Collaboration for Leadership in Applied Health Research and Care South London (CLAHRC South London)

National Institute for Health Research

The case for implementation science (session 1)

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Overall workshop goals

- Make you familiar with basic principles and concepts of implementation science
- Enable you to identify what makes a 'good project' from an implementation science perspective
- Enable you to identify opportunities to develop your projects further using implementation concepts, metrics and methods

Lecture aims

- **Introduce the need for a science of implementation** of evidence-based therapies, practices and interventions

- **Familiarise you with key elements** of implementation science:
  - Implementation outcomes
  - Implementation strategies

- Present an **overview of key differences** between clinical and implementation research

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Evidence is king – we just need to develop & apply interventions to improve care & outcomes

We don't need yet another 'science' – we need to do what we know is right


200
WIPES

BMJ

No 7237 18 March 2000

Reducing error Improving safety

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The story of the WHO Surgical Checklist

Surgical Safety Checklist

World Health Organization | Patient Safety — A World Alliance for Safer Health Care

Before induction of anaesthesia
(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision
(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are 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.

Revised 1 / 2009

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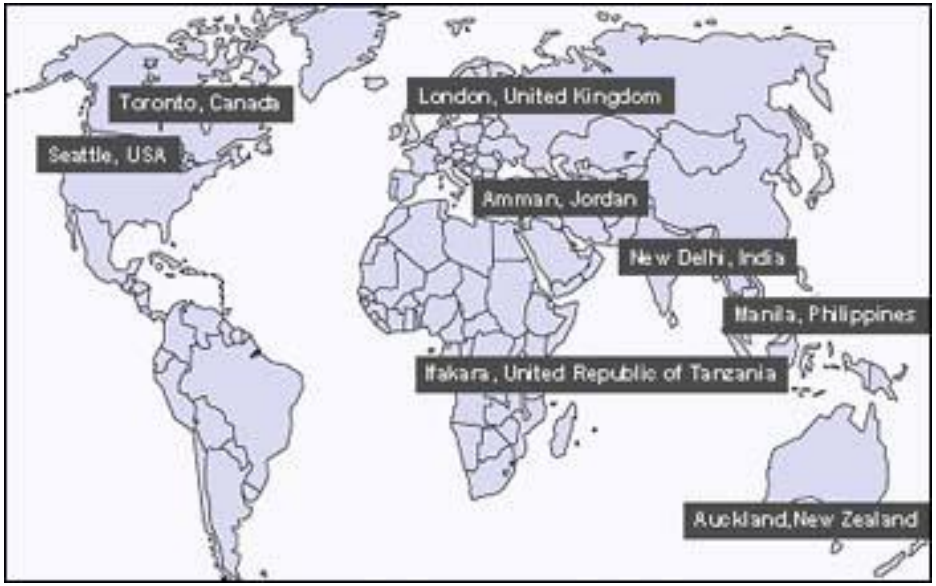
The first study (2009)



The NEW ENGLAND JOURNAL of MEDICINE

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. Kibatala, 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*

- Major complication rate decreased 36%
- Mortality decreased 47%
- Post-op infection decreased 48%

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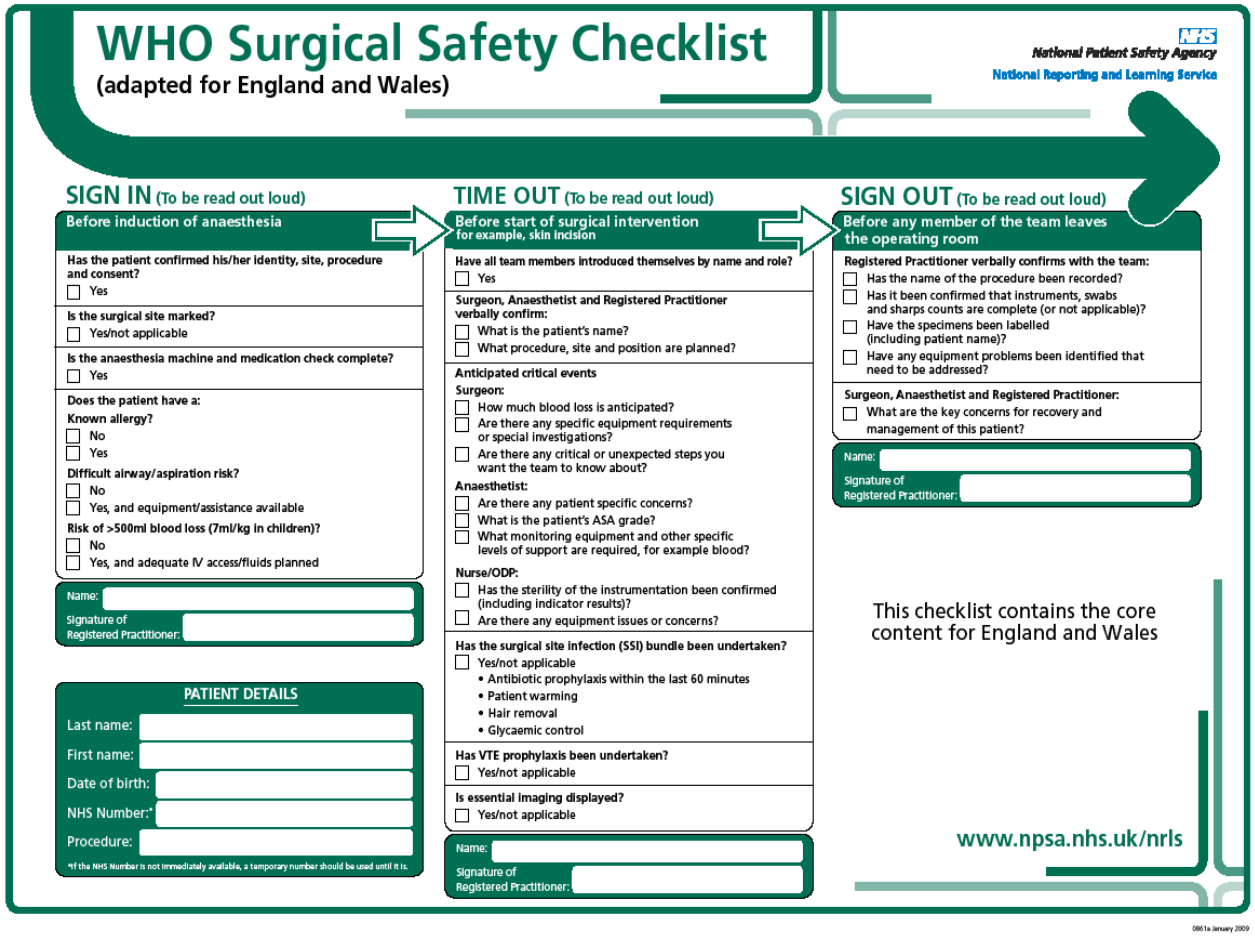
Within weeks of the publication…



