Checklists: are they all they're cracked up to be?

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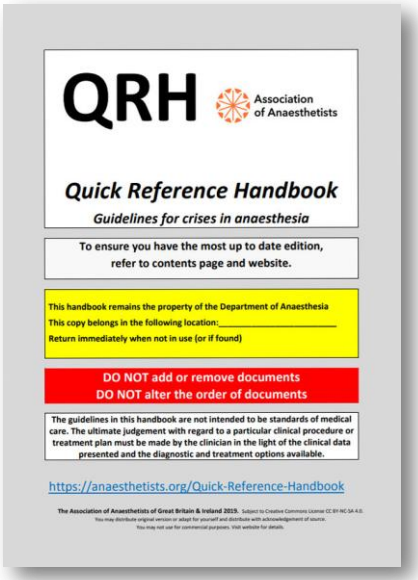
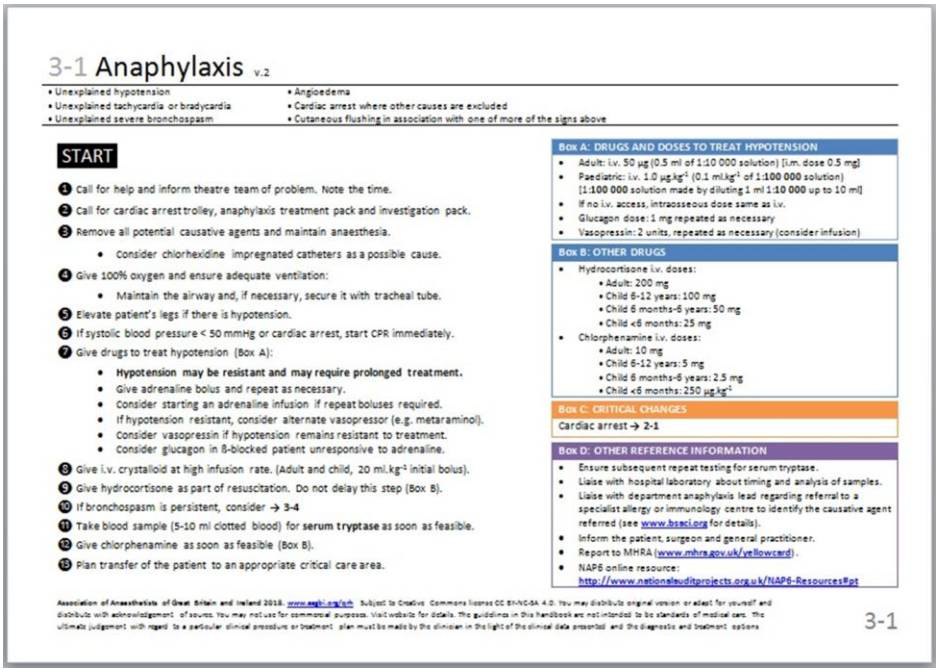
Association of Anaesthetists



www.anaesthetists.org/qrh



3-1 Anaphylaxis v.2

- Unexplained hypotension
- Unexplained tachycardia or bradycardia
- Unexplained severe bronchospasm
- Angioedema
- Cardiac arrest where other causes are excluded
- Cutaneous flushing in association with one of more of the signs above

START

1. Call for help and inform theatre team of problem. Note the time.
2. Call for cardiac arrest trolley, anaphylaxis treatment pack and investigation pack.
3. Remove all potential causative agents and maintain anaesthesia.
   - Consider chlorhexidine impregnated catheters as a possible cause.
4. Give 100% oxygen and ensure adequate ventilation:
   - Maintain the airway and, if necessary, secure it with tracheal tube.
5. Elevate patient's legs if there is hypotension.
6. If systolic blood pressure < 50 mmHg or cardiac arrest, start CPR immediately.
7. Give drugs to treat hypotension (Box A):
   - **Hypotension may be resistant and may require prolonged treatment.**
   - Give adrenaline bolus and repeat as necessary.
   - Consider starting an adrenaline infusion if repeat boluses required.
   - If hypotension resistant, consider alternate vasopressor (e.g. metaraminol).
   - Consider vasopressin if hypotension remains resistant to treatment.
   - Consider glucagon in ß-blocked patient unresponsive to adrenaline.
8. Give i.v. crystalloid at high infusion rate. (Adult and child, 20 ml.kg^{-1} initial bolus).
9. Give hydrocortisone as part of resuscitation. Do not delay this step (Box B).
10. If bronchospasm is persistent, consider → 3-4
11. Take blood sample (5-10 ml clotted blood) for **serum tryptase** as soon as feasible.
12. Give chlorphenamine as soon as feasible (Box B).
13. Plan transfer of the patient to an appropriate critical care area.

