# International Surgical

# Outcomes Study

www.isos.org.uk

@ISOSstudy

# An estimation of the global volume of surgery: a modelling strategy based on available data

Thomas G Weiser, Scott E Regenbogen, Katherine D Thompson, Alex B Haynes, Stuart R Lipsitz, William R Berry, Atul A Gawande
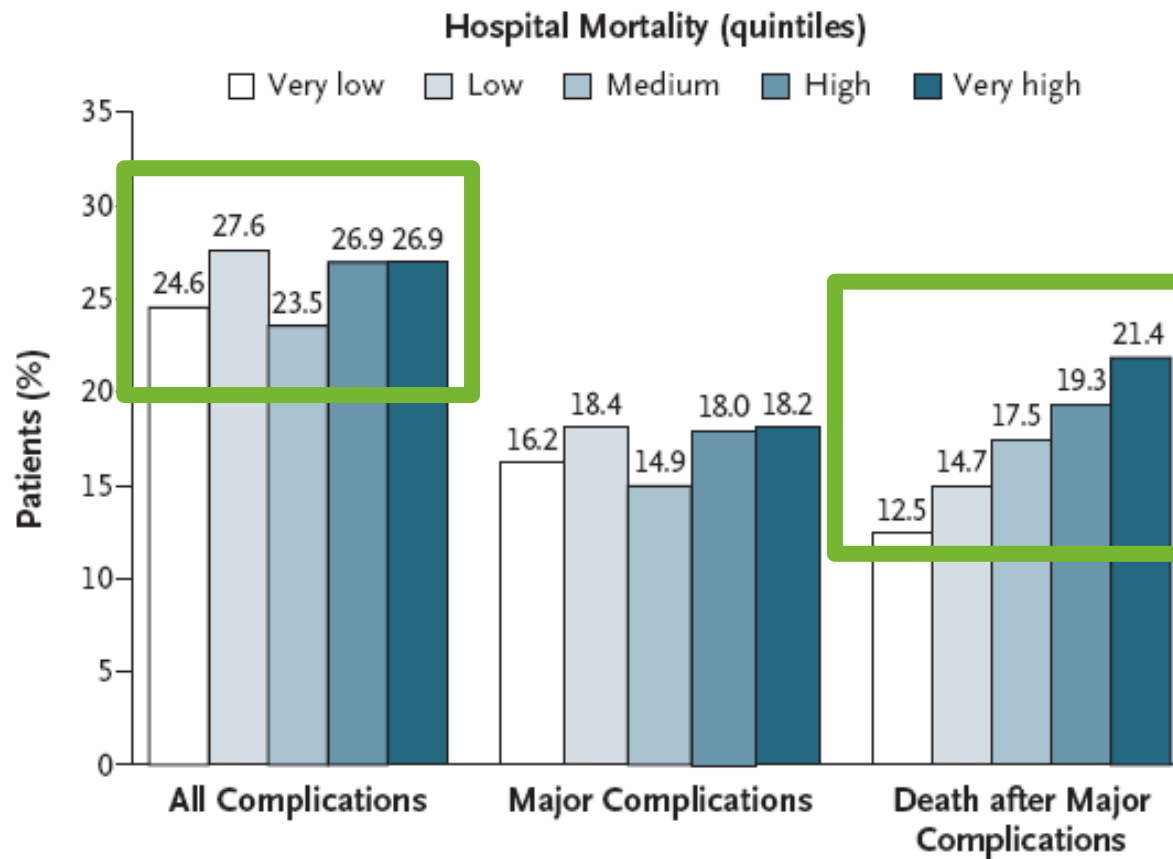
- **234 million major surgical procedures worldwide**