WHO Surgical Safety Checklist

(adapted for England and Wales)

National Patient Safety Agency
National Reporting and Learning Service

SIGN IN (To be read out loud)

Before induction of anaesthesia

Has the patient confirmed his/her identity, site, procedure and consent?
- ☐ Yes

Is the surgical site marked?
- ☐ Yes/not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Does the 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 IV access/fluids planned

Name:

Signature of Registered Practitioner:

PATIENT DETAILS

Last name:

First name:

Date of birth:

NHS Number:*

Procedure:

*If the NHS Number is not immediately available, a temporary number should be used until it is.

TIME OUT (To be read out loud)

Before start of surgical intervention for example, skin incision

Have all team members introduced themselves by name and role?
- ☐ Yes

Surgeon, Anaesthetist and Registered Practitioner verbally confirm:
- ☐ What is the patient's name?
- ☐ What procedure, site and position are planned?

Anticipated critical events

Surgeon:
- ☐ How much blood loss is anticipated?
- ☐ Are there any specific equipment requirements or special investigations?
- ☐ Are there any critical or unexpected steps you want the team to know about?

Anaesthetist:
- ☐ Are there any patient specific concerns?
- ☐ What is the patient's ASA grade?
- ☐ What monitoring equipment and other specific levels of support are required, for example blood?

Nurse/ODP:
- ☐ Has the sterility of the instrumentation been confirmed (including indicator results)?
- ☐ Are there any equipment issues or concerns?

Has the surgical site infection (SSI) bundle been undertaken?
- ☐ Yes/not applicable
  - Antibiotic prophylaxis within the last 60 minutes
  - Patient warming
  - Hair removal
  - Glycaemic control

Has VTE prophylaxis been undertaken?
- ☐ Yes/not applicable

Is essential imaging displayed?
- ☐ Yes/not applicable

Name:

Signature of Registered Practitioner:

SIGN OUT (To be read out loud)

Before any member of the team leaves the operating room

Registered Practitioner verbally confirms with the team:
- ☐ Has the name of the procedure been recorded?
- ☐ Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)?
- ☐ Have the specimens been labelled (including patient name)?
- ☐ Have any equipment problems been identified that need to be addressed?

Surgeon, Anaesthetist and Registered Practitioner:
- ☐ What are the key concerns for recovery and management of this patient?

Name:

Signature of Registered Practitioner:

This checklist contains the core content for England and Wales

www.npsa.nhs.uk/nrls

0861a January 2009

- National policy
- All hospitals were asked to implement the checklist within 12 months

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Further evidence

FEATURE

OPEN

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‡‡†*

Objectives: We hypothesized reduction of 30 days' in-hospital morbidity, mortality, and length of stay postimplementation of the World Health Organization's Surgical Safety Checklist (SSC).

Background: Reductions of morbidity and mortality have been reported after SSC implementation in pre-/postdesigned studies without controls. Here, we report a randomized controlled trial of the SSC.

Methods: A stepped wedge cluster randomized controlled trial was conducted in 2 hospitals. We examined effects on in-hospital complications registered by *International Classification of Diseases, Tenth Revision* codes, length of stay, and mortality. The SSC intervention was sequentially rolled out in a random order until all 5 clusters—cardiothoracic, neurosurgery, orthopedic, general, and urologic surgery had received the Checklist. Data were prospectively recorded in control and intervention stages during a 10-month period in 2009–2010.

