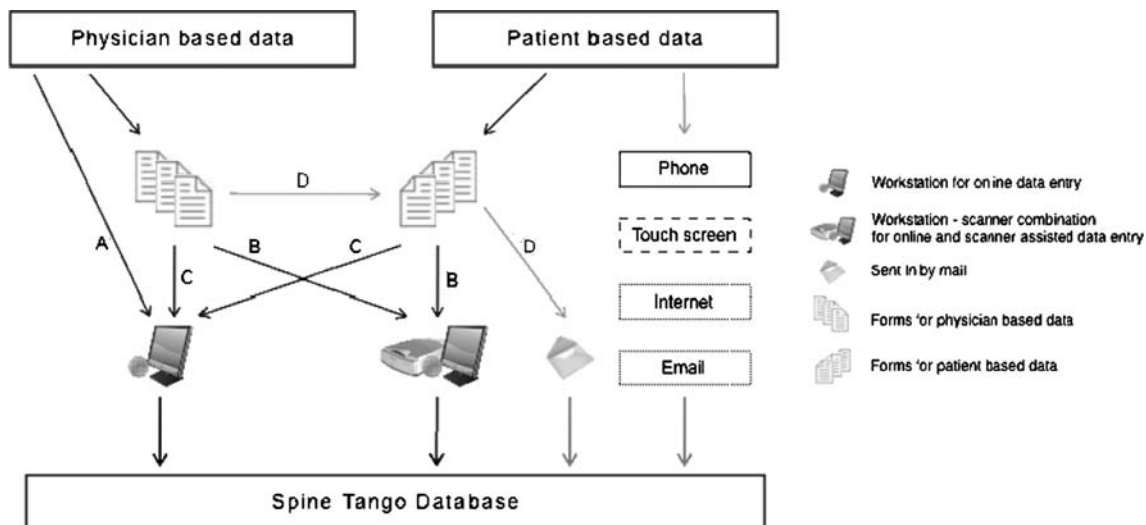


Fig. 3 Methods of data entry

through the application. Currently, patients cannot utilise this means of direct data entry, since they would be required to use the computer of the administrating Spine Tango participant (which has accompanying security issues); separate touch-screen solutions for these self-assessment tools (such as described by Schaeren et al. [6]) are currently not offered by the Spine Tango. The direct online data-entry mode is particularly popular in hospitals that do not carry out any patient-based documentation.

Paper-based data capture with OMR scanner-assisted entry of data

The scanner-assisted entry of data is an elegant method that requires the purchase of a special OMR scanner and the regular ordering of forms from the data centre in Bern. The paper-based documentation still conforms best to the reality of hospital workflows and most institutions use paper forms for their Spine Tango data collection. Paper-based data capture is the least time-consuming method for the surgeons and the easiest and most attractive method for the patients. Ideally a staff member like a secretary, study nurse, or dedicated part-time employee takes on the responsibility of questionnaire administration and scanning. This task should be considered a non-professional one but in some centers, young residents or medical or doctoral students become the Tango administrators. A fixed work-place like a documentation office is recommended for positioning the scanner and computer and for being able to store and archive empty and completed questionnaires. One advantage of this system is that only one or two persons have to be thoroughly educated in the data entry and data transfer process whilst the operating physicians simply



Fig. 4 Marking errors

need to know the structure and rules of the paper forms in order to complete them correctly. Scanning the data in the same institution where the information is entered on the form is superior to separating these two locations, since erroneous or missing information can be easily investigated and corrected in-house. The scanner itself is a high performance industrial device with a reading and detecting velocity of the calibre required for population censuses. If the marks are correctly placed and if pencils rather than ballpoint pens are used (a major problem for some users), the detection rate of the scanner is 100%. Several typical marking errors are displayed in Fig 4. After completing the first dozen forms, this matter ceases to be a major issue.