- **True mortality rate is not known**

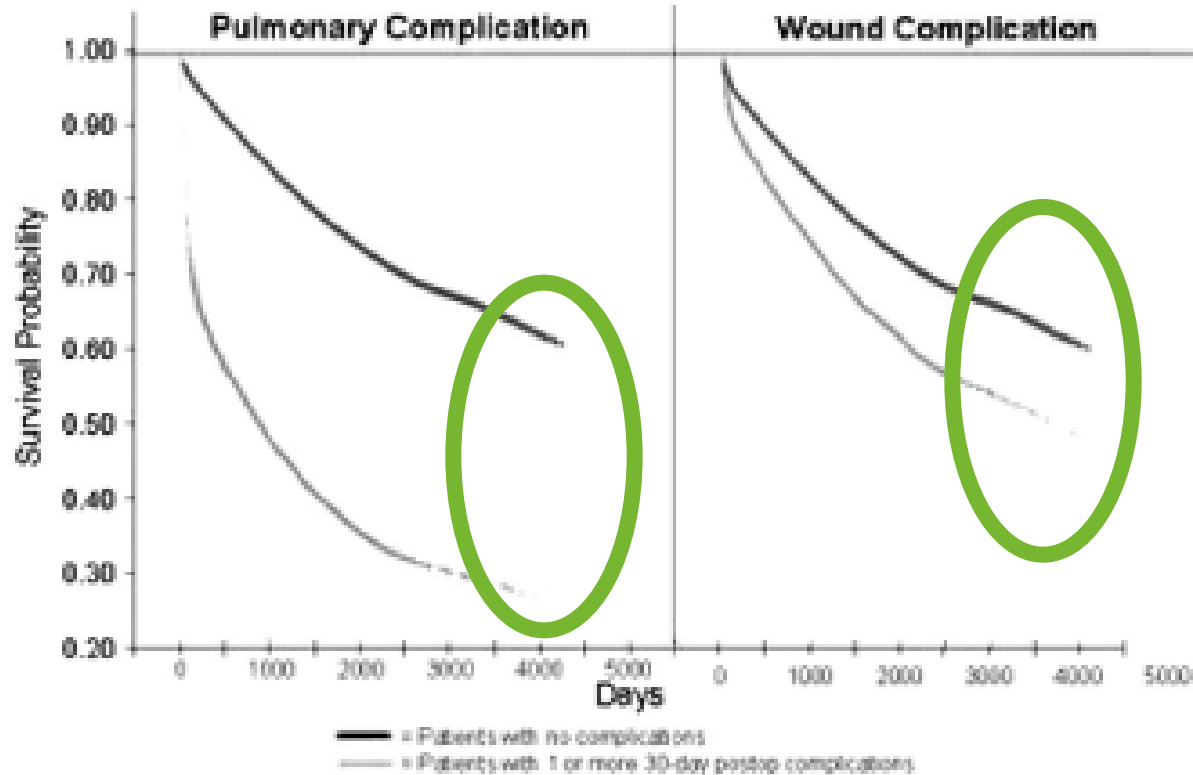- **A preventable death rate of 1% would result in...**