Results: A total of 2212 control procedures were compared with 2263 SCC procedures. The complication rates decreased from 19.9% to 11.5% ($P < 0.001$), with absolute risk reduction 8.4 (95% confidence interval, 6.3–10.5) from the control to the SSC stages. Adjusted for possible confounding factors, the SSC effect on complications remained significant with odds ratio 1.95 (95% confidence interval, 1.59–2.40). Mean length of stay decreased by 0.8 days with SCC utilization (95% confidence interval, 0.11–1.43). In-hospital mortality decreased significantly from 1.9% to 0.2% in 1 of the 2 hospitals post-SSC implementation, but the overall reduction (1.6%–1.0%) across hospitals was not significant.

Conclusions: Implementation of the WHO SSC was associated with robust reduction in morbidity and length of in-hospital stay and some reduction in mortality.

Keywords: checklist, morbidity, mortality, randomized controlled trial, surgery

(*Ann Surg* 2015;261:821–828)

As global surgical volume increase and exceed 234 million surgical procedures annually,[1] surgical mortality has declined over the previous decades.[2] Still, crude mortality rates are reported to vary between 0.4% and 4% in high-income countries.[3–5] Increased risk of mortality is associated with major complications in hospitals with higher overall mortality.[6] In-hospital complications occur in 3% to 22% of admitted patients, with 36% to 54% related to surgery.[7–9] Prevention of complications and incidents of iatrogenic harm are deemed feasible for nearly 50% of such incidents.[3,9] Introduction of checklists in surgery can intercept and prevent such incidents[10–12] and may reduce both morbidity and mortality.[13–16]

In 2008, the World Health Organization (WHO) introduced the Surgical Safety Checklist (SSC) designed to improve consistency of care.[17] The pilot pre-/postevaluation of the WHO SSC across 8 countries worldwide, which found reduced morbidity and mortality after SSC implementation,[14] constituted the first scientific evidence of the WHO SSC effects. A number of subsequent studies to date have reported improved patient outcomes with use of checklists.[18] Furthermore, checklists have also been shown to improve communication,[19–22] preparedness,[23] teamwork,[24,25] and safety attitudes[26]—findings that have been corroborated by a recent systematic review.[27]

Although checklists are becoming a standard of care in surgery,[28] the strength of the available evidence has been criticized as being low because of (i) predominantly pre-/postimplementation designs without controls; (ii) lack of evidence on effect on length of stay; and (iii) lack of evidence on any associated cost savings. Randomized controlled trials (RCTs) are required[29]—however, in some countries or settings, they can no longer be carried out, as the WHO SSC has already become national policy (eg, United Kingdom).

We report a stepped wedge cluster RCT aimed to evaluate the impact of the WHO SSC on morbidity, mortality, and length of hospital stay (LOS). We hypothesized a reduction of 30 days' in-hospital morbidity and mortality and subsequent LOS post-Checklist implementation.

METHODS

Study Design

We conducted a stepped wedge cluster randomized controlled checklist intervention trial in 2 hospitals in Norway[30]; a tertiary teaching hospital (1100 beds) and a central community hospital (300 beds). Following the WHO implementation guidelines for the SSC,

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Disclosure: This study received departmental support. A.S.H. was granted by the Western Regional Norwegian Health Authority (grant numbers 911635 and 911510). N.S. is affiliated with the Imperial Center for Patient Safety and Service Quality, which is funded by the National Institute for Health Research, UK. The funders had no role in the design, conduct, or analysis of this study. The authors report no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

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Implementation at scale?

SPECIAL ARTICLE

Introduction of Surgical Safety Checklists in Ontario, Canada

David R. Urbach, M.D., Anand Govindarajan, M.D., Refik Saskin, M.Sc., Andrew S. Wilton, M.Sc., and Nancy N. Baxter, M.D., Ph.D.

Pre-checklist (N=109,341)

30-day mortality = 0.71%

Complications risk = 3.86%

Post-checklist (N=106,370)

30-day mortality = 0.65%

Complications risk = 3.82%

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Problematic…

SPECIAL ARTICLE

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"The likely reason for the failure …is that it was not actually used"

Pre-checklist (N=109,341)

30-day mortality = 0.71%

Complications risk = 3.86%

Post-checklist (N=106,370)

