SPINE TANGO / EUROSPINE

GUIDE FOR SETTING UP A REGISTRY OF SPINAL TREATMENTS AND ITS OUTCOMES WITH MANAGEABLE EFFORTS

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Content

1. Background

We are working in an era in which documentation of the quality of our work has become an essential and unavoidable part of our work. At the same time, monitoring the quality of treatment enables its control and improvement.

In addition, the registration of spinal treatments and their outcomes may be necessary for the following reasons:

- a legal requirement;

- an organisational or contractual requirement;

- an institutional certification requirement;

- research using own data or data from the international data pool.

2. Setting up a registry system in your hospital

In principle, registration of spinal treatments and their outcomes is feasible with limited effort. One key aspect is the registration of medical data on diagnosis and treatment provided, and the second key aspect is the collection of Patient Reported Outcome Measures (PROM) from patients.

The following chapters provide recommendations from EUROSPINE, the Spine Society of Europe, and help to estimate the effort required.

a. Registry platform

The key decision to made is what platform you will use for the data capture.

If the country where the hospital is based in does not run a national spine registry, there are probably three ways to register data on spinal treatments: Spine Tango with its web-based registry platform, a commercial data collection platform, and a patient record system integrated with your hospital's information system.

- Spine Tango registry platform

The Spine Tango registry is offered by EUROSPINE to its members free of charge as a ready to use solution. A non-member may still use Spine Tango provided that he or she or somebody else from this hospital become a EUROSPINE member within one year of Spine Tango registration (To become a Spine Tango user please visit EUROSPINE's webpage). An overview of this platform is available here.

Once registered as a hospital or an individual user, one can log in at any time point, search existing patients, add a new patient, select the form type (surgery, conservative, physician follow-up) and enter data (additional tools including reporting are also offered).

If patient email and mobile number are entered among patient data, starting from June 2023 the chosen PROM forms can be send to the patients electronically as a link. The link forward the patient to a patient-friendly mask for PROM questions, and the questions can be answered

independently of the hospital. This new electronic PROMs function manages the PROM forms in a quasi-automatized manner. It sends up to two reminders, provides the hospitals with an overview of the status of the sent-out PROM forms, and sends out follow-up forms based on the surgery date.

Importantly, patient contact details for ePROM (email and mobile phone number) can only be registered with the patient explicit consent. Additionally, this approach should be checked and approved with the hospital's Data Protection Officer.

Patients may also fill out PROMs on a paper. In this case the data from the paper forms will have to be entered into the web-application either manually or with the help of an optical mark reader (such special scanners are, however, costly).

By choosing the manual or a scanner-based entry of the PROMs data, a set-up of a process in the hospital will be required to trigger the manual handover or postal send out of forms to the patient once they are on the list for surgery or for a conservative therapy. For the ePROMs the hospital should aim to register the patient details as early as possible after the decision to treat, as at this registration the pre-treatment ePROMs will be triggered.

- A commercial provider

Several companies offer a data capture and a PROM management platform that can be installed in your workplace, and that enables for example PROM forms to be sent to the patient electronically at the desired time points. These platforms still require a trigger from the hospital to send out the form at the desired time points. A commercial provider usually tries to integrate its platform in the hospital's information system. Also, a system for alerts, reminders, or any response rate enhancing method may be available in their portfolio. Providers may also offer you the option to fill out the physician-reported forms in their platform. The submitted data can then be regularly sent in a batch-mode to the Spine Tango platform, which would offer additional benefits for the hospitals including international benchmark, access to the international data pool, EUROSPINE certification, etc. The disadvantage of engaging a commercial provider is that their services are to be paid. Also, as the commercial provider will have access to particularly sensitive data, a contract with have to be negotiated with the legal department and the DPO of the hospital.

Examples of providers are Leapstation (https://leapstation.eu/) and Heartbeat (www.heartbeat-med.com).

- A patient record system integrated with the hospital's information system

Some hospitals have an own data registration platform and may prefer that all patient forms and other data are registered via their documentation system. Such system may integrate the physician-reported forms and required PROMs in their software. Examples are KWS, HIX, Epic.

To be able to send out PROMs electronically, the hospital still has to set a trigger for the system to send out patient questionnaires at the desired time points. To find out whether a hospital system can integrate the required forms, hospital's IT department is to be contacted. The advantage of this approach is that no contracts with external parties is required. The

submitted data can then be regularly sent in a batch-mode to the Spine Tango platform, which would offer additional benefits for the hospitals as mentioned above.

Independent of the data registration platform and approach, a set up will required some testing, which is also recommended. Especially in the initial phase, anticipate some efforts for setting up the registration approach both on the IT-technical, but also on the organisation level.

b. Scope of participation and selection of patients and/or treatments to register

Another decision is the scope of participation. A surgeon can participate individually, on its own, but also include its entire department, and other departments dealing with spine pathology.

The success of a new data collection system usually depends on several factors. If the sustainability of an approach is uncertain and personal resources limited, a hospital may consider starting with a selection of patients or treatments (for example based on the pathology) to ensure a smooth start.

c. Physician-reported forms and PROMs

The physician-reported forms (surgery and conservative treatment as well as physician follow-up forms) are rather straightforward. But for the PROMs a selection is available. There are disease-specific instruments like Spine Tango's COMI form and Oswestry Disability Index (ODI, also Neck Disability Index - NDI) as well as generic PROMs like EuroQol.

