Demystifying the last 20 years of translational research in health:

The science of implementation & other improbable animals

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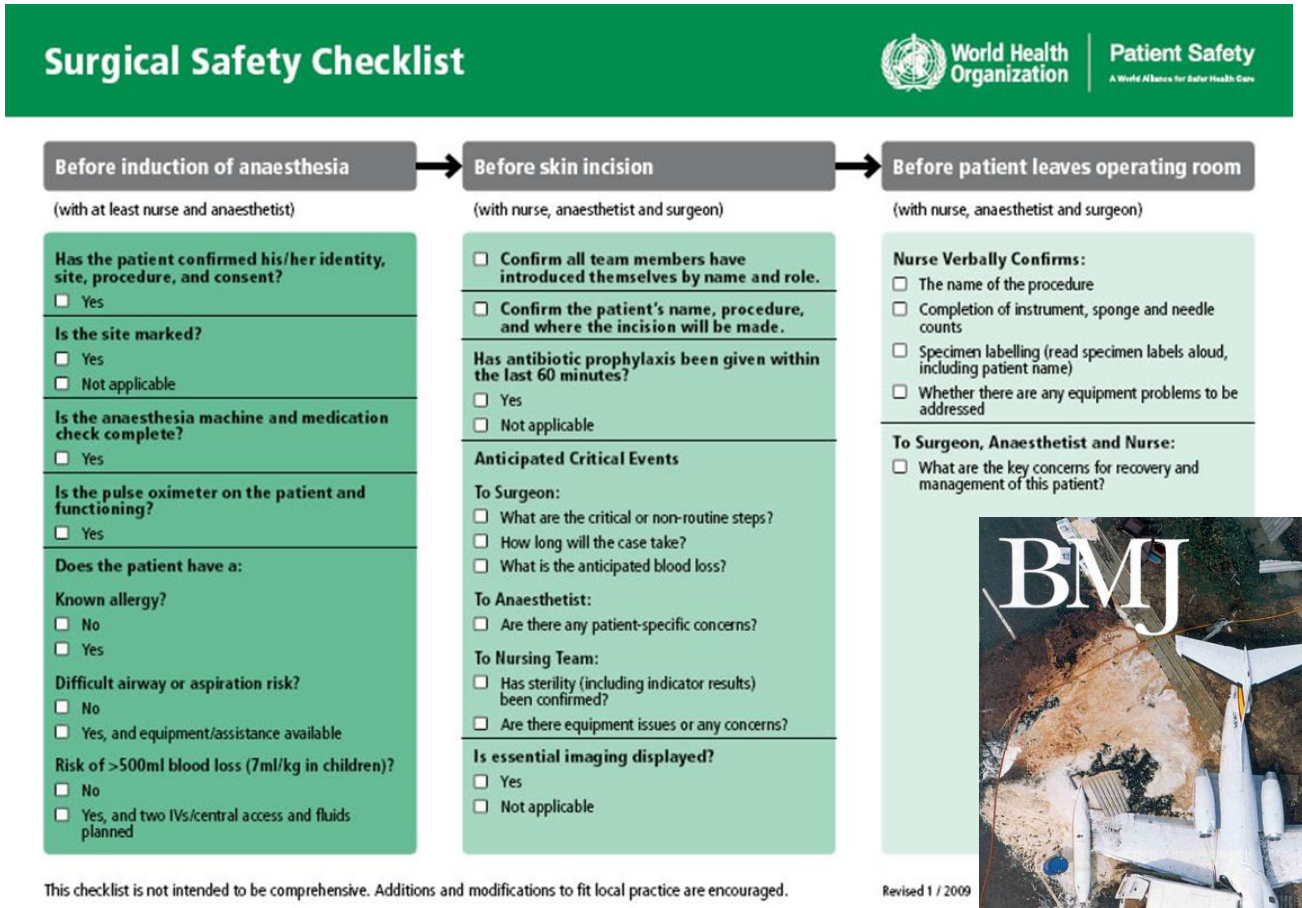
THE LATEST RESEARCH SHOWS THAT WE REALLY SHOULD DO SOMETHING WITH ALL THIS RESEARCH
SIBURNS

My aims today

- To make the case that evidence, on its own, whilst necessary, is typically not sufficient to change practice or behaviour
- To provide a rationale for a science of implementation phenomena
- To describe some key elements of that science
- To facilitate discussion of implementation needs and questions at national level and foster collaborations

A personal story – and a global intervention



Surgical Safety Checklist

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

Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
(with at least nurse and anaesthetist)	(with nurse, anaesthetist and surgeon)	(with nurse, anaesthetist and surgeon)
Has the patient confirmed his/her identity, site, procedure, and consent? ☐ Yes	☐ **Confirm all team members have introduced themselves by name and role.**	**Nurse Verbally Confirms:** ☐ The name of the procedure
Is the site marked? ☐ Yes ☐ Not applicable	☐ **Confirm the patient's name, procedure, and where the incision will be made.**	☐ Completion of instrument, sponge and needle counts
Is the anaesthesia machine and medication check complete? ☐ Yes	**Has antibiotic prophylaxis been given within the last 60 minutes?** ☐ Yes ☐ Not applicable	☐ Specimen labelling (read specimen labels aloud, including patient name)
Is the pulse oximeter on the patient and functioning? ☐ Yes	**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?	☐ Whether there are any equipment problems to be addressed
Does the patient have a: Known allergy? ☐ No ☐ Yes	To Anaesthetist: ☐ Are there any patient-specific concerns?	**To Surgeon, Anaesthetist and Nurse:** ☐ What are the key concerns for recovery and management of this patient?
Difficult airway or aspiration risk? ☐ No ☐ Yes, and equipment/assistance available	To Nursing Team: ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns?	
Risk of >500ml blood loss (7ml/kg in children)? ☐ No ☐ Yes, and two IVs/central access and fluids planned	**Is essential imaging displayed?** ☐ Yes ☐ Not applicable	