30-day mortality = 0.65%

Complications risk = 3.82%

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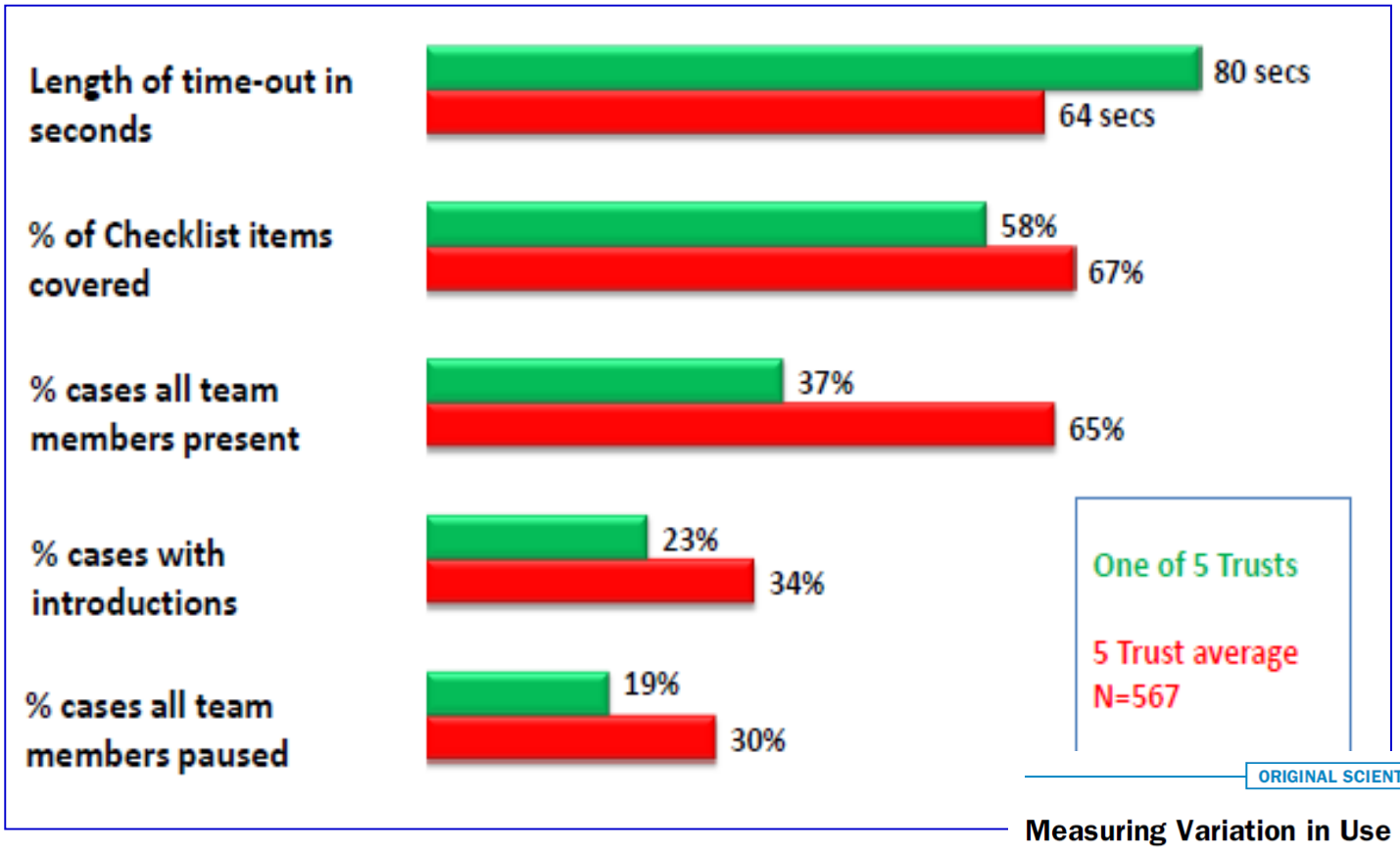
Variation in implementation at the 'coalface'



ORIGINAL SCIENTIFIC ARTICLES

Measuring Variation in Use of the WHO Surgical Safety Checklist in the Operating Room: A Multicenter Prospective Cross-Sectional Study

Stephanie Russ, PhD, Shantanu Rout, MRCS, Jochem Caris, MD, Jenny Mansell, MSc, Rachel Davies, BA, Erik Mayer, PhD, FRCS, Krishna Moorthy, MD, FRCS, Ara Darzi, MD, FACS(Hon), Charles Vincent, PhD, Nick Sevdalis, PhD

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Variable implementation at executive level

"It just appeared…"

"It was sth they were just doing one day"

"There was no discussion or introduction or anything. Typical."

"Our chief exec had a bee in their bonnet and it was 'no you will do this'…"

ORIGINAL ARTICLE

A Qualitative Evaluation of the Barriers and Facilitators Toward Implementation of the WHO Surgical Safety Checklist Across Hospitals in England

Lessons From the "Surgical Checklist Implementation Project"

Stephanie J. Russ, PhD, Nick Sevdalis, PhD, Krishna Moorthy, MD, FRCS, Erik K. Mayer, PhD, FRCS, Shantanu Rout, MRCS, Jochem Caris, MD,

REVIEW PAPER

Implementation Science

A Neglected Opportunity to Accelerate Improvements in the Safety and Quality of Surgical Care

Louise Hull, PhD, Thanos Athanasiou, PhD, FETCS,† and Stephanie Russ, PhD‡*

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Poor implementation = Loss of effectiveness?

Event type	N
Wrong site surgery	179
Retained foreign object post-procedure	107
Wrong implant / prosthesis	59
Misplaced naso- or oro-gastric tubes	40
Wrong route administration of medication	25
Overdose of insulin due to abbreviations or incorrect device	11
Other never events	21
TOTAL	**442**

Annual data summary, 2015-16

NHS Improvement

NeverEvents

Barriers to achieving improvement: evidence

	Design	Delivery	Dissemination
Initiative-related barriers			
Insufficient evidence base	X		X
Usability of interventions		X	
Fit with processes		X	
Individual barriers			
Staff resistance	X	X	
Staff skills and knowledge		X	
Role demarcation		X	
Organisational barriers			
Culture and stability	X	X	
Lack of leadership	X	X	
Management	X	X	X
Insufficient use of data	X	X	X
Lack of time allocated	X	X	X
Lack of funding	X	X	X
System-wide barriers			
NHS culture	X	X	X
Lack of stability	X	X	
Partnerships		X	X
Incentives and funding	X	X	
Note: crosses indicate where barrier have been found to exist most prominently			