Box A: DRUGS AND DOSES TO TREAT HYPOTENSION

- Adult: i.v. 50 µg (0.5 ml of 1:10 000 solution) [i.m. dose 0.5 mg]
- Paediatric: i.v. 1.0 µg.kg^{-1} (0.1 ml.kg^{-1} of 1:**100 000** solution) [1:**100 000** solution made by diluting 1 ml 1:**10 000** up to 10 ml]
- If no i.v. access, intraosseous dose same as i.v.
- Glucagon dose: 1 mg repeated as necessary
- Vasopressin: 2 units, repeated as necessary (consider infusion)

Box B: OTHER DRUGS

- Hydrocortisone i.v. doses:
  - Adult: 200 mg
  - Child 6-12 years: 100 mg
  - Child 6 months-6 years: 50 mg
  - Child <6 months: 25 mg
- Chlorphenamine i.v. doses:
  - Adult: 10 mg
  - Child 6-12 years: 5 mg
  - Child 6 months-6 years: 2.5 mg
  - Child <6 months: 250 µg.kg^{-1}

Box C: CRITICAL CHANGES

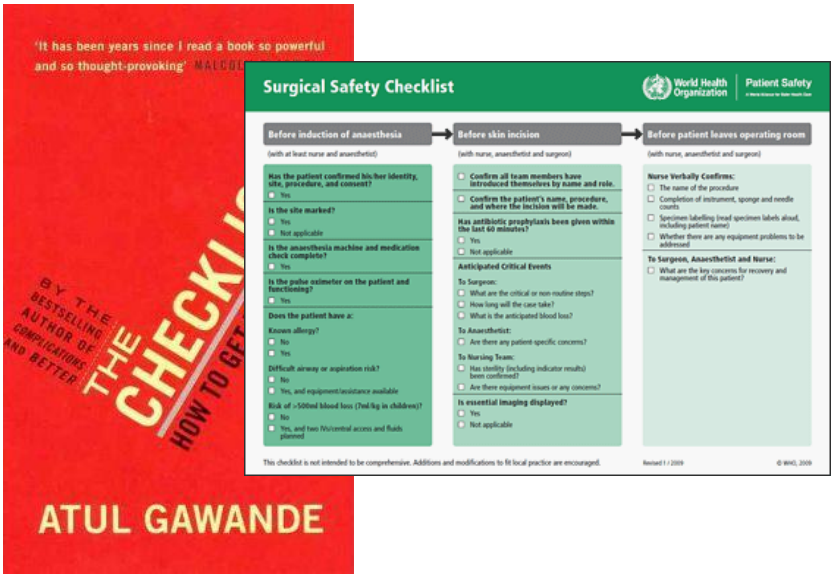
Cardiac arrest → 2-1

Box D: OTHER REFERENCE INFORMATION

- Ensure subsequent repeat testing for serum tryptase.
- Liaise with hospital laboratory about timing and analysis of samples.
- Liaise with department anaphylaxis lead regarding referral to a specialist allergy or immunology centre to identify the causative agent referred (see www.bsaci.org for details).
- Inform the patient, surgeon and general practitioner.
- Report to MHRA (www.mhra.gov.uk/yellowcard).
- NAP6 online resource: http://www.nationalauditprojects.org.uk/NAP6-Resources#pt

"Although there is no published evidence indicating a negative impact by using checklists, they could pose risks"

Winters et al, Critical Care 2009;13:210



Kittens: are they all they're cracked up to be?

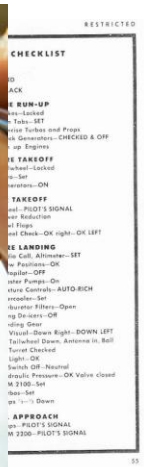
Pubmed results: 2019 only

"checklist": 3205

"safety checklist": 332

"patient safety checklist": 179

What is a checklist?



What is a checklist?

Usually possible to describe an ideal path for every process…

- Read and do
- Check and response
- Algorithm
- Cognitive aid
- Hybrid
- Static parallel
- Static sequential with verification
- Static sequential with verification and confirmation
- Dynamic

- ‘Normal’ vs ‘non-normal’ situations

Normal vs non-normal

Normal:

- Take-off, landing
- WHO checklist, machine check, RSI, G&S
- Action + verification steps
- Standardising performance
- Incorporated into workflow, time non-critical

Non-normal:

- Engine failure
- Cardiac arrest, anaphylaxis
- Boldface (‘crisis checklist’):
  - Time critical
  - Paired learned cognitive and motor activities
  - Check may occur after ‘automatic’ functions
- Non-boldface
  - Time non-critical
  - Flow chart, decision tree
  - Unusual presentations
  - Differential list: overcomes biases
  - Job aids, mnemonics etc

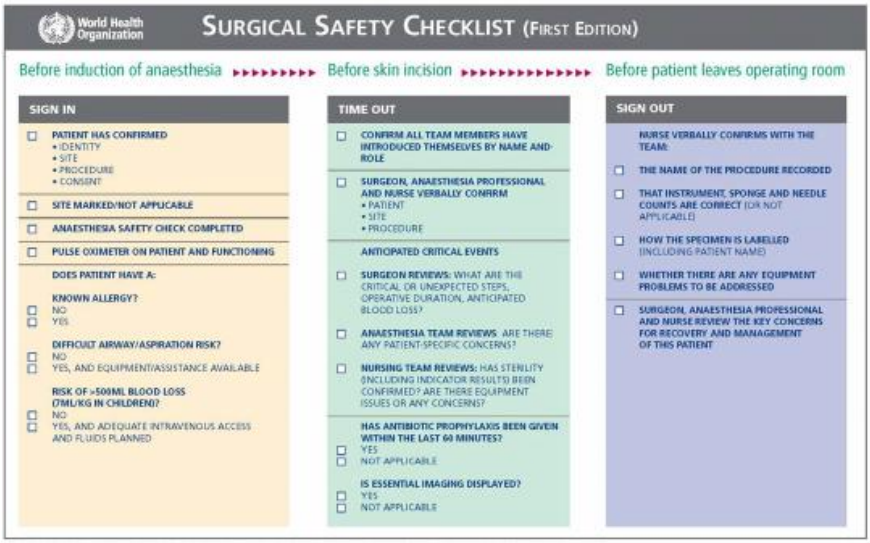
Why is a checklist?

