Designing a Good Registry, What Have we Learnt

Martin Lind

Division of Sports Trauma
Dept. of Orthopedics
Aarhus University hospital,
Denmark
History

• In Scandinavia 3 national registries was established in 2004 and 2005.

• Norway: June 2004

• Sweden: Jan 2005

• Denmark: July 2005
What is the advantage of a national registry

- High volume
- General surgical population
- All techniques and implants generate data
- Most feasible in small countries with central registration of population and hospital contacts
- Longterm follow-up data can be generated
- Follow evolution of new techniques
  - (like Double bundle)
  - Allografts
  - New implants
RANDOMISED STUDIES VS REGISTRY

- Randomised, driven by hypothesis, with few (often specialised) surgeons, limited cohorts and high cost

- Registry reflects "clinical reality", no selection bias, large cohorts, nation-wide investigation, low overall cost

- Registry gives BIG NUMBERS

- both are needed
Registries generally contain large patient cohorts with a representative cross-section of a real-world patient population, compared with RCTs.

- This increases statistical inference and generalizability (high external validity), but might reduce the confidence of the estimate (low internal validity).
REGISTRY STUDIES ADVANTAGES

- Very useful in determining the rate of adverse events which can be detected long before any interventional study would have detected them.

- No causality, but they are hypothesis generating
What are the challenges when designing a clinical registry

- Purpose of registry
- Clinician/surgeon participation
- Registry content
- Patient data entry
- Registry management
- Data protection legal issues
Purpose of registry

- Local clinic quality control

- Scientific group
  - MOON group
  - Kaiser permanente group

National clinical registry
- Safety and quality monitoring
- Scientific projects
Clinician /surgeon participation

- Clinician participation is ultimate

- Ensure this at initiation.

- Have motivation for participation
  - Access to own calculated data
  - Access to all data for research

- Government support
  - Participation by law
Registry content

- Surgeon data entry
  
  Use definitions, data coding similar to collaborating registries
  
  Surgical techniques
  
  Implants
  
  Meniscus/cartilage pathology

  Have easy access to data output
  
  Excel (no need for data management)
Patient data entry

- Patient related outcome measures (PROM)
  - IKDC subjective
  - KOOS
  - Lysholm
  - KNEES-ACL
PROM responsiveness

Cohens effect size (change/SD)

KOOS Symp, KOOS pain, KOOS ADL, KOOS sports, KOOS QoL, IKDC subj, Lysholm, KNEES-ACL sport, KNEES-ACL Slackness

Cohens effect size (change/SD)
Patient data entry

- **Knee function**
  - Tegner function score
  - Cincinatti score
  - Global score (0-100)
  - Return to sport ability
Patient data entry

• Quality of life

• Enable health-economic studies
  – EQ-5
  – SF-12, SF-32
  – Global score (0-100)
  – Return to sport ability
Registry management

• Establish a management organization
  – Motivate surgeon participation
  – Maintain registry data structure
  – Ensure financial support
  – Approve data for scientific projects
Data protection legal issues

- Local legal issues on data collection and storage
- Informed content from each patient might be necessary
- National registries can exempt from this
Limitations

• Bias due to limitation in follow-up
• Balance between data volume and feasibility
• Revision as endpoint is suboptimal as many patient accept to live with an unstable knee to avoid more surgery
• Poor implants
  – What outcome measures are influenced?

• Possible difference between Scandinavia and the rest of the world
  – Indications
  – Techniques
  – Patient succes criteria
What have we learnt

- Define purpose. Acknowledge limitations
- Ensure clinician participation (motivation)
- Coordinate data content with collaborators
- Use responsive validate outcome measures
  - For ACL reconstruction, subjective IKDC, KNEES ACL,
  - Include knee-function score and quality of life score
- Define management, leadership and data ownership
Thank you

Aarhus University Hospital