

Upper Gastrointestinal Research (UGIR)

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UGIR

- SIMSAM funding in 2008
 - Creation of UGIR (Upper Gastro-Intestinal Research)
 - Merging of 6 researchers and groups into one office
 - Recruitment of many post-docs and a biostatistician
- Clinical research profile
 - Clinical research using registry data

Current members

- 36 people:
 - 6 full-time researchers (2 professors)
 - 15 part-time researchers (clinicians)
 - 9 PhD students
 - 2 biostatisticians
 - 4 project coordinators/research secretaries

Research field

- Clinical research addressing diseases and surgery of the upper gastrointestinal tract
 - Oesophagus, Stomach, Duodenum, Pancreas, Liver, Bile ducts
- Main areas
 - Cancer, particularly oesophageal cancer
 - Gastro-oesophageal reflux
 - Obesity surgery
 - Pancreatitis
 - Peptic ulcer

“Study protocol strategy”

1. Idea: Hypothesis / research question
2. Literature review: What is known about the hypothesis?
3. Study protocol draft: Objective, Background, Design
4. Brainstorming meeting: Group members and invited experts
5. Detailed study protocol: *Next slide*
6. Send for comments: All brainstorming participants
7. Study protocol meeting: The potential authors
8. Final study protocol: When all authors agree
9. Conduct the study: Good luck!
10. Changes of the study: Documented and approved by all

Study protocol: Example

Subheading

- Authors
- PI
- Objective
- Background
- Design
- Analysis, power
- Time plan
- Work plan
- Significance
- Funding

Includes

Name and order

Name

Be specific

Gaps of knowledge

Epidemiologist, clinician, lab researcher, etc

Biostatistician

Realistic

The role of each author / collaborator

Why is this study motivated?

Required

Clinical register-based research?

- Example: Swedish Esophageal Cancer Surgery Study (SESS) – nationwide since 1987
 - Oesophageal cancer surgery cohort: Cancer Registry (diagnosis) + Patient Registry (surgery)
 - Exposures: Operation charts and histopathological records
 - Outcome: Causes of Death Registry
 - Censoring: Emigration Registry
 - Covariates: Socioeconomy (LISA), comorbidity Patient Registry), medications (Prescribed Drug Registry)

Examples of findings

- No decreased cancer risk after obesity surgery (*Ann Surg* 2010)
- Increased risk of colorectal cancer after obesity surgery (*Ann Surg* 2013)
- Antireflux surgery does not prevent oesophageal cancer (*Gastroenterology* 2010), which is due to recurrence of reflux after surgery (*Ann Surg* 2013)
- Higher annual surgeon volume of oesophageal cancer surgery increases the long-term survival (*J Clin Oncol* 2013)

Examples of findings, cont.

- Oral corticoids and tetracyclines increase risk of acute pancreatitis (*JAMA Intern Med* 2013 and *Gut* 2012)
- Increased prevalence of reflux (*Gut* 2012)
- Acute complications after oesophageal cancer surgery cause long-term reductions in HRQL (*J Clin Oncol* 2012)
- A subgroup of long-term survivors of oesophageal cancer surgery deteriorates strongly in HRQL (*J Clin Oncol* 2012)

Facilitate register-based research

- **Debate articles**
 - Läkartidningen x several, Dagens Medicin, Svensk Kirurgi
- **Validation studies**
 - Oesophageal cancer surgery in Patient Registry
 - Acute pancreatitis in Patient Registry
 - Reflux in the EORTC questionnaire
- **PhD courses**
 - Study design in clinical research
 - Clinical research in practice
 - Register-based Research – how to started

Some new projects

- **Barrett's Oesophagus in Sweden Study (BOSS):**
 - Risk of progression från Barrett to oesophageal cancer
 - Preventive factors and risk factors for progression
- **Nordic Obesity Surgery Cohort (NordOSCo):**
 - Prognosis after surgery
 - Cancer risk after surgery
- **Nordic Antireflux Surgery Cohort (NordASCo):**
 - Risk of oesophageal cancer

Some new projects, cont.

- **Swedish Esophageal cancer Surgery Study (SESS):**
 - Accidental splenectomy and survival and infections
 - Weekday of surgery and survival
 - Reoperations and long-term health care utilisation
 - Level of hospital and survival
 - Lymph node dissection and survival
 - Educational level and survival
- **Validation studies:**
 - Obesity surgery in the Patient Registry
 - Tumour stage (TNM) in the Cancer Registry

Beneficial factors

- Work in the same office
- Focus area
- Hypothesis-driven research (clinical observations)
- "Study protocol strategy"
- Methodological competence
- Biostatisticians
- Administrative staff
- Recruitment in open international competition
- International collaboration

Thank you!