**...2.3 million avoidable deaths each year**

ISOS
International Surgical Outcomes Study

Barts and The London
Queen Mary's School of Medicine and Dentistry
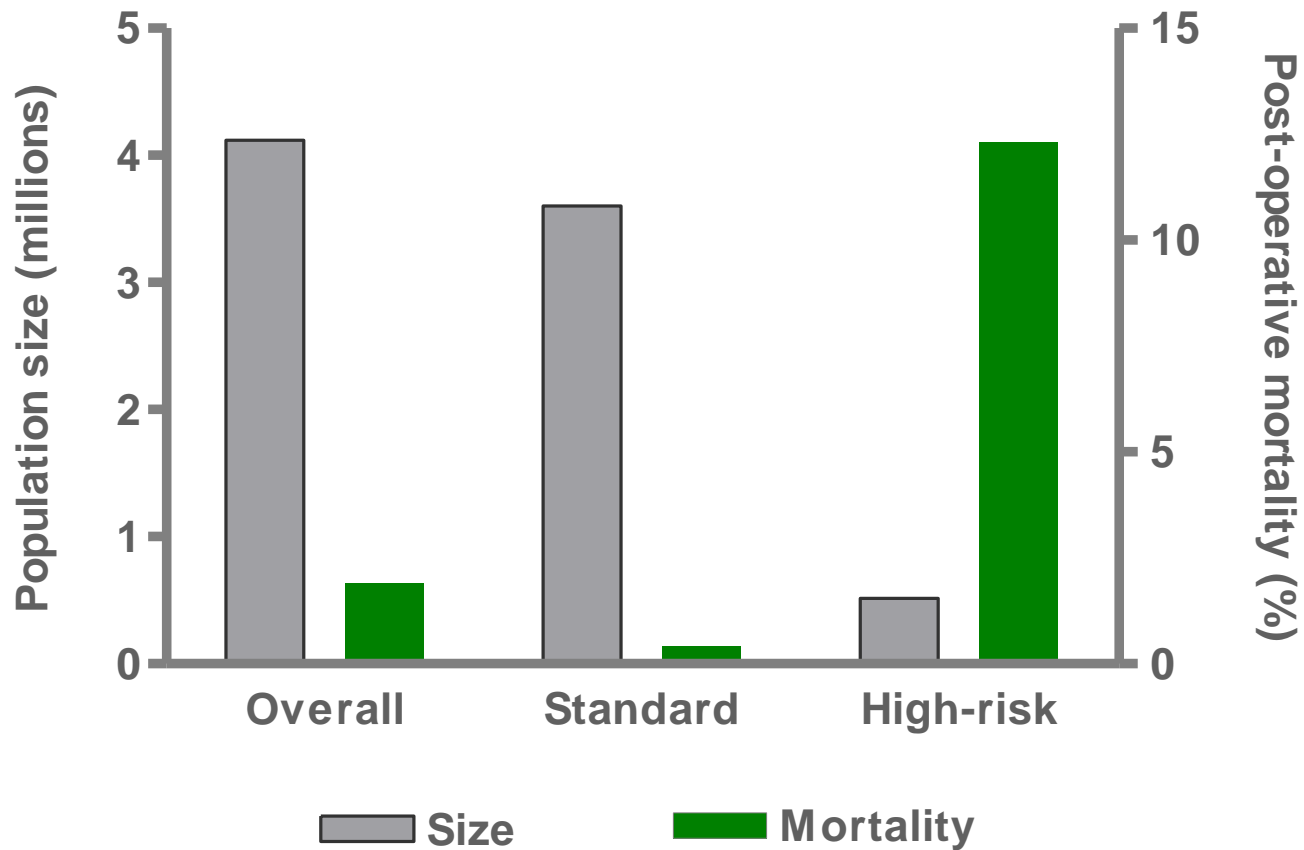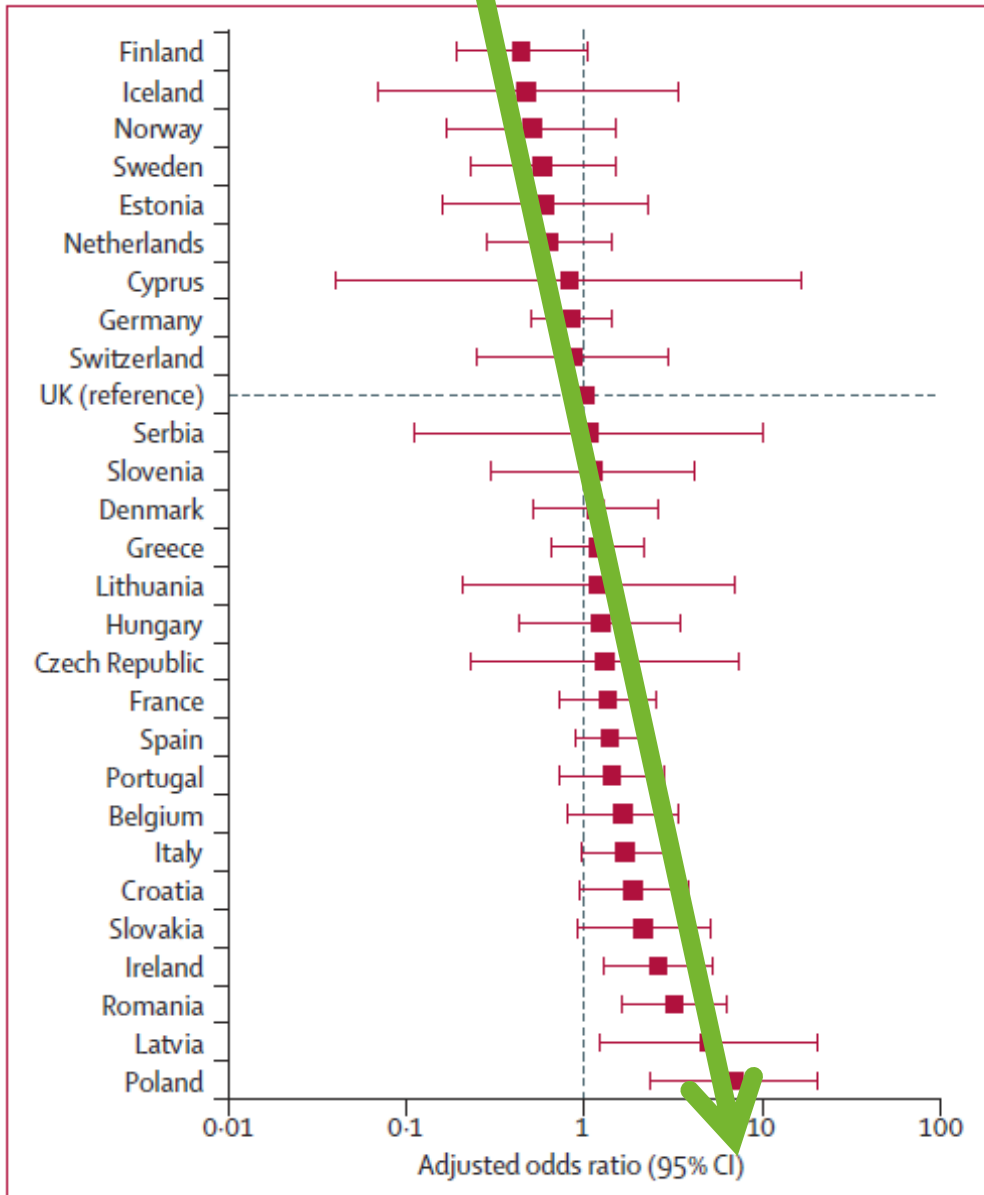
# 80% of surgical deaths are from the high-risk population