- Standardise procedures
- Reduce omissions
- Reduce reliance on memory
- "Democratisation of medicine"
- Healthcare norms are not like aviation norms
- Healthcare crises are not (usually) like aviation crises
- (but we can't stop talking about them…)
- QF32, UA232

WHO surgical safety checklist

- 2009 study
- 8 hospitals, worldwide, diverse
  - Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA
- Data on > 3k patients before and after implementation
- 19 item list
- Surgical complications 11% → 7%
  - (ARF, Transfusion > 4 u/ first 24 h, cardiac arrest w. CPR,DVT, MI, unplanned intubation, ventilation > 48 h, pneumonia, PE, stroke, major disruption of wound, surgical site infection, sepsis+/- shock, SIRS, unplanned return, vascular graft failure, death)
  - Similar in high and low income sites
- In-hospital death 1.5 → 0.8%
  - Only significant in low income sites
- Process adherence (6/6 measures): 34 → 57%

N Engl J Med 2009;360:491-499. Haynes et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

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 >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
  - ☐ NO
  - ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

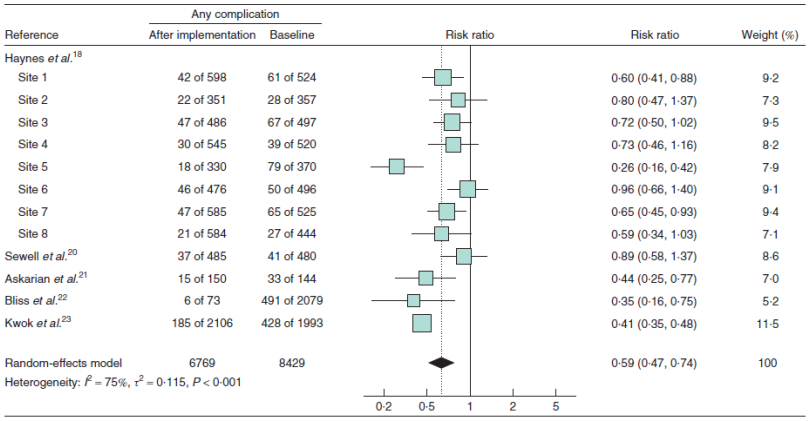
TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - PATIENT
  - SITE
  - PROCEDURE
- ANTICIPATED CRITICAL EVENTS
- ☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ 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?
  - ☐ YES
  - ☐ NOT APPLICABLE
- IS ESSENTIAL IMAGING DISPLAYED?
  - ☐ YES
  - ☐ NOT APPLICABLE

SIGN OUT

- NURSE VERBALLY CONFIRMS WITH THE TEAM:
- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications.
Bergs et al. Br J Surg. 2014 Feb;101(3)



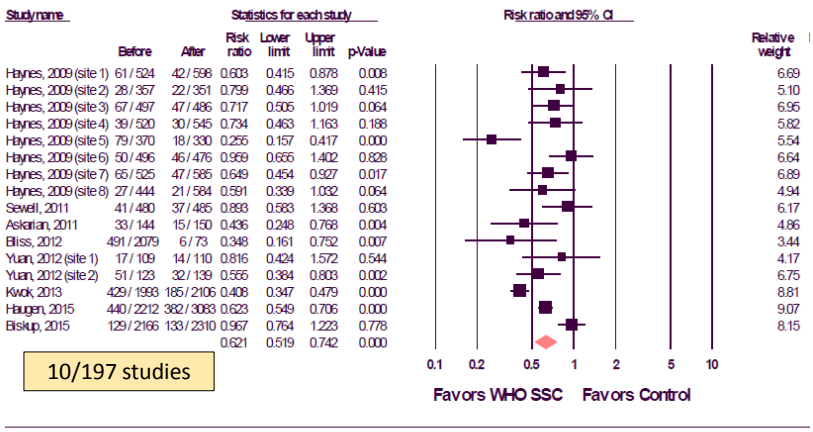
Reference	Any complication: After implementation	Any complication: Baseline	Risk ratio	Weight (%)
Haynes *et al.*[18]				
Site 1	42 of 598	61 of 524	0·60 (0·41, 0·88)	9·2
Site 2	22 of 351	28 of 357	0·80 (0·47, 1·37)	7·3
Site 3	47 of 486	67 of 497	0·72 (0·50, 1·02)	9·5
Site 4	30 of 545	39 of 520	0·73 (0·46, 1·16)	8·2
Site 5	18 of 330	79 of 370	0·26 (0·16, 0·42)	7·9
Site 6	46 of 476	50 of 496	0·96 (0·66, 1·40)	9·1
Site 7	47 of 585	65 of 525	0·65 (0·45, 0·93)	9·4
Site 8	21 of 584	27 of 444	0·59 (0·34, 1·03)	7·1
Sewell *et al.*[20]	37 of 485	41 of 480	0·89 (0·58, 1·37)	8·6
Askarian *et al.*[21]	15 of 150	33 of 144	0·44 (0·25, 0·77)	7·0
Bliss *et al.*[22]	6 of 73	491 of 2079	0·35 (0·16, 0·75)	5·2
Kwok *et al.*[23]	185 of 2106	428 of 1993	0·41 (0·35, 0·48)	11·5
Random-effects model	6769	8429	0·59 (0·47, 0·74)	100
Heterogeneity: $I^2 = 75\%$, $\tau^2 = 0{\cdot}115$, $P < 0{\cdot}001$				