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

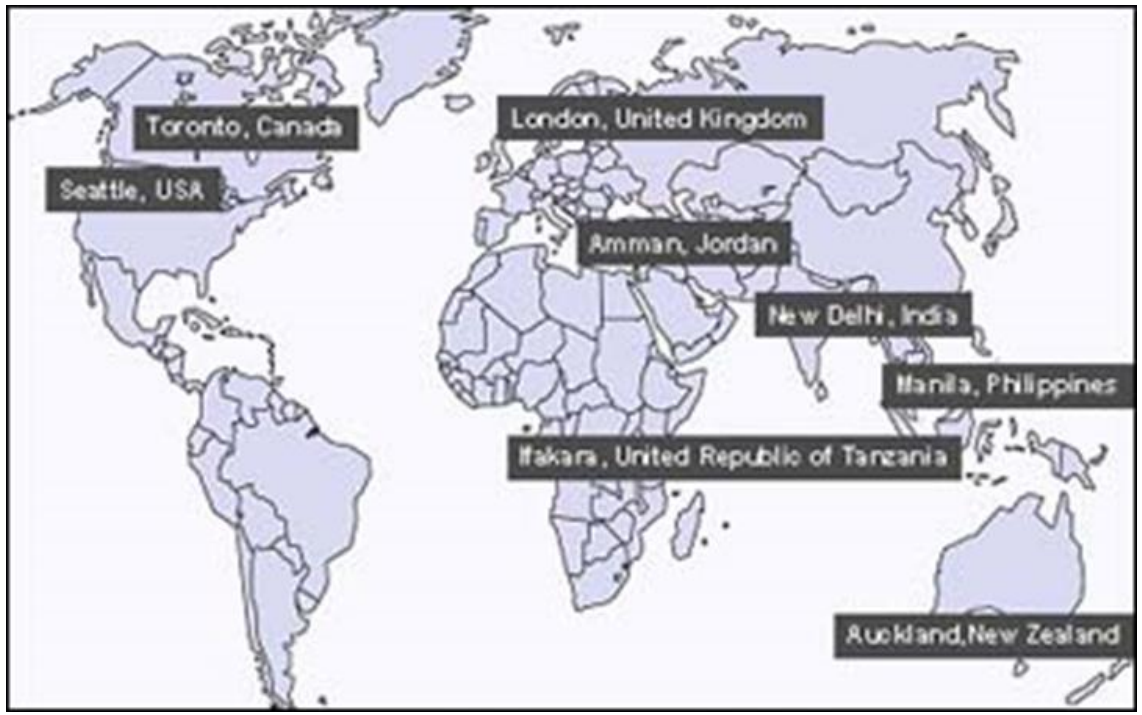
- Surgery becoming a public health-level concern: >312M surgical care episodes annually

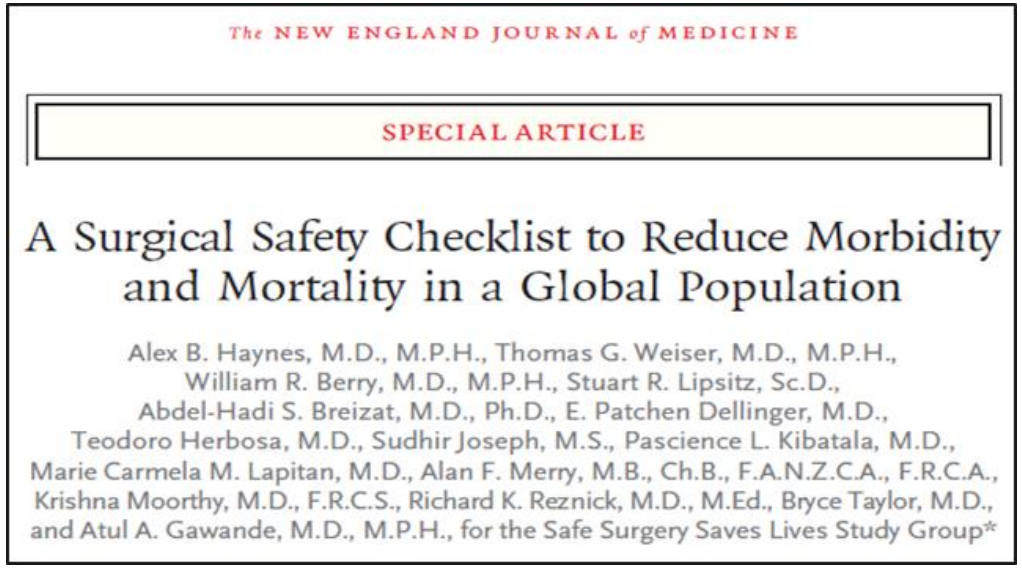
  Weiser et al, *Lancet* 2015;385 Suppl 2:S11

- A simple, inexpensive, one-page intervention to improve surgical care globally – inspired by aviation

- With WHO support, developed by clinicians

First study in 2009





The NEW ENGLAND JOURNAL of MEDICINE

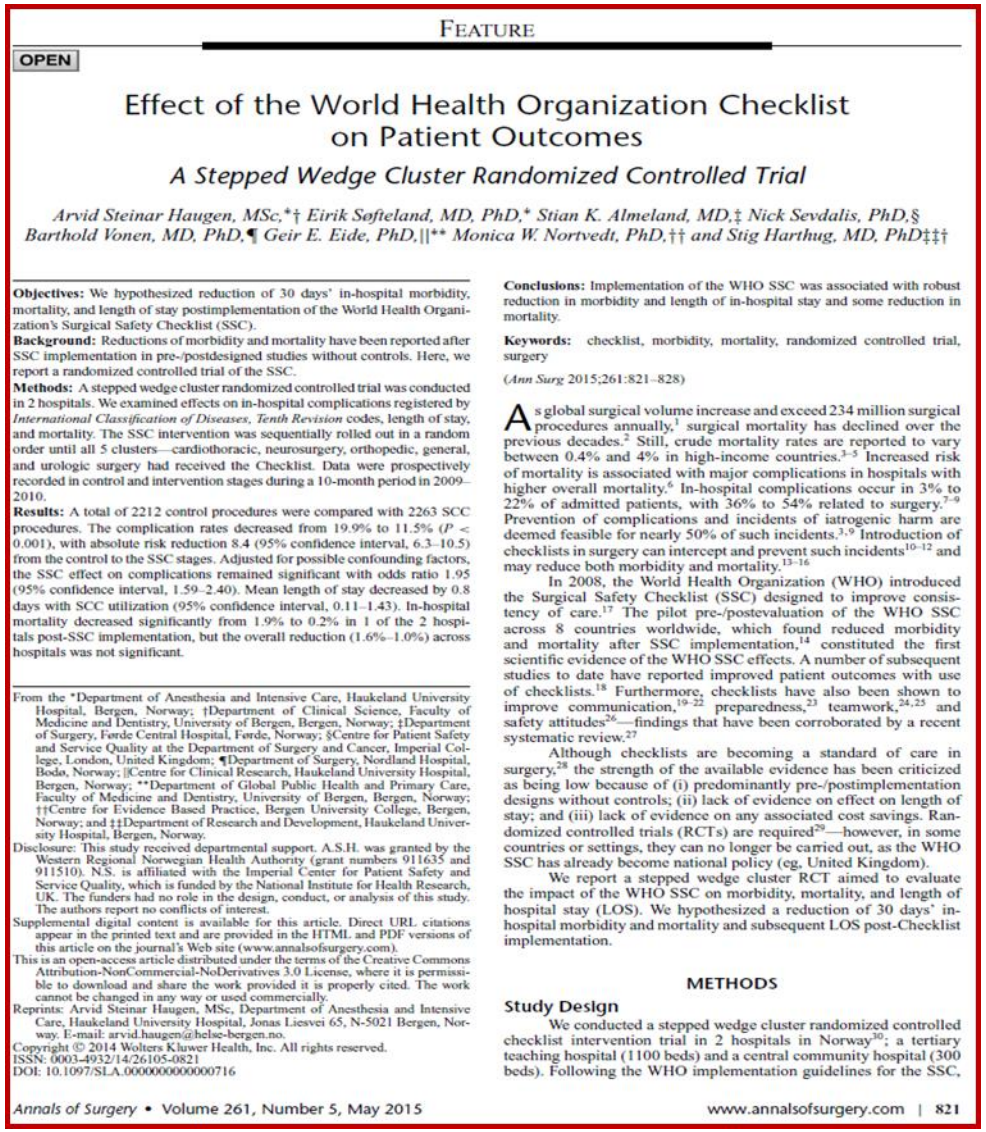
SPECIAL ARTICLE

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 complications reduced by **36%**
- Mortality decreased **47%**
- Postoperative infections decreased **48%**

First RCT published in 2015



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)

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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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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).