Health Foundation. *What's Getting in the Way? Evidence Scan*. 2015

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Deadly gap between research and real life

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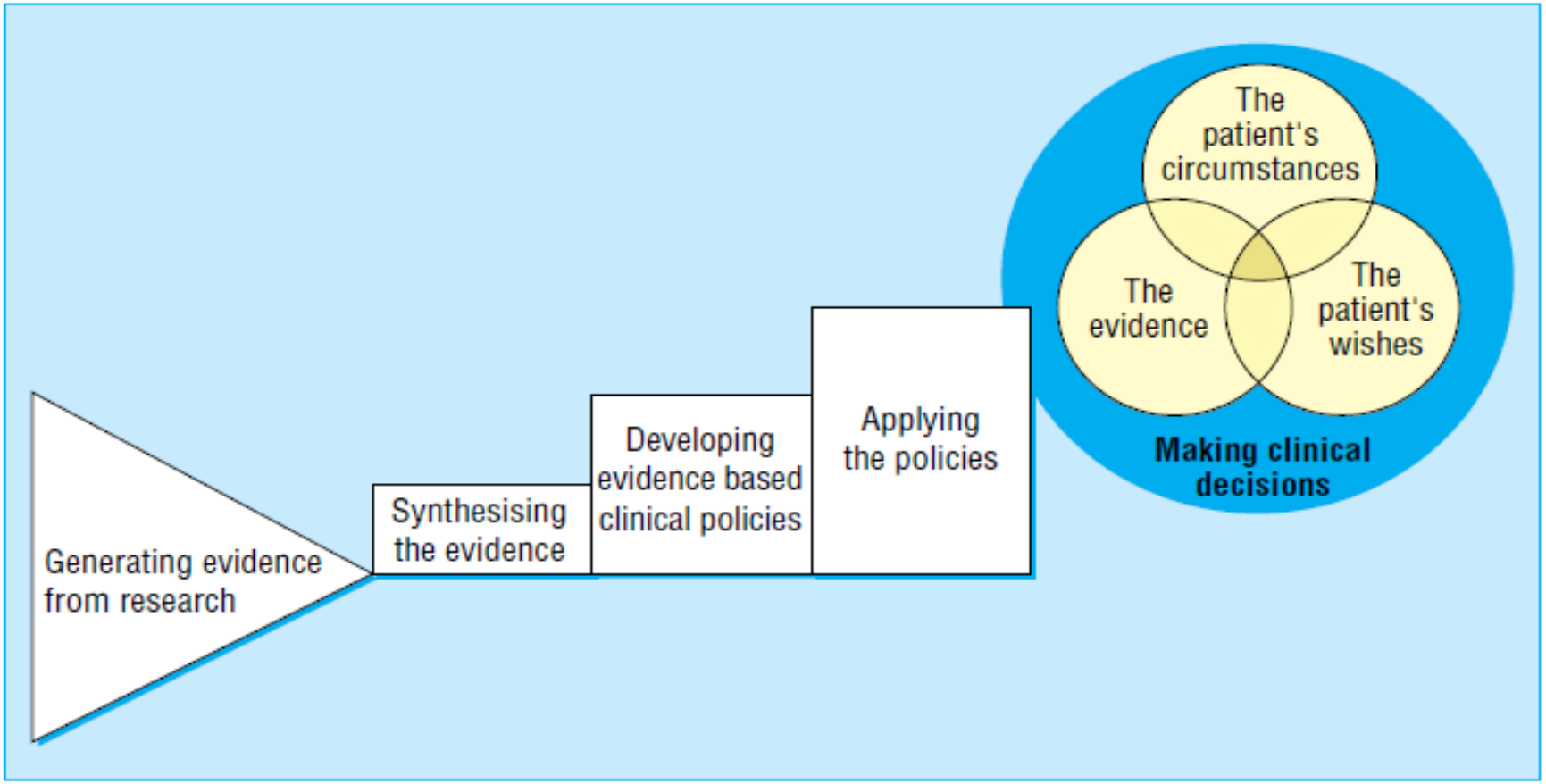
Deadly gap between research and real life

Slote Morris et al, J R Soc Med 2011;104:510-20

Path from generating to applying evidence



Haynes B, Haines A, BMJ 1998;317:273-6

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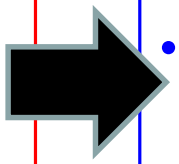
A tale of two worlds…