Spine Tango's COMI is the official and recommended instrument or EUROSPINE. It is brief and it assess the most important outcomes that matter to patients with back (neck) problems: pain, function, symptom-specific well-being, quality of life and disability. This instrument was developed in the early 2000s and does not require a licensing agreement.

ODI (NDI) was developed in the 1980s, but remains a commonly used PROM instrument for quantifying ability disorders in back problems. The questionnaire asks patients about their ability to manage everyday life and includes pain intensity, weightlifting, ability to care for oneself, walking ability, sitting ability, sexual function, standing ability, social life, sleep quality and ability to travel. The Neck Disability Index (NDI) is a modified version of the ODI that is used by clinicians and researchers to quantify ability problems associated with neck problems. ODI and NDI instruments require a licence agreement with https://eprovide.mapi-trust.org/. The conditions must be negotiated. Purely academic users normally receive a free licence.

Among the generic PROMs, the EuroQol-5D (EQ-5D) is one of the most frequently used in spinal surgery. The EQ-5D can also be applied to a variety of health conditions. It is used to quantify health-related quality of life (HRQL). This PROM measures a patient's health status in five different domains: Mobility, Self-care, Habitual activities, Pain/discomfort and Anxiety/depression. The EQ-5D is available with five (5L) or three (3L) answers per question, the EQ-5D-5L being the more modern and therefore the favoured version today.

EUROSPINE recommend using at least the Spine Tango's COMI form as the PROM with or without EQ-5D.

d. Patient materials

- Informed consent

For any prospective collection and use of patient-identifiable medical data (incl. its transfer to an international database) the patient have to give his or her consent first. A template for an informed consent form is available here. It may need to be adapted to the hospital needs and translate in all relevant languages of the patients.

- Patient information and motivation for filling PROM

Today patients (and people overall) receive many invitations for surveys. Without a context, explanation, and a motivation the likelihood that the patient will fill it out properly is rather low. Response rates in medical registries have been shown to correlate with trust in the institution behind the registry. As the patient's motivation is essential, it is strongly recommended that he/she is adequately informed orally and in writing. A template for a written patient information text is available on request. A short flyer or brochure may be created and hand out to the patients in the hospital. The aim of the information is for the patient to understand why the information they are being provided is so important. Once the patient understands this, the likelihood that they will act on it increases rapidly. It is also important that there are no insurmountable practical barriers for a patient to complete the PROM form.

- Other materials

One can consider posters or slides on wall-screens in the waiting rooms.

e. Registration of implants

EUROSPINE has developed in a close collaboration with the MedTech industry a detailed implant catalogue. It includes today roughly 200'000 individual implants from more than 60 manufacturers and is constantly further growing. The implant catalogue is integrated in the Spine Tango platform and enable the hospitals to add the used implants in a structured way. An implant can be added either by scanning its barcode or QR-code, out of the users favourite list, by typing in the article number, or by searching the catalogue with key words. Medical device manufacturers are willing to pay for the standard implant reports from the registry, and the Spine Tango registry provides a share to the hospital or the national society, depending on the contractual agreement.

If another platform or a system is used and if it collects implant on the article number level, Spine Tango can offer the use of it implant catalogue. It can propagate and link all implant specifications and categories based on the article number.

f. Ethics approval

For any prospective data collection an ethics approval is usually required. The ethics committee will want to know the entire set up of the data collection system, inclusion and

exclusion criteria, goals, and use of the data. Many hospitals in different countries have already received ethics approvals and may share their approval requests. For consulting ethics approval requests elaborated in other hospitals, please contact spinetango@eurospine.org.

g. Personnel and efforts required

It has been shown that both physician and patient response rates are higher in settings where staff are available to manage and monitor the registration process and take action to overcome barriers. It has been studied, but it has not been proven that systematic alerts or reminders improve patient response rates. But it seems that a personal touch does make a difference. Hence, a part-time dedicated personal (e.g. nurse or secretary) to monitor and support the registration process through clinicians and patients is reasonable and is recommended. It is, however, not a must.

h. Continuous registration and registration discipline

It is easy to forget filling out a physician-reported form and the data to enter. The longer the time since the treatment the more time and efforts it will cost to fill out the form. The best practice is to fill out the physician-reported form immediately after the treatment (e.g. when a surgery report is made) and to fill out the hospitalization part at the discharge (for surgical patients only). For conservative patients, the best practice is to fill out the form in part at the start and at the end of applied conservative treatment.

i. Monitoring the registration numbers and validating them

Once a new project has been up and running for some time, attention to it tends to diminish and response rates may drop. It is therefore important to set up a monitoring system that allows the hospital to check response rates regularly and to respond to changes (usually negative). Sometimes small actions can help, such as reminding relevant staff about the registry, or resuming distribution of leaflets, asking patients to complete their pre-intervention questionnaire on the ward if they have not done so, etc.

If possible, each hospital should ensure the monitoring of the registered treatments and patients and validate the numbers regularly to (i.e. response rates).

j. Reports

Spine Tango provides automated feedback reports that give an insight into treated patients and their outcomes and compare them to pooled data from other hospitals.

Similar reports may be programmed by a hospital IT, if a hospital is not using the Spine Tango web-based platform.

k. Contact us

For further information on Spine Tango, please contact spinetango@eurospine.org.

Spine Tango offers a user support during the working days and hours.