Mailing paper forms to the IEFO or other partner institutions results in a local separation of data creation and data entry, and incomplete or incorrect questionnaires have to be sent back to their source for correction. This takes time, and the corrections are often either not made at all or the information is generated retrospectively, posing a potential threat to its accuracy.

Paper-based data capture with data punching using the online interface

This seemingly cheaper version of the aforementioned method obviates the need for purchasing a scanner and using the special OMR precision printed forms produced in Bern. This gives more independence to the participating institution regarding the reproduction of forms as black and white or colour photocopies. Instead of scanning the data after form completion, the paper-based information is “punched” (input) into the system using the online interface. The longer this method is used, the smaller the initial financial advantage of not purchasing the scanner. The extra hours needed for manual data input, which takes considerably longer than data scanning, means that using this method may prove to be a false economy in the long term.

Paper-based data capture with mailing to the IEFO or other partner institutions for OMR scanner-assisted data entry

Some participants prefer sending the completed forms to the IEFO, which acts as first level supporter in all situations where a national data entry center is not available. Here, a centralised scanning process (not explicitly displayed in Fig. 3) is performed, but the aforementioned disadvantages of separating the place of data creation and data entry have to be taken into account. On the other hand, thanks to the application service provider principle of the application, the entered information is immediately available online for the partner hospital, and online statistical queries, print-outs or simply searching and viewing of the individual patient information is possible. This documentation mode is certainly the least cumbersome for the participant, though he loses the advantage of reacting immediately, should erroneous or incomplete forms be found. The newly introduced minimal format should help to lower the rate of forms that need to be returned to hospitals for completion, since more number of forms will fulfil the minimal standards for completeness, and thus compliance will hopefully be strengthened.

Hybrid method of direct online entry of surgical data and OMR scanner-assisted entry of patient questionnaires, or direct online entry of surgical data and delayed online entry of questionnaires that were completed on paper by the patients

Some hospitals prefer a mixed working mode where the physician-based surgery forms and sometimes also the follow-up forms are entered online, while the patient assessments, administered on paper are scanned in. This setup requires the highest degree of sophistication all

round, since all staff members must know the application sufficiently well. A good IT infrastructure must be in place, and the hardware (scanner) and a location for scanning must be available. An alternative solution involves the scanner being substituted by an employee performing online data punching. It is typically the assisting surgeon who performs the postoperative documentation in Spine Tango while the surgeon himself takes care of the routine paper work such as dictation of surgical reports and coding.

Micro procedures

Create patient

A form can only be generated electronically or scanned-in if the virtual chart for the given patient exists. The creation of a patient chart is the first step in the documentation of a case. In the case of online data entry, the documenting surgeon typically performs this work-step himself. In the case of data scanning, this step is “outsourced” to an administrative person. There are hospitals, however, where a non-medical staff member prepares the patient chart upon patient admission to the hospital, so that the surgeon only has to search for the patient in order to enter the clinical data. This helps to reduce the workload of the documenting surgeon. A critical aspect in the creation of a patient chart is the so-called medical record number (MRN). It must be a unique identifier that remains constant during the complete treatment period, i.e., during the index surgery, follow-up and reoperations or revisions. All forms are stored inside the digital patient chart that carries the MRN. Many hospitals have several administrative numbers for patients, most of which apply only for the current hospitalisation. None of these numbers are suitable for use in the Tango system.

Create form

Once the patient chart has been generated, an empty form must be selected from the electronic library, if online data entry is to be performed. Similar to the previous work-step, the documenting surgeon typically performs this step too. Ideally a non-medical staff member has not only created the patient chart, but also retrieved an empty form from the library. This can again save a couple of clicks and hence time for the documenting surgeon.