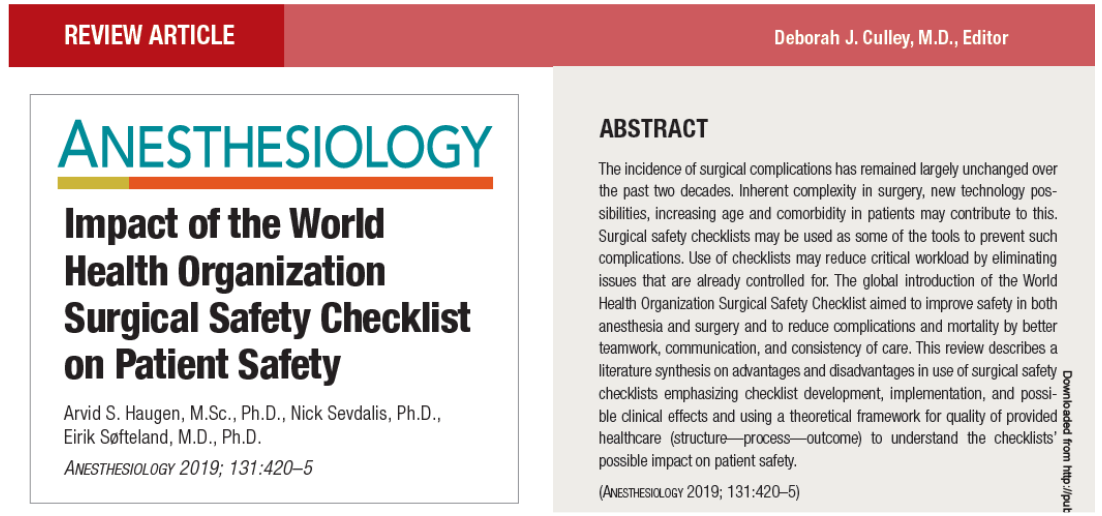
We report a stepped wedge cluster RCT aimed to evaluate the impact of the WHO SSC on morbidity, mortality, and length of hospital stay (LOS). We hypothesized a reduction of 30 days' in-hospital morbidity and mortality and subsequent LOS post-Checklist implementation.

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,

- Confirms beneficial effects:
- ✓Complications reduced **from 19.9% to 11.5%**
- ✓Length of hospital stay reduced by **0.8 days**
- ✓Mortality unaffected
- Numerous systematic reviews and meta-analyses followed



REVIEW ARTICLE

Deborah J. Culley, M.D., Editor

ANESTHESIOLOGY

Impact of the World Health Organization Surgical Safety Checklist on Patient Safety

Arvid S. Haugen, M.Sc., Ph.D., Nick Sevdalis, Ph.D., Eirik Søfteland, M.D., Ph.D.

ANESTHESIOLOGY 2019; 131:420–5

ABSTRACT

The incidence of surgical complications has remained largely unchanged over the past two decades. Inherent complexity in surgery, new technology possibilities, increasing age and comorbidity in patients may contribute to this. Surgical safety checklists may be used as some of the tools to prevent such complications. Use of checklists may reduce critical workload by eliminating issues that are already controlled for. The global introduction of the World Health Organization Surgical Safety Checklist aimed to improve safety in both anesthesia and surgery and to reduce complications and mortality by better teamwork, communication, and consistency of care. This review describes a literature synthesis on advantages and disadvantages in use of surgical safety checklists emphasizing checklist development, implementation, and possible clinical effects and using a theoretical framework for quality of provided healthcare (structure—process—outcome) to understand the checklists' possible impact on patient safety.

(ANESTHESIOLOGY 2019; 131:420–5)

Scaled implementation however…


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)	Post-checklist (N=106,370)
30-day mortality = 0.71%	30-day mortality = 0.65%
Complications risk = 3.86%	Complications risk = 3.82%

Clinician reviewer commented: "The likely reason for the failure…is that it was not actually used"

Implementation not always well designed

- Comments from staff interviewees in English hospitals:

✓ ***"It just appeared"***

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

✓ ***"It was something they were just doing one day"***

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

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, Jenny Mansell, MSc, Rachel Davies, BA, Charles Vincent, PhD, and Ara Darzi, MD, FACS

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Beyond checklists: Evidence not making it into practice…

Consistent failure to translate evidence into routine practice

- 50% of patients do not receive recommended care
- 30% of medical spending is on unnecessary care

Globally we spend over $200 billion on healthcare research and 85% of those research $$ are wasted because the research is never put into practice

