



# Developing a core outcome set for non-minimal invasive off- or on-pump cardiothoracic surgery

Carina Benstöm, MSc  
University Hospital RWTH Aachen

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# Background

- Cardiovascular disease (CVD) is the number one cause of death worldwide
- CVD is regularly treated with minimal or non-minimal-invasive off- or on-pump cardiothoracic surgery
- Outcome measures in cardiac trials are inconsistent
- Comparison across studies is problematic
- Focus is habitually on risk factors and adverse outcomes
- Patient-reported outcomes are hardly considered



# A minimum COS is needed!

## Scope of COS:

“Minimum COS for clinical trials investigating pre-, intra- or postsurgical interventions in non-minimal-invasive off- or on-pump cardiothoracic surgeries”

Conduct and reporting adheres to:

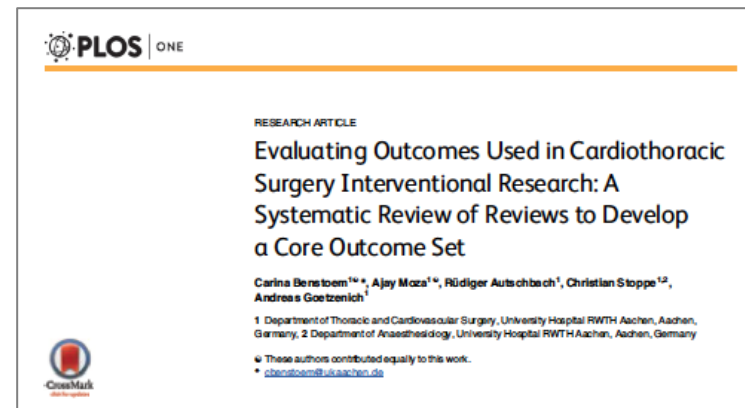
- ✓ Recommendations given by the COMET Initiative
- ✓ Methodological guidance provided by the OMERACT Initiative

This COS aims to provide methodological guidance for future cardiothoracic surgical trials.



# What we did so far...

- Literature review of existing knowledge (published)
- Study protocol for COS (submitted)
- Stepwise approach in developing the minimum COS (eDelphi exercise)
  - (1) “What to measure” (i.e., domains) → currently carried out
  - (2) “How to measure” (i.e. measurement instruments) → subsequent step
- Raising awareness amongst colleagues