Complete form

The online forms have a certain structure that has implications for the workflow. The surgery form, for example, consists of four sub-forms that can be completed by different staff members at different time points and from

different computers, as part of a team approach. A sub-form, however, is the smallest entity of information that must be entered and saved in order to transfer the data successfully to the database. Half-completed sub-forms can be neither transferred nor stored. The information is lost if the user logs out or leaves the system untouched for more than five minutes. Therefore, most surgeons complete the admission, surgery and surgical measures sub-forms online, postoperatively, and delegate completion of the discharge sub-form to a resident on the ward. As mentioned earlier, this critical work-step often fails and, as such, the discharge sub-form has subsequently been made optional. In contrast to the direct data entry procedure, when paper forms are used, each box that is ticked with the pencil is “stored” information so that staff members can contribute with individual entries. For example, a secretary can complete the demographic patient information (medical record number, date of birth, sex) and administrative information, such as admission and surgery dates.

Scanning/entering implants

Implant documentation is an important part of quality assurance and research initiatives that deal with post-market surveillance of medical products. The Spine Tango allows the integration of an automated barcode-based data capture for documenting the article number; LOT number and official implant description with the so-called secure data integration concept (SEDICO) system. The former Sulzer/Centerpulse software is now administered and marketed by Global Health Exchange (GHX) company (<http://www.ghx.com>, www.ghxeurope.com). The SEDI-CO system is used for just-in-time reordering and delivery of implants to keep pace with their usage. A copy of the implant dataset can automatically be linked to the respective medical dataset with linking parameters such as scan date/operation data, patient medical record number and location of intervention (e.g., cervical, thoracic, lumbar) by running the barcode scanner not only in “ordering” but also or solely in “tracking” mode. If used for reordering, the necessary hardware is provided by the industry. If solely used for implant tracking, hospitals have to purchase the hardware themselves.

Alternatively, implants can be documented manually by searching and selecting the respective products in the supplier catalogues online, or, if a supplier has not provided his catalogue, the name of the supplier, the article description and if desired, the article number can be entered by the users and linked with the medical dataset. A recently released “personal implant notebook” is a new feature of the documentation system that allows surgeons to create their own customised list of implants. This list can

be used for quicker and more convenient selection and linking of implants since it is smaller and easier to navigate than the supplier-catalogues. There is a small section in the surgery sub-form of the Tango surgical paper forms for indicating the implant information in words. Alternatively, the product stickers can be stuck onto a separate implant documentation sheet which is provided as a PDF in the Spine Tango section of the Eurospine webpage. In this way, the article and LOT number and the manufacturer’s official implant description can be recorded effortlessly by the surgeon and later input by the documentation staff.

Follow-up documentation

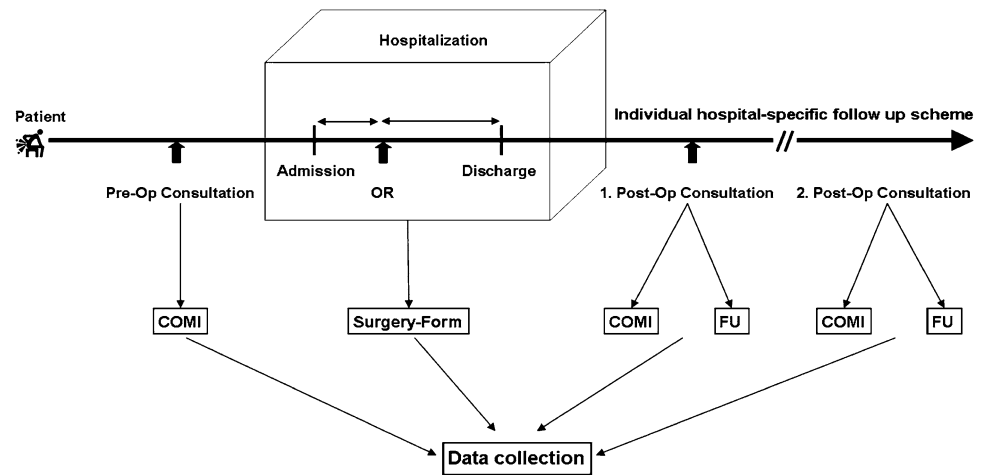
Following Ernest Codman’s “end result system” all patients should be followed up in order to assess the risks and benefits of a certain therapy. In many cases of spinal surgery, this can only be done after a minimum of 3–6 months followed by the surgery (Fig. 5). Eurospine additionally encourages the capture of complications at any time during the postoperative period. A critical aspect in the follow-up is the relationship between the surgical goals indicated on the surgery form and the assessment as to whether these goals were achieved, partially achieved or not achieved at all. In some instances the surgeon in the outpatient clinic cannot remember what he had indicated as his surgical goals or he is not the one who is seeing the patient at follow-up. Therefore, it should be ensured that a copy or print-out of the surgery form goes into the patient’s records used in the outpatient clinic or that the dictated and transcribed surgery report contains the information about the surgical goals as indicated on the surgery form.