Chalmers & Glasziou, *Lancet* 2009;374:86-9

…Or taking far too long to get there

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

Implementation science: intends to close the gap

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

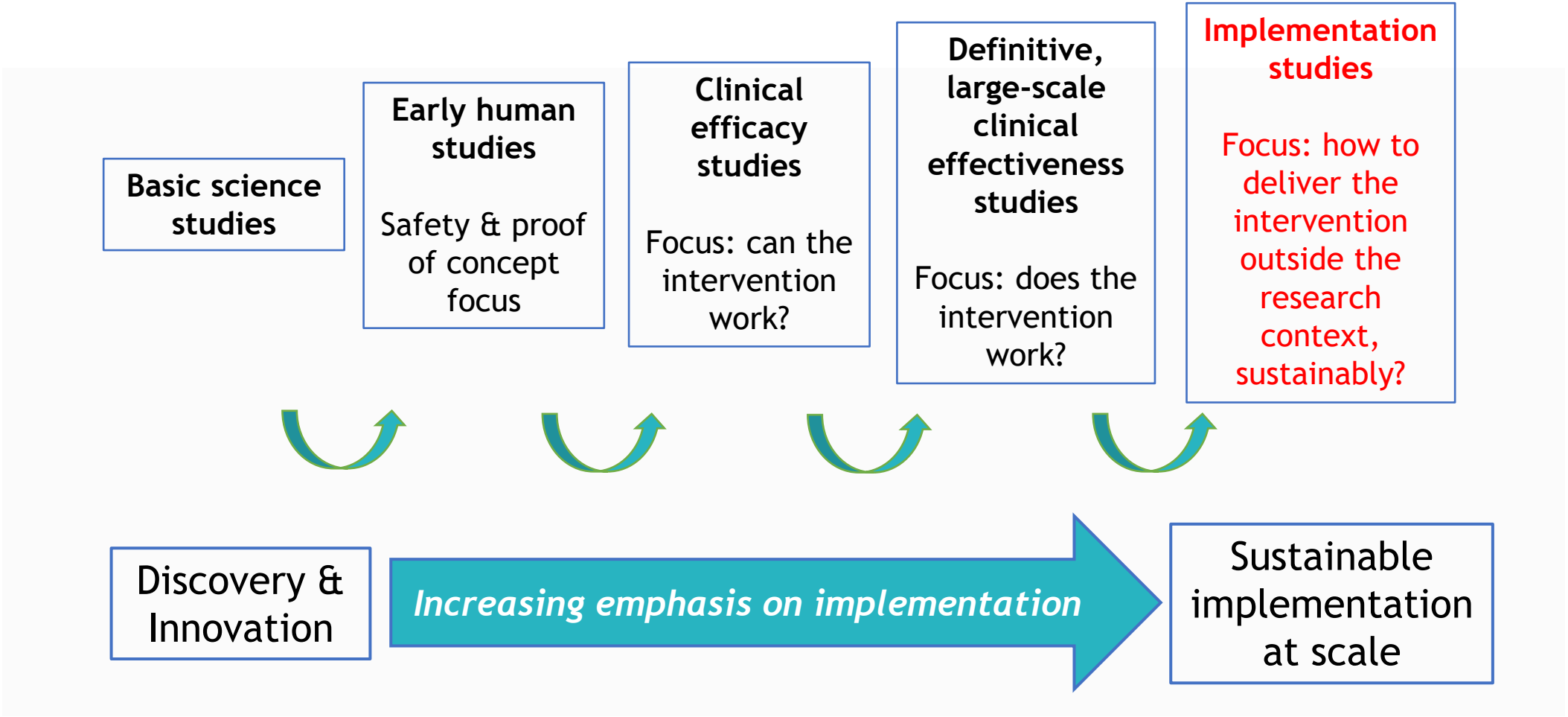
Implementation Science journal website

- 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

National Institutes of Health (USA), 2015

- Implementation requires **Behavioural Science**: the systematic study of understanding, predicting and influencing human behaviour – including in the context of health and healthcare delivery

Implementation Research within the 'Translational Continuum'



Peters et al, *Implementation Research in Health: A Practical Guide*. WHO, 2013.
Thornicroft et al, *Psychol Med* 2011;41:2015-21.

A few key concepts

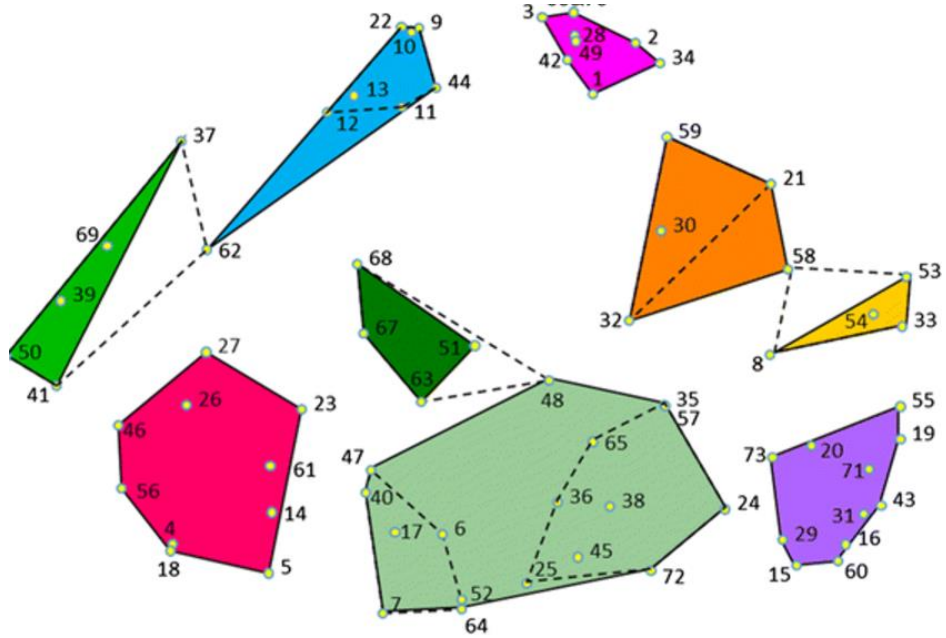
- **Implementation strategies**: Methods or techniques used to enhance the adoption, implementation, and sustainability of an clinical programme or intervention

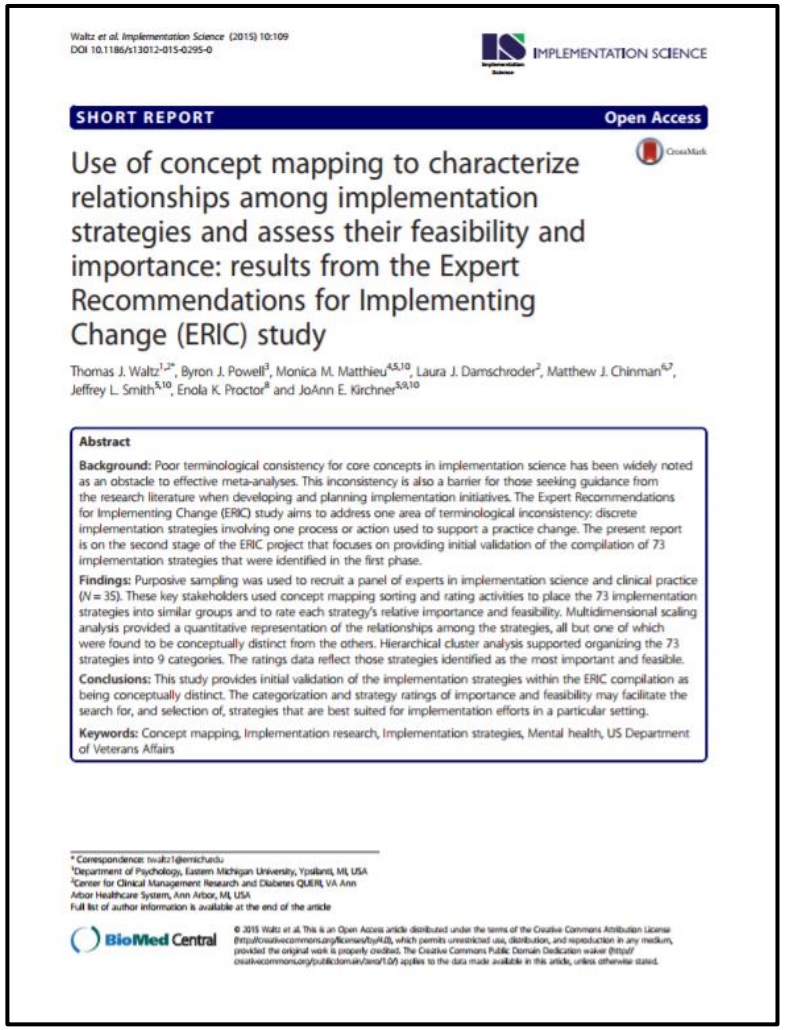
- **Implementation context**: Factors or attributes that are external to an intervention or programme and that facilitate or impede implementation efforts