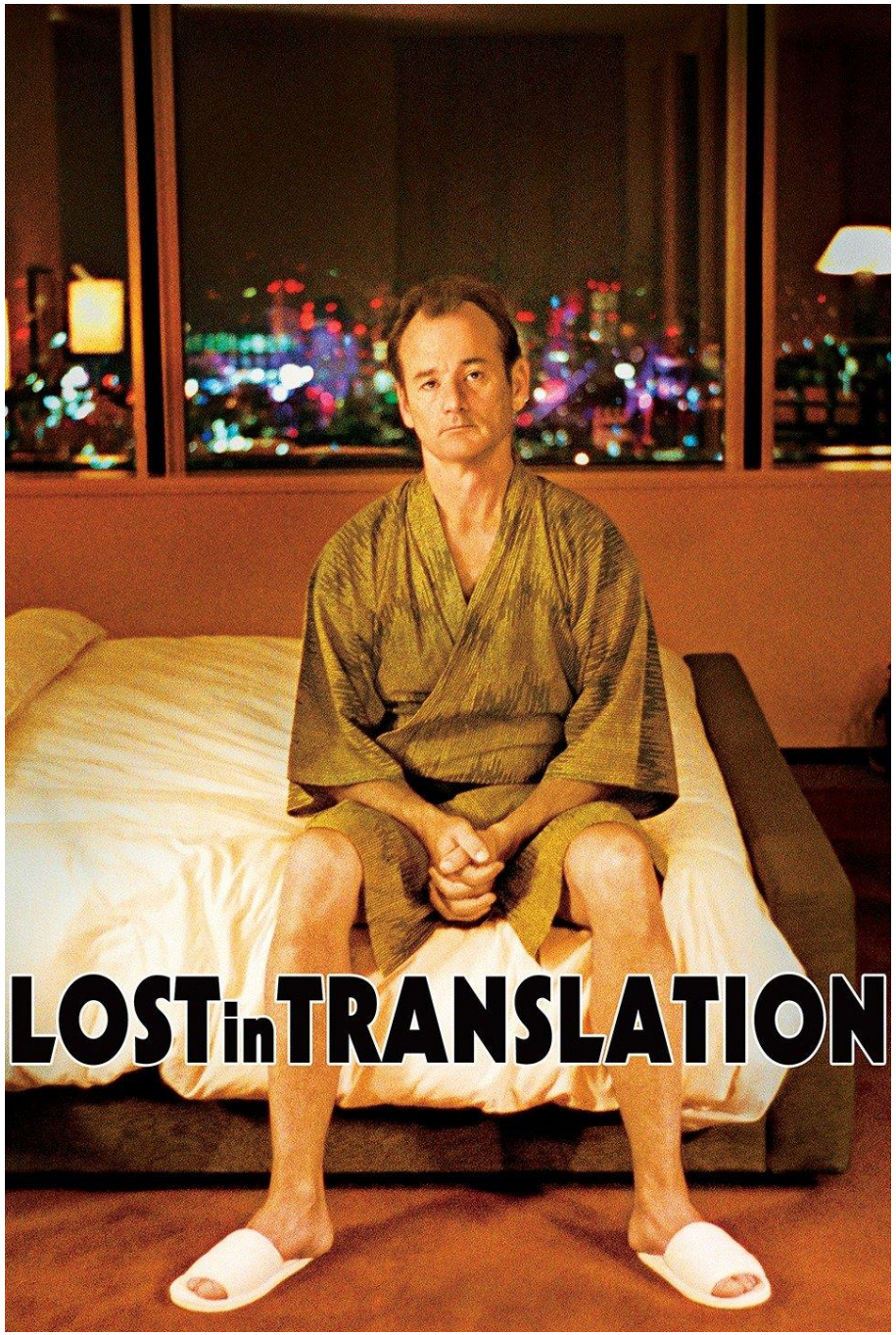
Research world

- Intention to maximise intervention efficacy
- Careful selection of patients
- Specialised+trained researchers implementing & measuring
- Research funds



Health services

- Intention to achieve sustainable delivery
- Widespread adoption/scale-up
- Generalist practitioners, often no further training, no ad hoc measurement
- Service delivery funds (limited)


LOST in TRANSLATION

Key implication

- We need a **science** that helps us understand these **phenomena**

- We need frameworks to
  - analyse implementation
  - improve implementation
  - explore links between implementation success & clinical effectiveness

"If you can't measure something, you can't understand it.
If you can't understand it, you can't control it.
If you can't control it, you can't improve it."

H James Harrington

Business quality management expert

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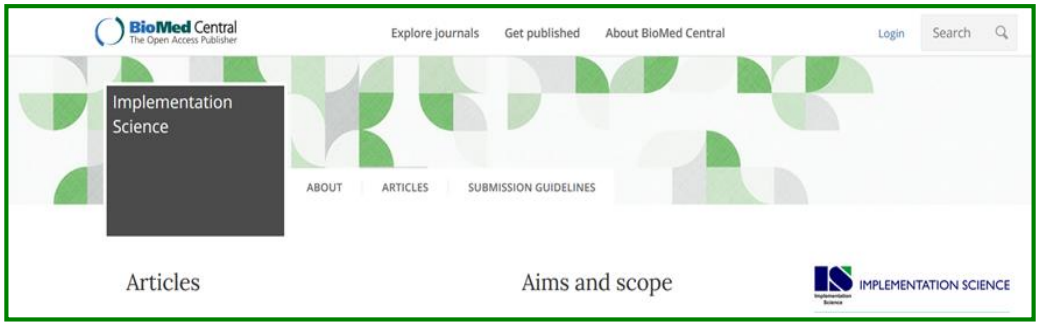
Closing the gap: Implementation science

- The **scientific study of methods to promote the uptake of research findings into routine healthcare** in clinical, organisational or policy contexts