0·2 0·5 1 2 5

Fig. 2 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing any complication. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

7/723 studies

The World Health Organization Surgical Safety Checklist Improves Post-Operative Outcomes: A Meta-Analysis and Systematic Review
Lau C, Chamberlain R. Surgical Science 2016, 7, 206-217.



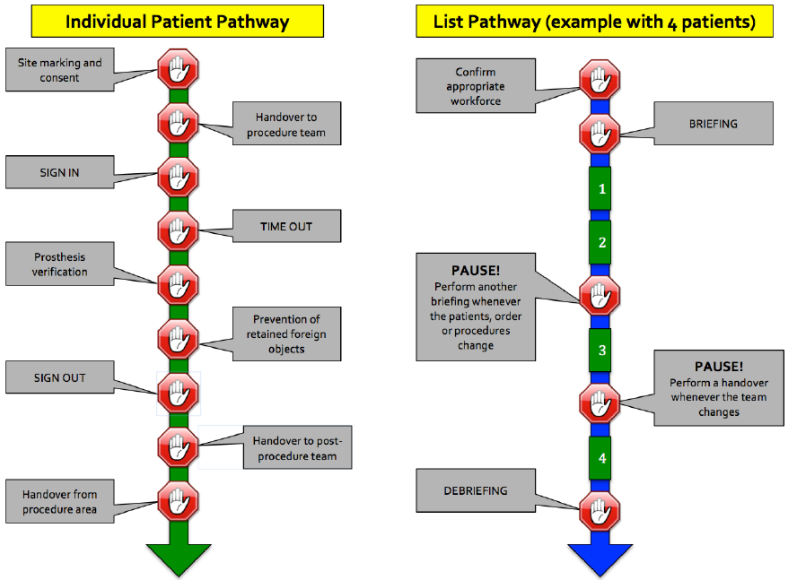
Study name	Before	After	Risk ratio	Lower limit	Upper limit	p-Value	Relative weight
Haynes, 2009 (site 1)	61 / 524	42 / 598	0.603	0.415	0.878	0.008	6.69
Haynes, 2009 (site 2)	28 / 367	22 / 351	0.799	0.466	1.369	0.415	5.10
Haynes, 2009 (site 3)	67 / 497	47 / 486	0.717	0.505	1.019	0.064	6.95
Haynes, 2009 (site 4)	39 / 520	30 / 545	0.734	0.463	1.163	0.188	5.82
Haynes, 2009 (site 5)	79 / 370	18 / 330	0.255	0.157	0.417	0.000	5.54
Haynes, 2009 (site 6)	50 / 496	46 / 476	0.959	0.655	1.402	0.828	6.64
Haynes, 2009 (site 7)	65 / 525	47 / 585	0.649	0.454	0.927	0.017	6.89
Haynes, 2009 (site 8)	27 / 444	21 / 584	0.591	0.339	1.032	0.064	4.94
Sewell, 2011	41 / 480	37 / 485	0.893	0.583	1.368	0.603	6.17
Askarian, 2011	33 / 144	15 / 150	0.436	0.248	0.768	0.004	4.86
Bliss, 2012	491 / 2079	6 / 73	0.348	0.161	0.752	0.007	3.44
Yuan, 2012 (site 1)	17 / 109	14 / 110	0.816	0.424	1.572	0.544	4.17
Yuan, 2012 (site 2)	51 / 123	32 / 139	0.565	0.384	0.803	0.002	6.75
Kwok, 2013	429 / 1993	185 / 2106	0.408	0.347	0.479	0.000	8.81
Haugen, 2015	440 / 2212	382 / 3083	0.623	0.549	0.706	0.000	9.07
Biskup, 2015	129 / 2166	133 / 2310	0.967	0.764	1.223	0.778	8.15
			0.621	0.519	0.742	0.000	

