




Designing Patient Safety Protocols and WHO Safe Surgery Saves Lives for Developed and Developing Countries

Alan Merry

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

Conflict of Interest

Alan Merry has financial interests in

Safer Sleep LLC

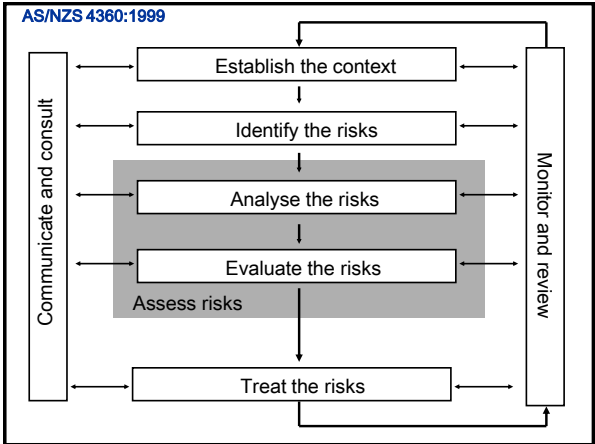
and has received support for research from

The Medicines Company
Neuren
Roche Pharmaceuticals
Baxter Healthcare
Various Granting Agencies

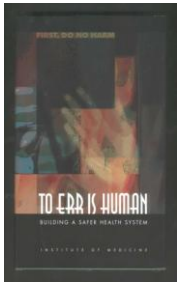
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Harvard Medical Practice Study
Quality in Australian Health Care Study
Medical Injuries Utah and Colorado
UK and NZ Studies

Adverse events are common in hospitals, and are often the result of substandard care



Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer

Structured review of 111 hospital deaths at 7 VA Medical Centres 1995-6
→ 22.7% judged at least possibly preventable with optimal care

But even with optimal care ...

- 6.0% would have left hospital alive
- 0.5% would have lived ≥ 3 months in good cognitive health

Poor inter-rater reliability (as with other studies)

Hayward RA Hofer TP JAMA 2001

The Global Burden of Disease Study

- 1990 – 50 million people died
- DALYs and morbidity
 - IHD
 - war
 - poverty
 - depression
 - pneumonia and diarrhoeal diseases
 - trauma
 - cancer

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- 1990 – 50 million people died
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 - pneumonia and diarrhoeal diseases
 - trauma
 - cancer
- surgical conditions →
164 million DALYS**

Per capita total expenditure on health US\$	Surgical Rate (per 100,000 population)	Estimated volume of surgery M	
POOR Expenditure Countries ≤\$100			
LOW Expenditure Countries \$101-400			
MIDDLE Expenditure Countries \$401-1000			
HIGH Expenditure Countries >\$1000			
Total Global Volume of Surgery			
Average Surgical Rate			Modified from Weiser et al Lancet 08

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Total Global Volume of Surgery		234.2 M	
Average Surgical Rate	4016		Modified from Weiser et al Lancet 08

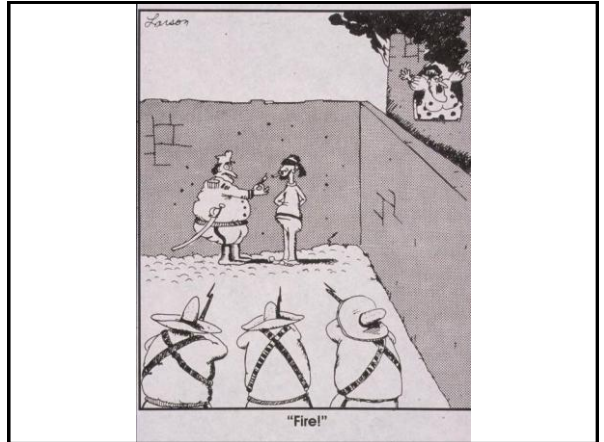
Per capita total expenditure on health US\$	Surgical Rate (per 100,000 population)	Estimated volume of surgery M	
POOR Expenditure Countries ≤\$100	295	8.1	34.8%
LOW Expenditure Countries \$101-400	2255	53.8	35.0%
MIDDLE Expenditure Countries \$401-1000	4248	34.3	14.6%
HIGH Expenditure Countries >\$1000	11110	138.0	15.6%
Total Global Volume of Surgery			234.2 M
Average Surgical Rate	4016		Modified from Weiser et al Lancet 08



A Death at Duke
 [Perspective]
 Campion, Edward W.

“Last month, a 17-year-old girl died at Duke University Medical Center after receiving a heart-lung transplant from an incompatible donor. Her blood type was O, the donor's was A and the mismatch was not recognized until after the transplant operation was over. [] A severe rejection reaction and multiple complications followed, and the patient died.”