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

Implementation strategies: state of the art

- Evidence review & expert consensus
- 73 strategies grouped into 9 thematic categories
- These are the interventions we are interested in





Waltz et al. Implementation Science (2015) 10:109
DOI 10.1186/s13012-015-0295-0

IMPLEMENTATION SCIENCE

SHORT REPORT Open Access

Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study

Thomas J. Waltz[1,2*], Byron J. Powell[3], Monica M. Matthieu[4,5,10], Laura J. Damschroder[2], Matthew J. Chinman[6,7], Jeffrey L. Smith[5,10], Enola K. Proctor[8] and JoAnn E. Kirchner[5,9,10]

Abstract

Background: Poor terminological consistency for core concepts in implementation science has been widely noted as an obstacle to effective meta-analyses. This inconsistency is also a barrier for those seeking guidance from the research literature when developing and planning implementation initiatives. The Expert Recommendations for Implementing Change (ERIC) study aims to address one area of terminological inconsistency: discrete implementation strategies involving one process or action used to support a practice change. The present report is on the second stage of the ERIC project that focuses on providing initial validation of the compilation of 73 implementation strategies that were identified in the first phase.

Findings: Purposive sampling was used to recruit a panel of experts in implementation science and clinical practice ($N = 35$). These key stakeholders used concept mapping sorting and rating activities to place the 73 implementation strategies into similar groups and to rate each strategy's relative importance and feasibility. Multidimensional scaling analysis provided a quantitative representation of the relationships among the strategies, all but one of which were found to be conceptually distinct from the others. Hierarchical cluster analysis supported organizing the 73 strategies into 9 categories. The ratings data reflect those strategies identified as the most important and feasible.

Conclusions: This study provides initial validation of the implementation strategies within the ERIC compilation as being conceptually distinct. The categorization and strategy ratings of importance and feasibility may facilitate the search for, and selection of, strategies that are best suited for implementation efforts in a particular setting.

Keywords: Concept mapping, Implementation research, Implementation strategies, Mental health, US Department of Veterans Affairs

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Waltz et al, *Implement Sci* 2015;10:109

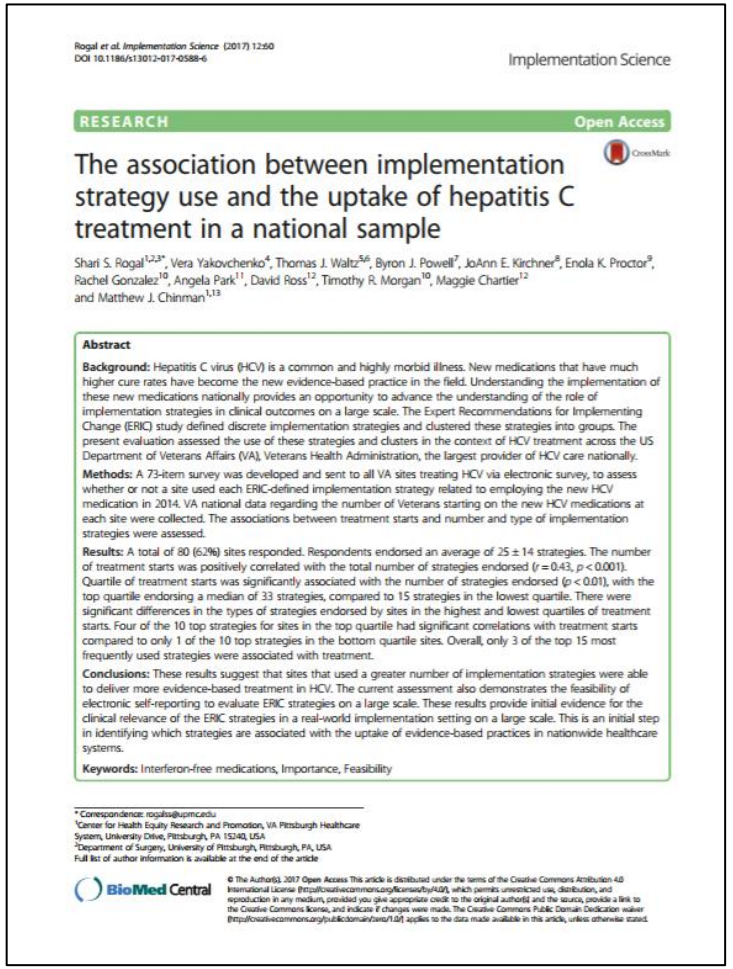
How many strategies are needed to optimize uptake of a treatment?

Methods

- 73-item survey sent to all Veterans Affairs sites treating Hep C to assess whether or not a site used each one of the strategies
- Assessed associations between treatment starts and number of implementation strategies used

Results

- Between 1 and 59 strategies used (average: **25 ± 14**)
- Number of treatment starts correlated with total number of strategies used (**r=0.43**, p<0.001)



Rogal et al. Implementation Science (2017) 12:60
DOI 10.1186/s13012-017-0588-6

Implementation Science

RESEARCH Open Access

The association between implementation strategy use and the uptake of hepatitis C treatment in a national sample

Shari S. Rogal[1,2,3*], Vera Yakovchenko[4], Thomas J. Waltz[5,6], Byron J. Powell[7], JoAnn E. Kirchner[8], Enola K. Proctor[9], Rachel Gonzalez[10], Angela Park[11], David Ross[12], Timothy R. Morgan[10], Maggie Chartier[12] and Matthew J. Chinman[1,13]

Abstract

Background: Hepatitis C virus (HCV) is a common and highly morbid illness. New medications that have much higher cure rates have become the new evidence-based practice in the field. Understanding the implementation of these new medications nationally provides an opportunity to advance the understanding of the role of implementation strategies in clinical outcomes on a large scale. The Expert Recommendations for Implementing Change (ERIC) study defined discrete implementation strategies and clustered these strategies into groups. The present evaluation assessed the use of these strategies and clusters in the context of HCV treatment across the US Department of Veterans Affairs (VA), Veterans Health Administration, the largest provider of HCV care nationally.

Methods: A 73-item survey was developed and sent to all VA sites treating HCV via electronic survey, to assess whether or not a site used each ERIC-defined implementation strategy related to employing the new HCV medication in 2014. VA national data regarding the number of Veterans starting on the new HCV medications at each site were collected. The associations between treatment starts and number and type of implementation strategies were assessed.

Results: A total of 80 (62%) sites responded. Respondents endorsed an average of 25 ± 14 strategies. The number of treatment starts was positively correlated with the total number of strategies endorsed ($r = 0.43$, $p < 0.001$). Quartile of treatment starts was significantly associated with the number of strategies endorsed ($p < 0.01$), with the top quartile endorsing a median of 33 strategies, compared to 15 strategies in the lowest quartile. There were significant differences in the types of strategies endorsed by sites in the highest and lowest quartiles of treatment starts. Four of the 10 top strategies for sites in the top quartile had significant correlations with treatment starts compared to only 1 of the 10 top strategies in the bottom quartile sites. Overall, only 3 of the top 15 most frequently used strategies were associated with treatment.