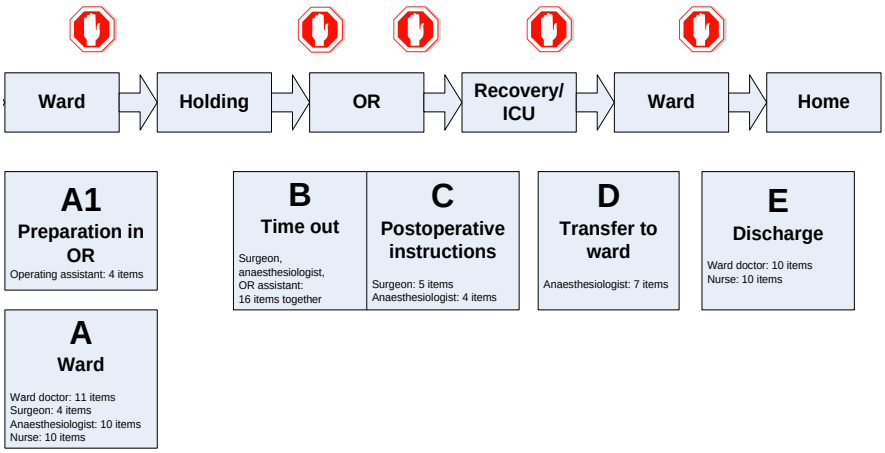
10/197 studies

Figure 2. Forest plot evaluating the relative risk of total complications following implementation of the World Health Organization surgical safety checklist.

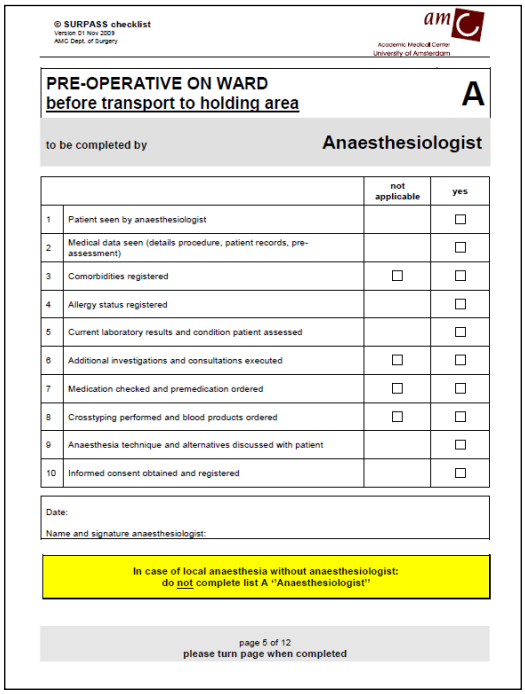
Effect of a Comprehensive Surgical Safety System on Patient Outcomes. Eefje N. de Vries, et al
N Engl J Med 2010; 363:1928-1937

- In wake of SSSL/WHO
- Surgical Patient Safety System (SURPASS) checklist
  - Multidisciplinary checklist
  - Follows surgical pathway from admission to discharge
  - Multiple checklists
  - Multiple 'hold points' (cf NatSSIPs)
  - Six centres, >3k in pre- and post-implementation groups
  - Five control centres
- Complications
  - Twelve categories…
  - Respiratory; Cardiac; Abdominal; Infectious; Wound; Bleeding; Genitourinary; Nervous system; Technical/interoperative; Organisational; Disturbed function; Other (including 'clubfoot' and 'avascular testis')





https://www.nvz-ziekenhuizen.nl/_library/10750/Marja%20Boermeester%20-%20Safety%20in%20the%20operating%20theatre.pdf



© SURPASS checklist
Version 01 Nov 2009
AMC Dept. of Surgery

amc
Academic Medical Center
University of Amsterdam

PRE-OPERATIVE ON WARD
before transport to holding area **A**

to be completed by **Anaesthesiologist**

		not applicable	yes
1	Patient seen by anaesthesiologist		☐
2	Medical data seen (details procedure, patient records, pre-assessment)		☐
3	Comorbidities registered	☐	☐
4	Allergy status registered		☐
5	Current laboratory results and condition patient assessed		☐
6	Additional investigations and consultations executed	☐	☐
7	Medication checked and premedication ordered	☐	☐
8	Crosstyping performed and blood products ordered	☐	☐
9	Anaesthesia technique and alternatives discussed with patient		☐
10	Informed consent obtained and registered		☐

Date:

Name and signature anaesthesiologist:

In case of local anaesthesia without anaesthesiologist:
do not complete list A "Anaesthesiologist"

page 5 of 12
please turn page when completed

Preparation in surgical suite	Day before surgery	Operating assistant
Pre-operative on ward	Before transport to holding area	Ward doctor
Pre-operative on ward	Before transport to holding area	Surgeon
Pre-operative on ward	Before transport to holding area	Anaesthesiologist
Pre-operative on ward	Before transport to holding area	Ward nurse
Time out in OR	Before start of procedure	Surgeon, anaesthesiologist & assistant and operating assistant together
Post-operative in OR	After procedure before transfer to recovery/ICU	Surgeon
Post-operative in OR	After procedure before transfer to recovery/ICU	Anaesthesiologist
TRANSFER recovery/ICU to ward	Before transfer to ward	Anaesthesiologist or Intensivist
Before discharge		Ward doctor
Before discharge		Ward nurse

