

“The Stanmore initiative”

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Genesis

With the increase in regulation in Europe with the MDR, it has become very likely that manufacturers are going to be approaching registries for data about their implants so they can meet the requirements for new and legacy devices. Without it they will find it very difficult to sell their implants.

The organisers thought it would be worth holding a meeting so that the issues around the need for registry data could be discussed.

Meeting in Stannmore, March 2023

American Spine Registry
Australian Spine Registry
Britsich Spine Registry
Canadian Registry
Finish Spine Registry
German Spinal Registry
Hong Kong Registry
International Spine Registry Spine Tango
Italian Spine Registry
Kaiser Permanente Registry
Netherlands Spinal Registry
New Zealand Spine Registry
Norwegian Spine Registry
Swedish Spine Registry
Swiss Spine Registry

Outcome of the 1st meeting

- Further collaboration between spinal registries would be most beneficial
- Decision to do workshop sessions with registries and representatives of medtech and regulatory during the annual EUROSPINE meeting in Frankfurt

Workshops in Frankfurt

- 1) registration of implants
- 2) common minimal dataset
- 3) common PROMs

Workshop on registration of implants: outcome

- very few spinal registries are collecting implant data
- there was a mixture of either brand only recording and device level capture
- the challenges of recording implant data at a brand level were discussed. Two main challenges are:
 1. Lack of traceability. Brand only recording does not permit identification of exactly device.
 2. Data management and reporting. Limited if information is only available at a brand level. There is a risk that any sub brand under performing within the brand will go unnoticed due to the lack of granularity available for reporting

Facit:

- implant data collection is recommended at a device level

Workshop on common minimal dataset: outcome

- may be very beneficial, while understanding that registries have today their individual data structures and also understanding that individual data structures are needed
- understanding that all spine registries do collect key data on surgical interventions, which may well be standardized. Short list to be confirmed by the minutes of the workshop:
 - Age, gender
 - Pathology
 - BMI, number of previous surgeries, smoking status
 - Level of surgery, type of surgery
 - Implants
 - Complications as well as reoperations and revisions

Facit:

- To assess this approach in each registry and collaborate to test the data sharing potential (until the next annual EUROSPINE meeting)

Workshop on common PROMs: outcome

- may be very beneficial, while understanding that registries have today their individual approaches
- the most widely used generic instrument seems to be EQ5D
- Oswestry/NDI and COMI are frequently used as disease specific instruments
- Overall treatment outcome question, patient satisfaction, NPS, VAS and few more instruments are also used

Facit (to be confirmed by the minutes of the workshop):

- A combination of a generic, a disease specific instrument, a pain level scale, an overall treatment outcome question is seen as reasonable and recommendable. But further discussion is expected and concretisation required.

Summary

Great initiative

- Registries are talking to each other
- The initiatives is becoming a platform for harmonisation and further development of spinal registries
- A lot of potential as well as work ahead
- Fun
- To be continued