

Devices to be registered and how?

FinSpine. “Practical examples from Finland”

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FinSpine



- Since 2017
 - Hospitals have joined 2017-2023
- 2023: statutory
 - under controller liability of THL by a decree of the Ministry of Health
 - *THL = Finnish Institute for Health and Welfare*
- Permanent government funding
- Coverage: 21 / 22 public hospitals and 1 / 4 private hospitals
- **90%** of the annual amount of spine procedures are in the registry
- **100 %** of the procedures are identified and entered automatically
 - data by the surgeons **80 %**
- Patients: **60 %** baseline
 - Best hospitals 90 %

FinSpine: current status of implants in the registry

- minimum data set: no implants
- multiple information systems in hospitals
 - Mostly implants in containers without UDI
 - file only brand and size; code for each size
 - Some brands with container implants are marked with UDI
- Used to inventory accounting
- Used to supplement the stock
- Invoicing
- "dead end" = no integration between systems
- Only 1 hospital
 - integration btw the medical information system of the operative department and the registry



MDR – requirements of manufacturers

1st and 2nd working meeting
of spine registries 2023

- **GOOD QUALITY DATA**

- Social security number unique for each patient in the nordic countries
- Coverage / completeness / hospitals / patients / information systems

- “It is easy to pay for data with high quality.”

- Joshua Bridgens, 2023

- Manufacturers need **implant level data** (UDI)
- Data available to the industry “**raw** or **via good quality reports**”
- Patient data
 - **PROM**



FinSpine in the near future



- Implants to become a part of the minimum national data set
 - FinSpine can develop an own system to register implants
 - FinSpine can investigate current status of systems already in use
- Implant level data (UDI)
 - barcode
- Follow-up of an implant over the whole device lifetime (10 years) is not a problem
 - Timepoints up to 10 years
- FinSpine sees the co-operation with international spine registry group and industry very important
 - And we are ready for that!

Thank you!