Effect of a Comprehensive Surgical Safety System on Patient Outcomes. Eefje N. de Vries, et al
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- Complications
  - Twelve categories…
  - Respiratory; Cardiac; Abdominal; Infectious; Wound; Bleeding; Genitourinary; Nervous system; Technical/interoperative; Organisational; Disturbed function; Other (including 'clubfoot' and 'avascular testis')
- Results:
  - Complications 27.3 → 16.7/100 pts [-10.6]
  - Varied by unit (0.5-19.5 reduction)
  - Fewer complications α better checklist completion
  - No reduction in five control units

Association Between Implementation of a Medical Team Training Program and Surgical Morbidity.
Yinong Young-Xu et al, Arch Surg. 2011;146(12):1368-1373

- Medical Team Training (MTT) program:
  - 'Based on aviation CRM'
  - OR team training, two month implementation
  - Checklists, debrief tools
  - Encourage challenge
- Change in annual surgical morbidity rate:
  - 1 year after MTT program
  - vs 1 year before
  - vs Non-MTT program sites

https://jamanetwork.com/journals/jamasurgery/fullarticle/1107263

Association Between Implementation of a Medical Team Training Program and Surgical Morbidity.
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- 119,383 procedures
- 74 facilities
  - 42 adopted MTT (2007), 32 did not
- Morbidity:
  - MTT 17% decrease ($p<0.01$), non-MTT 6% (NS)
  - 15% vs 10% with risk adjustment
  - 88% MTT facilities vs 69% non-MTT improved risk adjusted mortality
- Specifically:
  - DVT, ~~PE~~, DVT+PE, superficial surgical infection, deep wound infection, all infections

https://jamanetwork.com/journals/jamasurgery/fullarticle/1107263

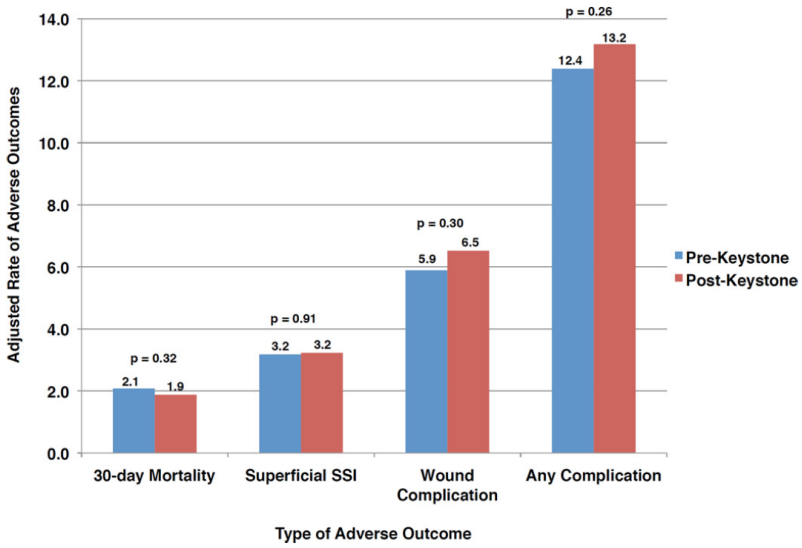
But…

Introduction of Surgical Safety Checklists in Ontario, Canada
David R. Urbach et al
N Engl J Med 2014;370:1029-1038

- 101 hospitals, 3 months pre and post checklist introduction
  - WHO or local version
- 109k vs 106k procedures
- Death during/30d: 0.71 vs 0.65%
- Surgical complications 3.86 vs 3.82%

A Checklist-based Intervention to Improve Surgical Outcomes in Michigan: Evaluation of the Keystone Surgery Program.
Reames et al. JAMA Surg. 2015 Mar 1; 150(3): 208–215.

- Evaluation of checklist-based quality improvement intervention, Keystone Surgery Program
- (Keystone ICU Patient Safety Program, Michigan 2009)
- 2006–2010, 64,891 patients, 29 hospitals:
  - Superficial surgical site infection (3.2 vs. 3.2%, p=0.91)
  - Wound complications (5.9 vs. 6.5%, p=0.30)
  - Any complication (12.4 vs. 13.2%, p=0.26)
  - 30-day mortality (2.1 vs. 1.9%, p=0.32)
- Not the same as the WHO checklist:
  - Antibiotics x 3, hair removal, glucose control, temperature control



Simulation-Based Trial of Surgical-Crisis Checklists. Arriaga et al. N Engl J Med 2013; 368:246-253

- Harvard group, OR crisis checklists
  - 12 checklists
  - 17 OR teams, 106 simulations
  - Random allocation: checklist or memory
- Failure to adhere less common during simulations when checklists were available:
  - 6% steps missed with checklist, 23% without
  - 97% participants would want checklist used if crisis occurred while they were undergoing operation

https://www.nejm.org/doi/full/10.1056/NEJMsa1204720#t=articleTop

Studies are mixed

(but only slightly)

So what's wrong with checklists?

- Think about WHO:
  - Procedures AND discussion
  - Linear vs Complex procedures
  - Require a cognitive shift
- Who does what in the checklist is not clear and defined
  - A by-product of flattened hierarchy?
- Problems of the time out:
  - Requires a stop moment exactly when most problematic, esp. in emergency
  - Paradoxically time when time out most needed also hardest to perform
  - Plane does not cease workflow for its time out.