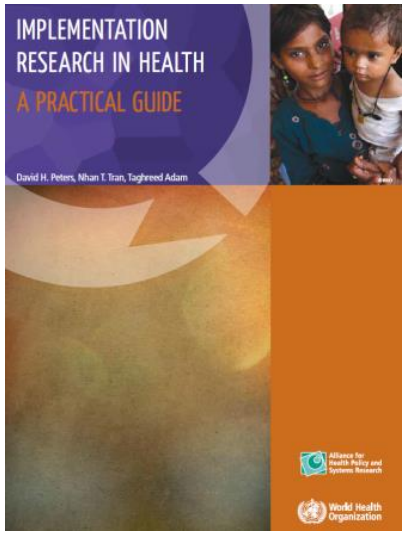
[*Implementation Science* journal website]

- It supports **innovative approaches to identifying, understanding, and overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions**, tools, policies, and guidelines



[NIH, 2015]

Implementation research within translational continuum



INNOVATION

RESEARCH

Proof of concept: Is it safe and does it work?	Proof of implementation: How does it work in real-world settings?	Informing Scale-up: Health systems integration and sustainability

Implementation not relevant	Implementation relevant but not considered	Implementation relevant but effects reduced	Implementation studied as contributing factors	Implementation as primary focus
Research question: Basic sciences, product development, or inquiry unrelated to implementation **Context:** Controlled or not related to implementation **Implementation strategies and variables:** not relevant	**Research question:** Susceptible to implementation variables, but not considered **Context:** Largely controlled, highly selected population, factors affecting implementation fixed or ignored **Implementation strategies:** None or one type only, not considered in research **Implementation variables:** Can influence results but assumed to be controlled or not relevant	**Research Questions:** Secondary question, e.g. average effectiveness of a program **Context:** Real-world setting with partially controlled intervention **Implementation strategies:** Identified and described, but uses one type only and effects are controlled **Implementation variables:** Assumed to be equal or unchanging, or effects controlled (e.g. adjusted as confounding factors)	**Research Questions:** Co-primary or secondary question, e.g. effectiveness of program in all its variation **Context:** Real-world setting and population **Implementation Strategies:** One or more studied **Implementation variables:** May be used as independent variables	**Research Questions:** Primary question, e.g. How do parts of a program change and why? What are the effects of implementation strategies? **Context:** Real-world setting and population **Implementation strategies:** May be primary focus **Implementation variables:** May be primary outcomes or determinants
Examples: Basic science; Phase I & II clinical trials; Qualitative studies unrelated to implementation issues (e.g. perceptions of illness)	**Examples:** Efficacy studies, Phase III randomized controlled clinical trial; Qualitative study on health service use that does consider how well the services are provided.	**Example:** Pragmatic trials, Quasi-experimental study with intervention and comparison areas; Observational studies with implementation as secondary issue	**Examples:** Effectiveness-Implementation trials; Observational studies assessing implementation variables as secondary factors; Participatory research	**Examples:** Mixed methods and quasi-experimental studies to determine the changes in delivery or acceptability of a program; Observational studies on adaptation, learning, and scaling-up of a programme

Implementation research terms

- **Implementation strategies**: Methods or techniques used to enhance the adoption, implementation, and sustainability of an clinical programme or intervention

- **Implementation theories & frameworks**: Proposed generalisable explanations regarding how interventions or programmes are implemented; whether implementation is successful, and why

- **Implementation context**: Factors or attributes that are external to an intervention or programme and that facilitate or impede implementation efforts

Typical clinical vs implementation studies

	Clinical effectiveness research	Implementation research
Study aim: to evaluate a…	clinical intervention	implementation strategy
Interventions…	drug, procedure, therapy	clinician, organisational practice change
Primary outcomes…	symptoms, health outcomes, mortality	adoption, adherence, fidelity
Units of analysis & randomisation…	group of patients, patient	clinician, team, facility

[Curran et al, Med Care 2012;50:217-26]