NEJM 20 March 2003



Surgical Safety is a Serious Public Health Issue

- 234 million operations
 - poorly distributed
 - 3-17% complications
 - 1 million deaths
 - 7 million disabling complications (half preventable)

Weiser T et al *Lancet* 08



Runciman B Merry A Walton M 2007
Safety and Ethics In Healthcare Ashgate



Surgical Vital Statistics

Structure

- number of ORs per 100,000 population
- number of surgeons and anaesthesia professionals per 100,000 population

Process

- number of surgical procedures per 100,000 population per year

Outcome

- day-of-surgery mortality rate
- postoperative in-patient mortality rate

2008 International Standards for a Safe Practice of Anaesthesia

(An update of the Standards developed by the International Task Force on Anaesthesia Safety that were adopted by the WFSA 13 June 1992)



Essential Safe Surgery Objectives

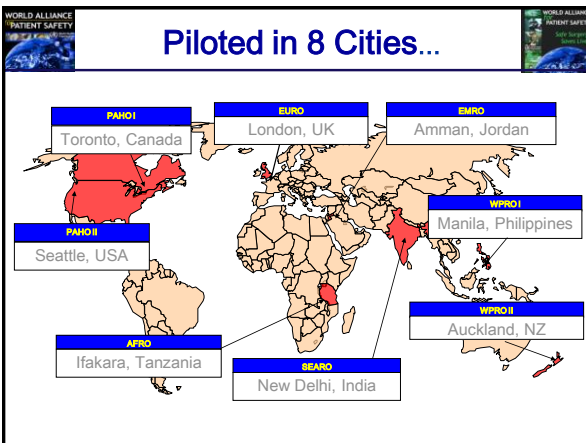
The team will...

- operate on the **correct patient and site**
- use methods known to prevent **harm from anaesthesia** while protecting the patient from **pain**
- recognize and effectively prepare for life-threatening **loss of airway** or respiratory function.
- recognize and effectively prepare for risk of high **blood loss**.
- avoid inducing any **allergic or adverse drug reaction** known to be a significant risk for the patient.
- consistently use methods known to minimize risk of **surgical site infection**.
- prevent inadvertent **retention of instruments or sponges** in surgical wounds.
- secure and accurately identify any **surgical specimens**.
- effectively communicate and exchange **critical patient information** for the safe conduct of the operation.
- establish **routine surveillance of surgical capacity and results**.

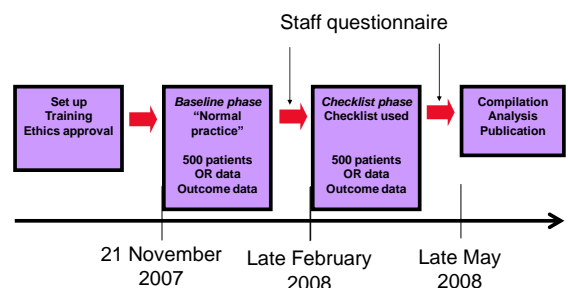
World Health Organization SURGICAL SAFETY CHECKLIST (FIRST EDITION)		
Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
SIGN IN <input type="checkbox"/> PATIENT HAS CONFIRMED + IDENTITY + SITE + PROCEDURE + CONSENT <input type="checkbox"/> SITE MARKED/NOT APPLICABLE <input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED <input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING DOES PATIENT HAVE A: <input type="checkbox"/> KNOWN ALLERGY? NO <input type="checkbox"/> YES <input type="checkbox"/> DIFFICULT AIRWAY/ASPIRATION RISK? NO <input type="checkbox"/> YES, AND EQUIPMENT/ASSISTANCE AVAILABLE RISK OF -NORMAL BLOOD LOSS (EMERGENCY OR OTHERWISE) <input type="checkbox"/> NO <input type="checkbox"/> YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED	TIME OUT <input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE <input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM + PATIENT + SITE + PROCEDURE ANTICIPATED CRITICAL EVENTS <input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS? <input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS? <input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY INCLUDING INDICATOR RESULTS BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS? HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES? <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> IS ESSENTIAL IMAGING DISPLAYED? <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE	SIGN OUT <input type="checkbox"/> NURSE VERBALLY CONFIRMS WITH THE TEAM <input type="checkbox"/> THE NAME OF THE PROCEDURE RECORDED <input type="checkbox"/> THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE) <input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME) <input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED <input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Piloted in 8 Cities...