Professional problems

- Insult to the intelligence
- Machismo of memorising
- Doubt that checklists can improve performance
- “I have my way of doing things”
- The maestro and the “Wizard of Oz” effect
- Threat to hierarchy
- Imposed by outsiders

Problems of design

- The wrong checklist
- Wrong designer
  - Lack of team
  - “The Laminator”
- No thoughts on implementation
  - Wrong team
- Complexity
  - Patients versus machines

Problems of observation

- Hawthorne effect
- Is it the checklist or the increased scrutiny/changed environment (beyond Hawthorne)?
- Checklist compliance monitoring
  - Unintended consequences
  - Do what's best for the patient or best for the compliance?

Back to basics: checklists in aviation and healthcare

Clay-Williams R, et al. BMJ Qual Saf 2015;24:428–431

- Large-scale implementations → conflicting outcomes
  - ?Not as simple or effective as hoped
- Success requires complex, cultural and organisational change efforts, not just the checklist
- May be confounded by a mix of the technical and socioadaptive elements
- Local contexts may either augment or undermine outcomes

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Implementation of safety checklists in surgery: a realist synthesis of evidence.

Gillespie & Marshall. Implementation Sci 2015;10:137

- Probably a really good paper…
- Rehearses the known successes: mortality, morbidity, pneumonia, blood loss, any complications
- But "any intervention only as strong as its weakest link"
- Overview of literature from 2008
- Pawson's and Rycroft-Malone's realist evaluation approach
  - Why implementation and interventions may work, for whom, in what contexts
  - What aspects of checklist implementation determined success or failure in various situations and why

Implementation of safety checklists in surgery: a realist synthesis of evidence.

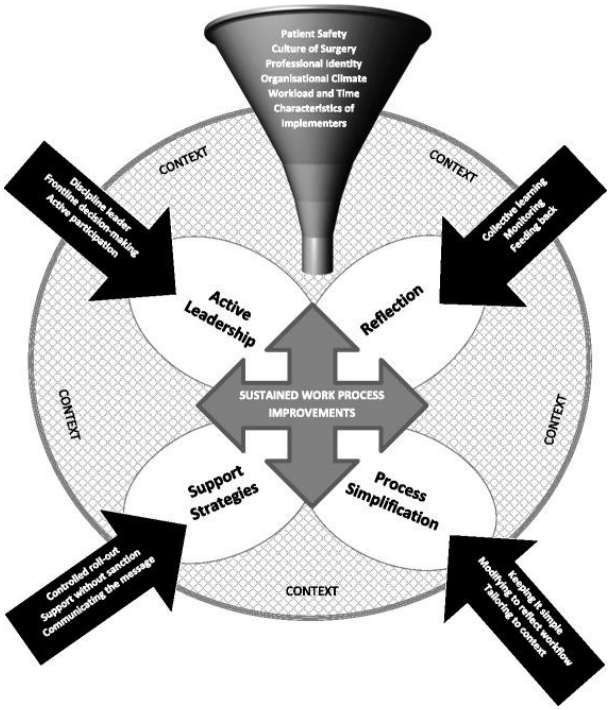
Gillespie & Marshall. Implementation Sci 2015;10:137

- Literature search:
  - Quantitative/qualitative, surgery, aspect of implementation
- Assessed against:
  - Normalisation Process Theory (NPT) - how things become normalised into everyday practice
  - Responsive Regulation Theory (RRT) – mechanism of persuasion based on trust and respect rather than enforcement
- Findings
  - Clinicians (especially) were unable to perceive overall benefits to team and believed they were already enacting these in practice

Implementation of safety checklists in surgery: a realist synthesis of evidence.

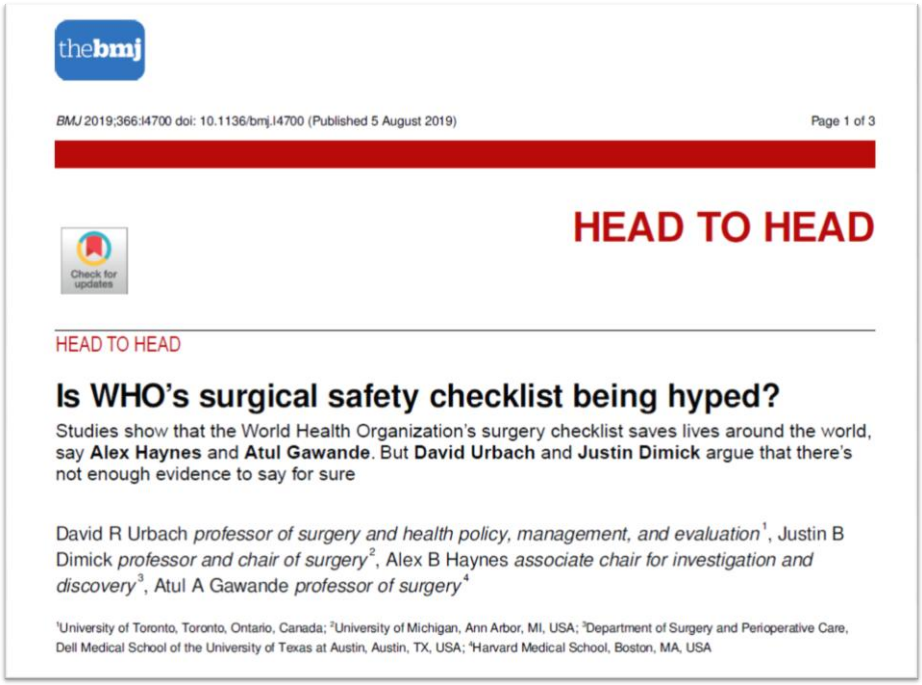
Gillespie & Marshall. Implementation Sci 2015;10:137