Conclusions: These results suggest that sites that used a greater number of implementation strategies were able to deliver more evidence-based treatment in HCV. The current assessment also demonstrates the feasibility of electronic self-reporting to evaluate ERIC strategies on a large scale. These results provide initial evidence for the clinical relevance of the ERIC strategies in a real-world implementation setting on a large scale. This is an initial step in identifying which strategies are associated with the uptake of evidence-based practices in nationwide healthcare systems.

Keywords: Interferon-free medications, Importance, Feasibility

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The type of evidence we produce and apply: What strategies are effective for provider behaviour change?

Meta-analyses	Number of studies/individuals	Effect sizes
Printed educational materials (35)	14 RCTs and 31 ITS	Median absolute improvement of 2.0% (range 0% to 11%)
Educational meetings (31)	81 RCTs (involving more than 11,000 health professionals)	Median absolute improvement in care of 6.0% (interquartile range 1.8% to 15.3%)
Educational outreach (36)	69 RCTs (involving more than 15,000 health professionals)	Median absolute improvements in: -Prescribing behaviors [17 comparisons] of 4.8% (interquartile range 3.0–6.5%) -Other behaviors (e.g., providing screening tests; 17 comparisons) of 6.0% (interquartile range 3.6–16.0%)
Local opinion leaders (33)	18 RCTs (involving more than 296 hospitals and 318 primary care physicians)	Median absolute improvement of care of 12% across studies (interquartile range 6.0–14.5%)
Audit and feedback (9)	140 RCTs	Median absolute improvement of 4.3% (interquartile range 0.5–16%)
Computerized reminders (8)	28 RCTs	Median absolute improvement of care 4.2% (interquartile range 0.8–18.8%)
Tailored implementation strategies (37)	32 RCTs	Meta-regression using 15 randomized trials. Pooled odds ratio of 1.56 (95% CI, 1.27–1.93, $p < 0.001$)

Table updated from Grimshaw et al. (34), and draws upon Cochrane Reviews from the Effective Practice and Organization of Care (EPOC) group (38).

The type of evidence we produce and apply: What strategies are effective for provider behaviour change?

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Audit and feedback (9)	140 RCTs	5–16%)
Computerized reminders (8)	28 RCTs	ange
Tailored implementation strategies (37)	32 RCTs	trials: pooled odds ratio of 1.56

Table updated from Grimshaw et al. (34), and draws upon Cochrane Re m the Effective Practice and Organization of Care (EPOC) group (38).

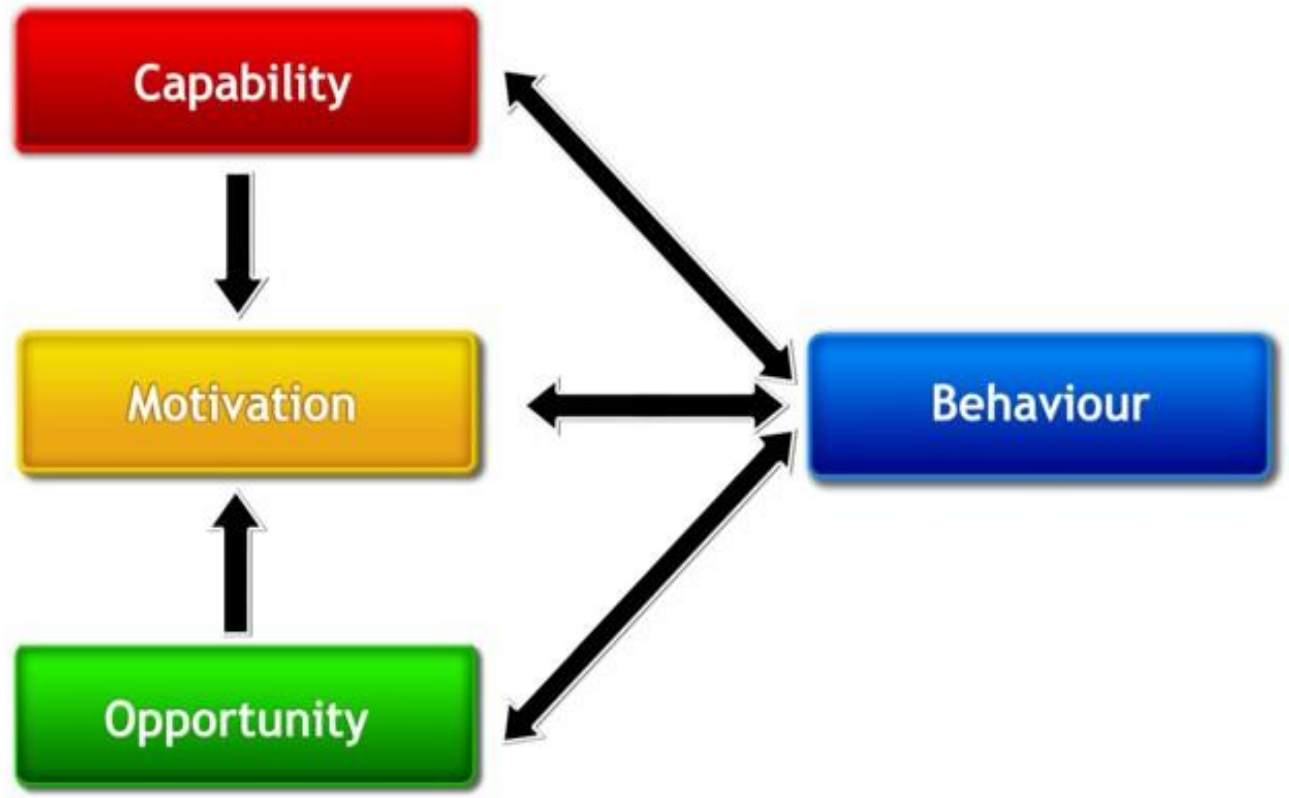
OK, BUT:

- **These strategies seem complex and are likely costly too**
- **How do you select what strategies to apply…?**
- **You use a <u>theory</u> to help you analyse the <u>context</u> of your implementation and work out the <u>barriers</u>**

Sample theory, behaviour change: COM-B

Individual:
Skills and resources
(money, time, information, support)

Interaction of individual and environmental factors : preferences/values, perceptions of risk/reward and decision process