# Mortality variation suggests preventable death after surgery

# Surgical complications decrease long-term survival

**Khuri et al.** *Ann Surg* **2005; 242: 326–343**

# International variation in adjusted mortality risk

Odds ratios adjusted for country, urgency of surgery, grade of surgery, surgical procedure, age, ASA score, metastatic disease and cirrhosis in a two level binary logistic regression model with patient at the first level and hospital at the second.

# **Why we need the ISOS study**

- Poor understanding of overall surgical population

- To understand how complications relate to deaths

- Potential for large number of preventable deaths

- Stimulate further research and public audit

# ISOS: Study design

- Highly pragmatic design

- Observational seven day cohort study

- Follow-up until hospital discharge

- Web-site entry of anonymous patient data

- Funded by Nestle Nutrition

# ISOS objectives: what is the…

## Primary:

- Incidence of 30-day in-hospital complications after elective surgery

## Secondary:

- 30-day in-hospital mortality associated with complications

- Relationship between complications and use of critical care

- Effect of complications on duration of hospital stay

# **ISOS**: Inclusion criteria

**All** adult patients (≥18 years)

undergoing in-patient surgery during

the seven day study period

**Start: 08:00 [enter date] 2014**

**Finish: 07:59 [enter date] 2014**

# **ISOS: Exclusion criteria**

- **Emergency surgery**

- **No planned overnight hospital stay**

- **Radiological procedures**

# ISOS: Local investigator role

- **Ensure ethics / IRB approval if required**

- **Supervise daily data collection**

- **Timely upload of data via internet**

- **Act as guarantor for data accuracy**

# **ISOS**: Data collection

- Collect data on **ALL** eligible patients during cohort week

- Baseline data in operating room

- Follow patients in hospital for complications (max 30 days)

- Easier if anaesthetists and surgeons both contribute

- Anonymous internet based entry from paper case records

- Basic data describing hospital uploaded once to website

# ISOS: Data analysis

- Each hospital team can download data when complete

- Hospital teams may be asked to check data after entry

- Data presented by geographical region (groups of nations)

- Statistical modelling to describe relationships

- Only hospitals with 20 valid patients will be included

# **ISOS**: Case record form

**17. Example Case Record Form**

Age [ ][ ][ ] years    Gender ☐ M   ☐ F    **Current smoker** ☐ Y ☐ N

ASA ☐ I   ☐ II   ☐ III   ☐ IV   ☐ V    **Black ethnicity (eGFR)** ☐ Y ☐ N

**Chronic Co-Morbid Disease (tick all that apply):**

☐ Coronary Artery Disease    ☐ Congestive Heart Failure

☐ Diabetes Mellitus    ☐ Cirrhosis

☐ Metastatic cancer    ☐ Stroke or Transient Ischaemic Attack

☐ COPD / Asthma    ☐ Other

**Most recent blood results (no more than 28 days before surgery):**

Haemoglobin [ ][ ][ ] . [ ] g/L    Leucocytes [ ][ ] . [ ] $\times 10^9$/L

Sodium [ ][ ][ ] mmol/L    Creatinine [ ][ ][ ] . [ ] µmol/L *

Anaesthesia induction time & date: [ H ][ H ] [ m ][ m ] [ D ][ D ] [ M ][ M ] [ 2 ]

Anaesthetic technique (tick all that apply):

# ISOS: Taking part

- Every investigator is a named member of the ISOS group

- After EuSOS all 2000 investigators were listed on PubMed

- Every investigator can download certificate of participation

- Local investigators receive data for their hospital

- ISOS investigators have priority for secondary studies

# ISOS: Summary

- Important study of surgical outcomes

- Pragmatic design providing preliminary data

- Aim to support further research and audit

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