- Propositions:
  - Checklist protocols that are prospectively tailored to the context are more likely to be used and sustained in practice – unknown
  - Fidelity and sustainability is increased when checklist protocols can be seamlessly integrated into daily professional practice – limited support
  - Routine embedding of checklist protocols in practice is influenced by factors that promote or inhibit clinicians' participation – moderate support
  - Regulation reinforcement mechanisms that are more contextually responsive should lead to greater compliance in using checklist protocols - partial support



Implementation of safety checklists in surgery: a realist synthesis of evidence.
Gillespie & Marshall. Implementation Sci 2015;10:137

- Conclusions:
  - *"First, the sustained use of surgical checklists is discipline-specific and is more successful when physicians are actively engaged and leading implementation.*
  - *Second, involving clinicians in tailoring the checklist to their context and encouraging them to reflect on and evaluate the implementation process enables greater participation and ownership."*



thebmj

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HEAD TO HEAD

Check for updates

HEAD TO HEAD

Is WHO's surgical safety checklist being hyped?

Studies show that the World Health Organization's surgery checklist saves lives around the world, say **Alex Haynes** and **Atul Gawande**. But **David Urbach** and **Justin Dimick** argue that there's not enough evidence to say for sure

David R Urbach *professor of surgery and health policy, management, and evaluation*[1], Justin B Dimick *professor and chair of surgery*[2], Alex B Haynes *associate chair for investigation and discovery*[3], Atul A Gawande *professor of surgery*[4]

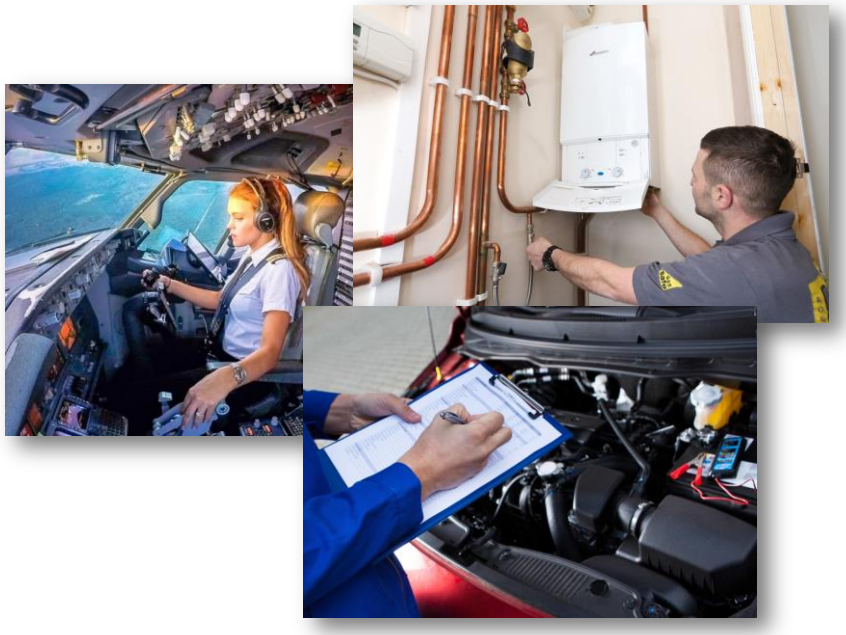
[1]University of Toronto, Toronto, Ontario, Canada; [2]University of Michigan, Ann Arbor, MI, USA; [3]Department of Surgery and Perioperative Care, Dell Medical School of the University of Texas at Austin, Austin, TX, USA; [4]Harvard Medical School, Boston, MA, USA

"Some may argue that the effect of the checklist can't be separated from the implementation program and associated training.

"Teams with the capacity for improvement are the most likely to effectively integrate… the checklist into their workflow, leading to the criticism that studies of checklist implementation simply identify "improvers."

"… even highly motivated teams need tools for implementation, and the evidence suggests that the WHO surgical safety checklist is among the most powerful tools for improving the safety of surgical care…

"… and continue to evaluate results"



NatSSIPs

So…

… are checklists all they’re cracked up to be?

Yes

Yes

(if done properly)

Creating a checklist

- Review the existing literature and offerings
  - Don't re-invent the wheel
- Understand the needs and work-place of the user
- Include a multidisciplinary group in the design
  - Use topic experts
  - Use right people to implement and sustain
- Use an iterative approach
  - Reductionist design
  - Concentrate on high impact, low barriers
- Rigorous pilot testing and validation of the checklist
- "Checklists must remain wise"
  - Change, evolve, responsive, evaluate evidence for each step

Questions?

Association of Anaesthetists