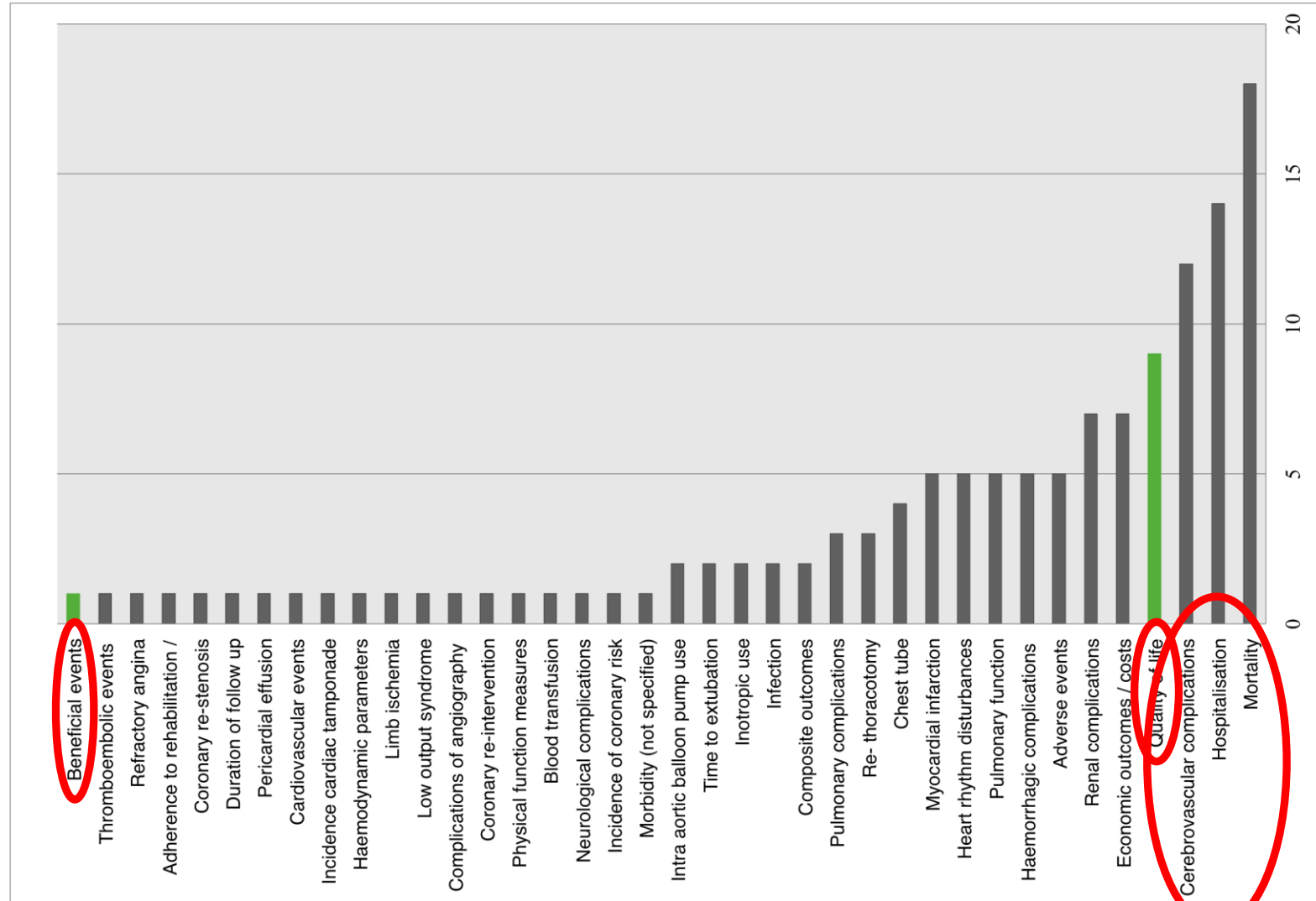
# Results of literature review

- 15 systematic reviews
- 371 randomised trials (1971 – 2013)
- 58,253 patients
- 123 individual outcomes
- 38 outcome domains
- 50% of outcomes were reported only once

# Heterogeneity in outcome reporting



# Identified outcome domains



# Consensus method for COS

- 3- round eDelphi exercise
  - Using the online software QuestionPro®
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- + International participation
  - + No time lag between successive rounds
  - + Relatively low cost structure
  - + Increases data collection efficiencies
  - + Rapid communication with participants
  - + No influence of panel by individuals
- 
- Bigger group can influence the overall result
  - More difficult to involve patients



# Invited stakeholders / panellists

- Adult patients in need or after cardiothoracic surgery
  - German Heart Foundation, British Cardiac Patients Association, European Heart Network, Support Network of the American Heart Association
- Cardiothoracic surgeons
  - German Society for Thoracic and Cardiovascular Surgery (DGTHG), European Association for Cardio Thoracic Surgery (EACTS), American Association for Thoracic Surgery (AATS), Society of Thoracic Surgeons (STS), Cardiothoracic Surgery Network (CTSNet)
- Anaesthesiologists
  - German Society of Anaesthesiology and Intensive Care Medicine, European Society of Anaesthesiology, American Society of Anaesthesiologists
- Nursing staff
- Researchers
  - Cochrane Heart Group

→ Snowball-Sampling

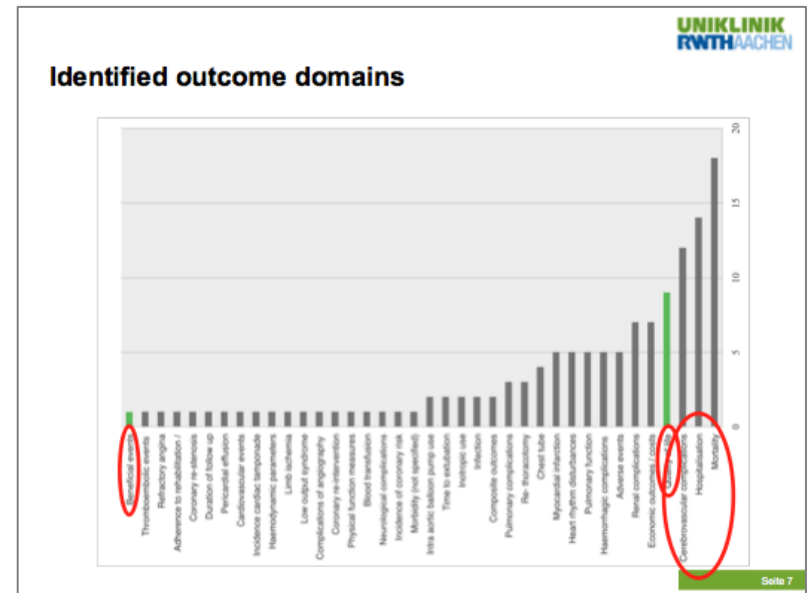


## Delphi Exercise (Round 1-3)

- Plain language summary (COMET Initiative)
- Introduction of OMERACT filter 2.0
  - Four core areas: death, life impact, resource use and pathophysiological manifestations
- Participants were asked to indicate if a domain was important enough to be included as a core domain:
  - 1) “yes”, 2) “no” and 3) “unsure / I do not know
- Participants were also asked to indicate:
  - Conceptual overlap of domains
  - Addition of missing domains
  - Modifications of terminology
- A priori definition of consensus
- In every round, patients responses were analysed separately to “hear their voice”

# Preliminary analyses

- Frequency of close-ended questions and feedback in each round
- Subjective group assessment of provided comments and feedback to panel
- Consistency of rating across participant groups
- Identified core domains will be much alike the domains identified via the literature review



# Experienced obstacles

- Problems caused by inconsistent outcome measures in clinical trials are hardly recognised
- Approach of minimum COS are barely known
- Cardiothoracic surgeons / researchers in this medical field are therefore hard to convince of the necessity of a minimum COS
- Publication of study protocols seems difficult





# Thank you for your attention!

[cbenstoem@ukaachen.de](mailto:cbenstoem@ukaachen.de)