Study Timeline



Results – All Sites

	Baseline	Checklist	P value
Cases	3733	3955	-
Death	1.5%	0.8%	0.003
Any Complication	11.0%	7.0%	<0.001
SSI	6.2%	3.4%	<0.001
Unplanned Reoperation	2.4%	1.8%	0.047

Haynes et al *NEJM* 360 491-9 2009

SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Alex B. Haynes, M.D., M.P.H., Thomas G. Weiser, M.D., M.P.H., William R. Berry, M.D., M.P.H., Stuart R. Lipsitz, Sc.D., Abdel-Hadi S. Breizat, M.D., Ph.D., E. Patchen Dellinger, M.D., Teodoro Herbosa, M.D., Sudhir Joseph, M.S., Pascience L. Kibatata, M.D., Marie Carmela M. Lapitan, M.D., Alan F. Merry, M.B., Ch.B., F.A.N.Z.C.A., F.R.C.A., Krishna Moorthy, M.D., F.R.C.S., Richard K. Reznick, M.D., M.Ed., Bryce Taylor, M.D., and Atul A. Gawande, M.D., M.P.H., for the Safe Surgery Saves Lives Study Group*

“... the rate of postoperative complications and death were reduced by more than one-third”

Haynes et al *NEJM* 360 491-9 2009

What Problems Does This Checklist Address?

- **Correct patient, operation and site**

- 1500 - 2500 wrong site surgery incidents every year in the United States.¹
- In a survey of 1050 hand surgeons, 21% reported having performed wrong-site surgery at least once during their careers.²

¹Seiden *Archives of Surgery* 2006

² Joint Commission *Sentinel Event Statistics* 2006

What Problems Does This Checklist Address?

- **Safe anaesthesia and resuscitation**

- An analysis of 1256 incidents involving general anaesthesia in Australia showed that pulse oximetry on its own would have detected 82% of them

Webb *Anaesthesia and Intensive Care* 1993





Safety of Anaesthesia

A review of anaesthesia-related mortality reporting in Australia and New Zealand 2003-2005

Editor: Neville Gibbs, MBBS, MD, FANZCA

Mortality = 1:53000

- Assessment
- Planning
- Airway management

SIGN IN

PATIENT HAS CONFIRMED

- IDENTITY
- SITE
- PROCEDURE
- CONSENT

SITE MARKED/NOT APPLICABLE

ANAESTHESIA SAFETY CHECK COMPLETED

PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?

NO

YES

DIFFICULT AIRWAY/ASPIRATION RISK?

NO

YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >30ML BLOOD LOSS (7ML/KG IN CHILDREN)?

NO

YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

What Problems Does This Checklist Address?

• Risk of infection

- Giving antibiotics within one hour before incision may reduce surgical site infection by 50%
- In the evaluation sites, failure to give indicated antibiotics on time occurred in almost one half of surgical patients

Bratzler *The American Journal of Surgery* 2005
Classen *NEJM* 1992

What Problems Does This Checklist Address?

• Effective teamwork

- Communication is a root cause of nearly 70% of events reported to the Joint Commission (1995-2005).¹
- Preoperative team briefing → enhanced prophylactic antibiotic choice and timing + better maintenance of intraoperative temperature and glycemia.^{2, 3}

¹ Joint Commission *Sentinel Event Statistics* 2006
² Makary *Joint Commission Journal on Quality and Patient Safety* 2006
³ Aitpeter *Journal of the American College of Surgeons* 2007

BEFORE TAKEOFF

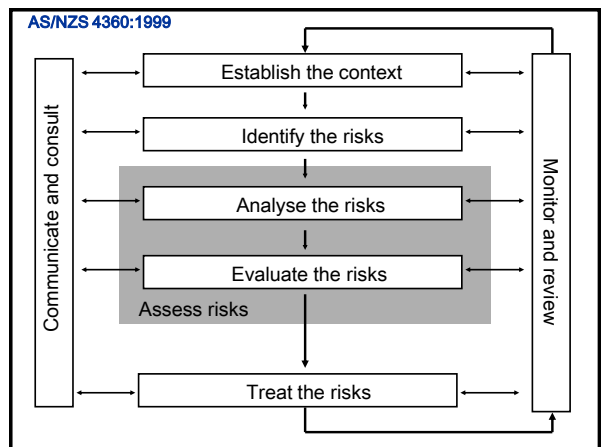
• Parking Brakes	SET
• Flight Controls	FREE & CORRECT
• Flight Instruments	SET
• Fuel Selector	BOTH
• Elevator & Rudder Trim	SET
• Mixture	RICH FOR RUNUP
• Autopilot	CHECK DISCONNECT
• Thrustle	1800 RPM
• Engine Instruments	CHECK
• Suction	CHECK
• Magnets	CHECK (125/50)
• Thrustle	IDLE CHECK
• Smooth & 600 RPM ± 25 THEN 1000 RPM	SET
• Brakes	SET
• Brakes	RELEASE
----- Final Items -----	
• Doors/Windows	CLOSED
• Flaps	AS REQUIRED
• Mixture	RICH (BELOW 3000 FT)

Flight TE901

On the day of the accident the computer track was altered without telling the crew...
routing the planned track over Mount Erebus on Ross Island

No problem if >1830 m – but the crew were not told of the change

Map: www.nzhistory.net





“The real problem isn’t
how to stop bad
doctors from
harming, even killing
their patients. It’s
how to prevent good
doctors from doing
so.”

Atul Gawande 1999
The New Yorker