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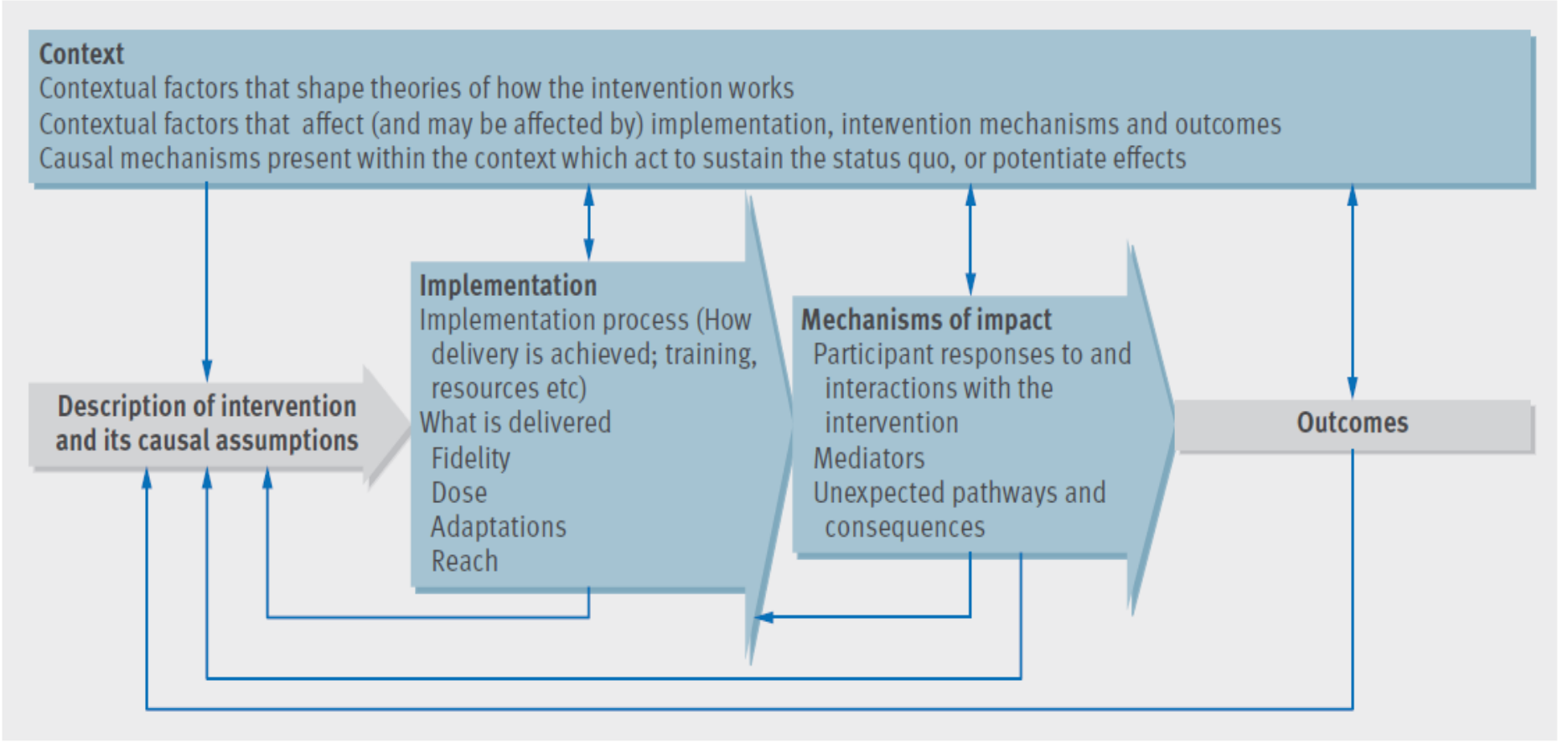
Evaluating effectiveness + implementation



Moore et al, BMJ 2015;350:h1258

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Summary

- **Implementation science offers a language and a way of thinking around how interventions work (or not) in the real world**
  - Takes us from research to real life settings

- **Without studying and optimising implementation improving patient care will remain slow at best**

Further resources for you

Launch event!
April 18th,
9:30-13:30

Implementation research projects	Quality improvement projects	Evaluation of quality improvement programmes and service developments
Target audience: Researchers, healthcare professionals, managers, patients and the public seeking to utilise implementation science to embed research findings into practice	**Target audience:** Healthcare professionals, managers, students, patients and the public who are planning to undertake a quality improvement project in a healthcare setting	**Target audience:** Quality improvement leads, transformation leads and programme managers who wish to assess the worth of a quality improvement programme Healthcare professionals, managers, patients and the public who wish to judge a service through systematic assessment of its aims, activities, outcomes and costs
Implementation Science Research Development (ImpRes) tool and guide	***Step 1: KIS introduction to quality improvement*** ***Step 2: KIS guidance for deciding what to improve and assessing feasibility of a quality improvement project*** ***Step 3: KIS template for planning and evaluating a quality improvement project***	***KIS guide to evaluation resources***

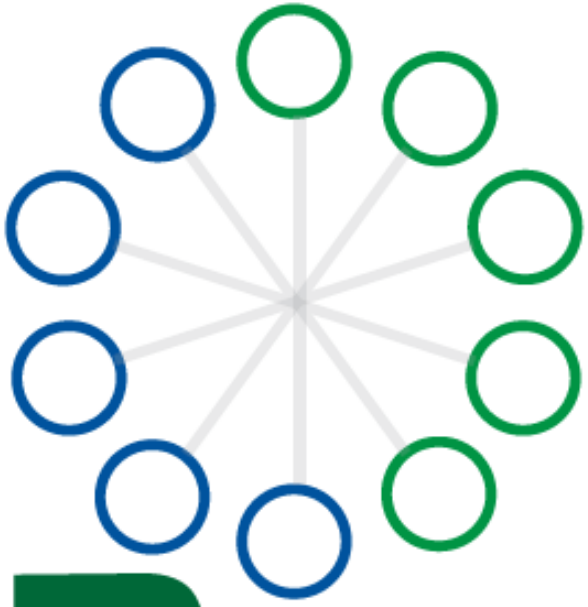
Communication: A practical resource

KIS advice for patient and public involvement

KIS glossary (coming soon)

Additional support via longer term collaboration with KIS or one-off advice via ***Project Design Clinic***

Available at www.kingsimprovementscience.org



ImpRes

Implementation Science Research Development Tool

ImpRes covers the core principles and methods of implementation science that should be considered when planning a project

We can advise further as part of our Advice Clinic

ADVICE CLINIC: FOR QUALITY IMPROVEMENT AND IMPLEMENTATION SCIENCE PROJECTS

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St George's University of London
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