Environmental: Physical, financial and social enablers

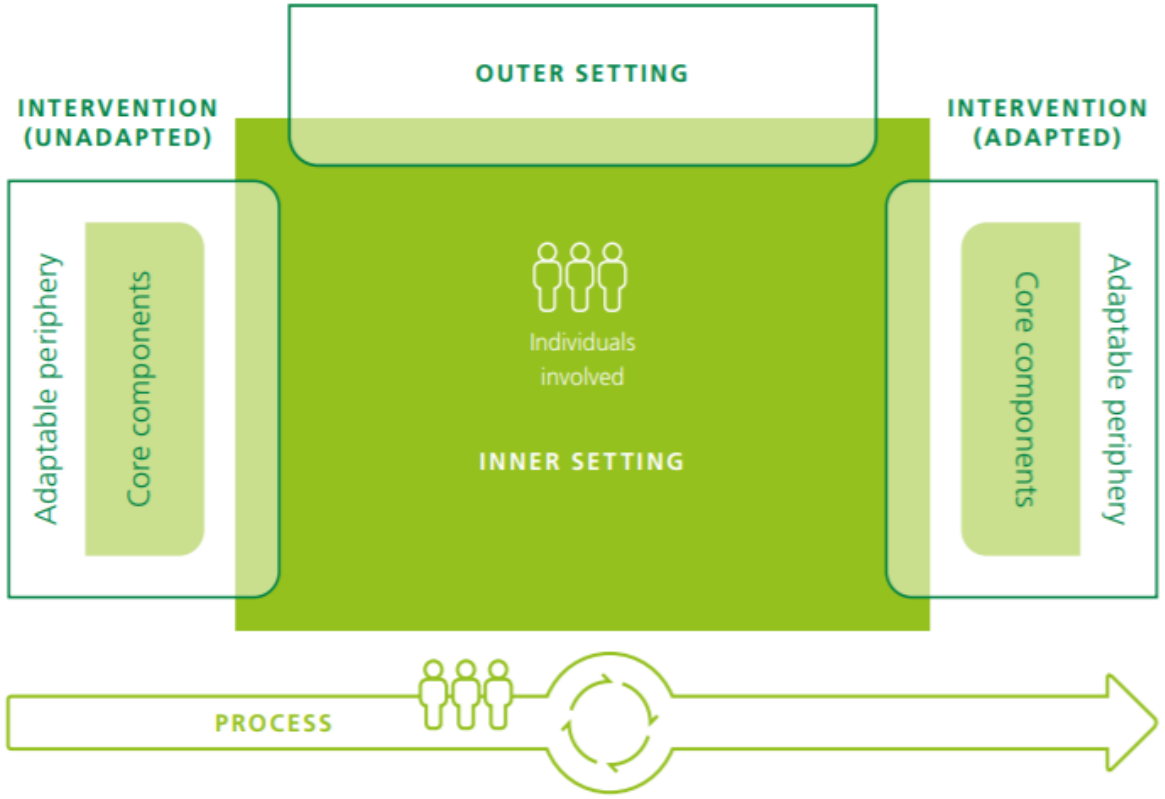
Michie et al, *Implement Sci* 2011;6:42

Sample theory: barriers & drivers to implementation

Barriers/drivers will relate to…

1. Intervention characteristics
   (what you're trying to implement, its evidence, its format, etc)
2. Local setting
   (your hospital or service)
3. Wider setting
   (national/regional healthcare system)
4. Individuals involved
5. Process of implementation

Consolidated Framework for Implementation Research

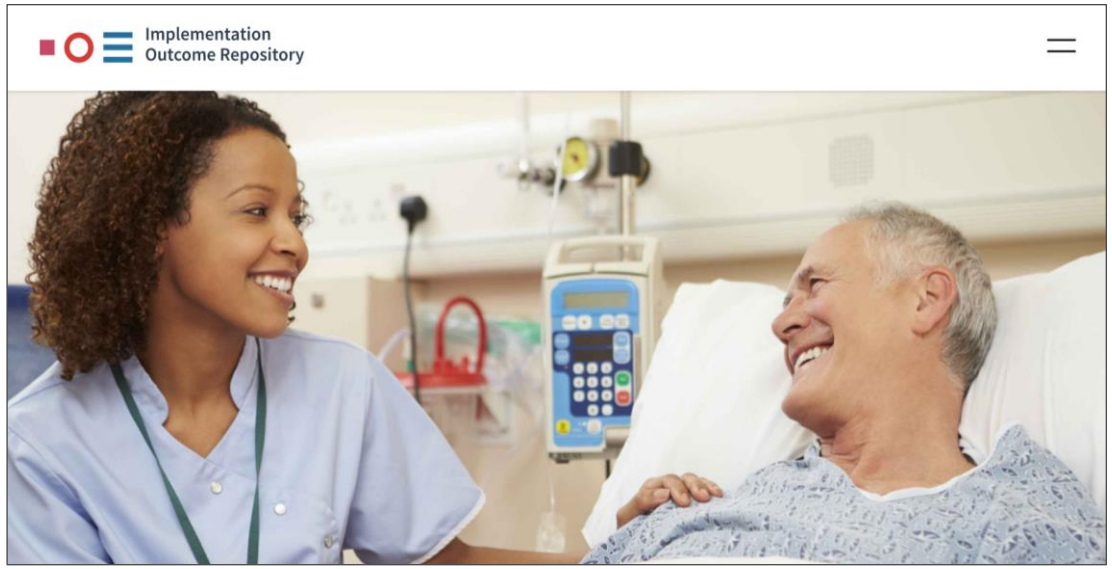


Damschroder et al, *Implement Sci* 2009;7:50

What outcomes allow us to evaluate implementation?

Implementation Outcomes: Current state of the art

- Acceptability
- Feasibility
- Appropriateness
- Adoption
- Fidelity
- Costs of implementation
- Penetration/Reach
- Sustainability

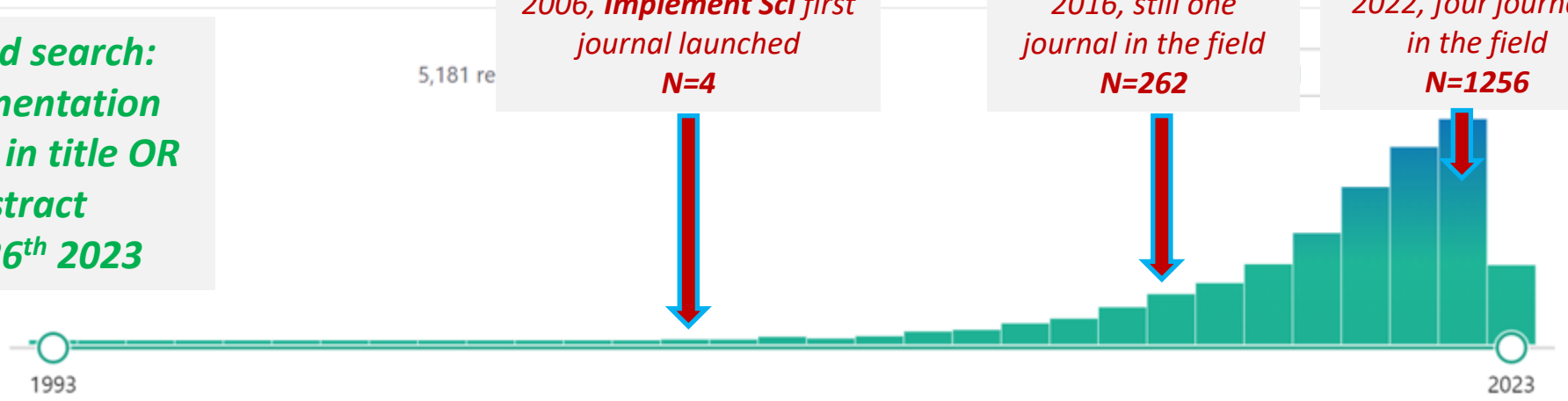


www.implementationoutcomerepository.org

Khadjesari et al, *Implement Sci*, 2020;15:66

Expansive science, that works!