Preoperative patient documentation

Patient-based outcome documentation with the COMI questionnaires for neck or back pain has become an essential part of the Spine Tango documentation [7]. Currently the paper-based data capture is the preferred mode of administration, since touch screen applications in waiting areas and/or web-based applications for home use are not yet available (a dashed box indicates that status in Fig. 3).

Since the preoperative information is crucial for assessing the patient’s preoperative baseline status, great efforts should be made to ensure that the patients complete these forms before surgery. A common solution is to hand over the forms to patients at the last outpatient visit before surgery or with the invitation letter for surgery. Patients can then complete the forms at home and hand over them to the staff at the time of hospital admission. If forms are forgotten, or if it is not possible to administer the forms

Fig. 5 Time line



before admission, the preoperative day is probably the last chance for getting valid baseline information from patients. The operative day itself is usually too stressful for the patients, and asking patients postoperatively to remember their preoperative status is an inappropriate solution, from scientific perspective (Fig. 5).

Patient documentation at follow-up

Taking into account the aforementioned minimum requirement of one documented follow-up at least 3–6 months after surgery, there are a number of ways that this can be administered. Patients can complete the COMI forms in the waiting zone, or can send the forms by post if they cannot attend clinical follow-up. Some institutions only administer the patient questionnaire by mail, running a separate system of organisation from that of the clinical follow-ups to ensure complete control of this important part of the documentation process [8]. Other methods include giving the patient the postoperative COMI form upon discharge from the hospital, and asking him/her to complete it at the chosen time of the postoperative outcome assessment. In all cases where the questionnaire is administered by post, it should be accompanied by a stamped addressed return-envelope to improve patient compliance. The COMI is so short that it lends itself to administration by phone, although its validity under these circumstances has not been formally assessed; this method should hence be used sparingly, for cases when data are unable to be acquired by any other way.

Informed consent

The Tango has turned into an international spine registry, for which many different laws and regulations about

patient privacy exist. The data encryption methods and especially the use of the national filter servers are major measures for protection of patient privacy by decentralised anonymisation of identifiable data [4]. The best of all measures, however, lies in the hands of the surgeons and patients and it is the informed consent of the patient regarding the electronic recording and transfer of his data for reasons of quality assurance and academic research. Many hospitals have integrated a corresponding paragraph as part of the hospital contract or the informed consent to surgery, or in a cover letter to the patient accompanying the questionnaire sent by post. On the Spine Tango web page there is a text template for the acquisition of informed consent, based on the European telecommunication law about electronic data transfer.

Smart solutions

Here we want to briefly describe two extremes of data entry into the Spine Tango registry that show how different and diverse the various hospitals' workflow solutions can be.

Scenario 1: No surgeon is involved in data entry. One of our participating hospitals restructured the surgical report in a common session with all involved surgeons to ensure that all variables needed for completing the surgery form were mentioned in the report, using the terminology used on the Spine Tango form. No Tango surgery form is ever completed by the surgeons; instead, a non-medical staff member enters the data online on the basis of the surgery report. The same principle can be applied for the follow-up forms.

Scenario 2: All surgeons are involved in data entry. A seemingly opposite approach was chosen by another hospital, where the Tango sheets for each patient operated on the previous day are completed with all involved during the

