EXPERIENCES ON UTILIZATION OF A STEPPED WEDGE CLUSTER RANDOMIZED CONTROLLED TRIAL DESIGNED IMPLEMENTATION OF SURGICAL SAFETY CHECKLISTS IN TWO NORWEGIAN HOSPITALS

Arvid Steinar Haugen
RN, Nurse Anaesthetist, MSc, PhD, Post-Doctoral Fellow
Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen, Norway
GLOBAL CHALLENGE

234 million surgical procedures
3-17% surgical complications
0.4-6.9% mortality
7 million disabling complications
1 million deaths worldwide each year
50% of complications are preventable

CHALLENGE – NORWAY

16-14% in-hospital adverse events

1.5% in-hospital mortality

Aim – reduce preventable events by 50%

Jammer et al. BJA 2015, 114(5):801-7
8 hospitals – 8 countries
3733 patients before
3955 patients after

Complications 11% vs. 7% (P < 0.001)
Mortality 1.5% vs. 0.8% (P = 0.003)
Effect of the World Health Organization Checklist on Patient Outcomes

A Stepped Wedge Cluster Randomized Controlled Trial

Arvid Steinar Haugen, MSc,*† Eirik Søfteland, MD, PhD,* Stian K. Almeland, MD,‡ Nick Sevdalis, PhD,§ Barthold Vonen, MD, PhD,¶ Geir E. Eide, PhD,||** Monica W. Nortvedt, PhD,||†† and Stig Harthug, MD, PhD††††
IMPLEMENTATION OF THE WHO CHECKLIST
STEPPED-WEDGE CLUSTER RCT

Control (Care As Usual)

Surgical Safety Checklist

IMPLEMENTATION

✓ Quality Improvement & Research Project
✓ Multi-disciplinary
✓ Education
  ✓ Lectures – videos – on site training – learning material available
  ✓ Feedback and evaluation
✓ Bottom up and Top down

Haugen AS et al, 2013 British Journal of Anaesthesia
STUDY OUTCOME

Primary
- Complications up to 30 days
- Mortality up to 30 days

Secondary
- Length of in-hospital stay

Checklist compliance
DATA COLLECTION/HANDLING

Checklist compliance registered

✓ Paper form and electronical

Data recorded as usual

Data extracted electronically

Data verified against medical records
EXPERIENCES

Reduction of bias

✓ Information
✓ Blinding
✓ External influence

Possible to adjust for time (months)

Patient safety intervention
2 hospitals in Norway
2212 procedures before
3083 procedures after

Mortality  1.6% vs.  1.0% (P = 0.151)
Morbidity  19.9% vs. 12.4% (P < 0.001)

Length of stay: 7.8 days vs. 7.0 days (P = 0.022)

In 2009, when The New England Journal of Medicine published the 8-city trial of the World Health Organization’s Safe Surgery Checklist, the idea that a formal system of planning and communication could significantly improve patient outcomes was outside the surgical mainstream. The pre-post study outcome of that study did not show a significant benefit to using a checklist, a finding that has been commonly interpreted to mean that checklists are ineffective. However, the Ontario’s government’s mandate was not accompanied by a sustained and systematic implementation program with these kinds of features and resulted in little measurable change in outcomes, at least in a short-term evaluation.\(^6\)

In sum, Haugen and colleagues have made an invaluable contribution. Using a cluster randomized control methodology, a care-fully structured implementation program, and measurement of the actual use of the checklist, they conducted the most rigorous study of surgical safety checklists to date. They confirmed substantial pa-tient benefit from taking this kind of formalized checklist approach.
Causal Analysis of World Health Organization’s Surgical Safety Checklist Implementation Quality and Impact on Care Processes and Patient Outcomes

Secondary Analysis From a Large Stepped Wedge Cluster Randomized Controlled Trial in Norway

Arvid Steinar Haugen, MSc, PhD,* † Hilde Valen Wæhle, MSc,‡§ Stian Kreken Almeland, MD,¶
Stig Harthug, MD, PhD,‡§ Nick Sevdalis, PhD,† Geir Egil Eide, PhD,‡*††
Monica Wammen Nortvedt, MSc, PhD,§*** Ingrid Smith, MD, PhD,‡§ and Eirik Søfteland, MD, PhD*