PubMed search: 'Implementation Science', in title OR abstract
April 26th 2023



*2006, **Implement Sci** first journal launched*
N=4

2016, still one journal in the field
N=262

2022, four journals in the field
N=1256

Implementation Science

Implementation Science Communications

Frontiers in Health Services – Implementation Science section

Implementation Research & Practice

Expansive science, that works!

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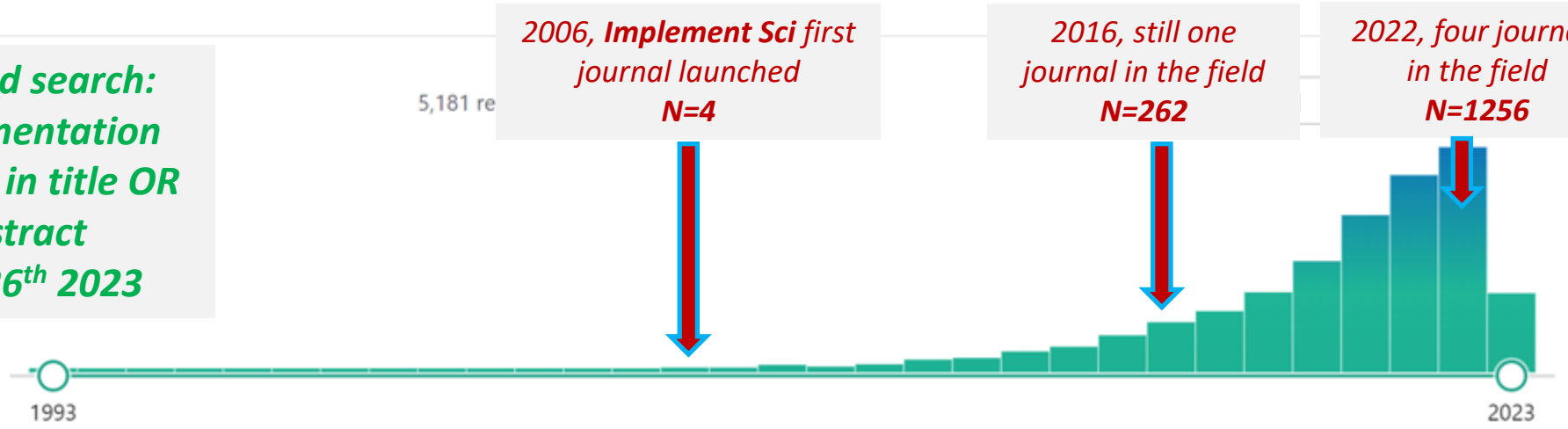


*2006, **Implement Sci** first journal launched* ***N=4***

2016, still one journal in the field ***N=262***

2022, four journals in the field ***N=1256***

Implementation Science

Implementation Science Communications

Frontiers in Health Services – Implementation Science section

Implementation Research & Practice

- Case studies of successful scale up/sustainability in chronic disease management, integrating depression care into primary health services, HIV prevention, patient safety checklists in ICU, community-based diabetes prevention programmes

- I revisit some of these areas in the afternoon session in the Advancing Population Health stream!

JGIM

PERSPECTIVE

What Can Implementation Science Do for You? Key Success Stories from the Field

Check for updates

Amy M. Kilbourne, PhD, MPH[1,2], Russell E. Glasgow, PhD[3,4], and David A. Chambers, DPhil[5]

[1]Quality Enhancement Research Initiative (QUERI), Health Services Research and Development, Veterans Health Administration, US Department of Veterans Affairs, Washington, DC, USA; [2]Department of Learning Health Sciences, University of Michigan Medical School, Ann Arbor, MI, USA; [3]University of Colorado Anschutz Medical Campus, Aurora, CO, USA; [4]ACCORDS Dissemination and Implementation Science Program, Aurora, CO, USA; [5]Division of Cancer Control and Population Sciences, National Cancer Institute, Bethesda, MD, USA.

J Gen Intern Med 35(Suppl 2):S783–S7
DOI: 10.1007/s11606-020-06174-6

Our goal was to identify key examples (see Table 1) from

Lilbourne et al, *J Gen Intern Med* 2020;35(Suppl 2):783-7

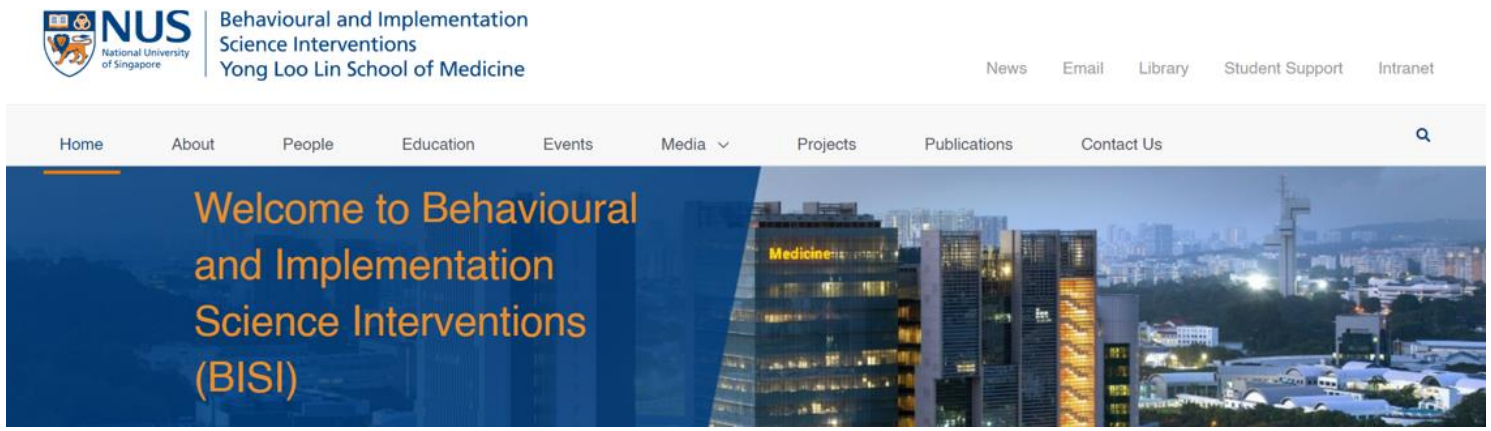
A summary and a vision

- Implementation and behavioural sciences focus on **understanding barriers/drivers** to evidence uptake and **addressing them**

- In the past 15 years, there has been in health and healthcare interventions **a surge in research on assessing implementation processes**

- **BISI** aims to work collaboratively with you to address questions such as:
  - Can we design **RCTs that include implementation elements** – so as to accelerate the process of research translation?
  - **How applicable are theories about individual and organisational behaviour** developed in the West for use in Asian settings?
  - What is the **internal and external validity of implementation measurement** scales with Asian participants and settings?

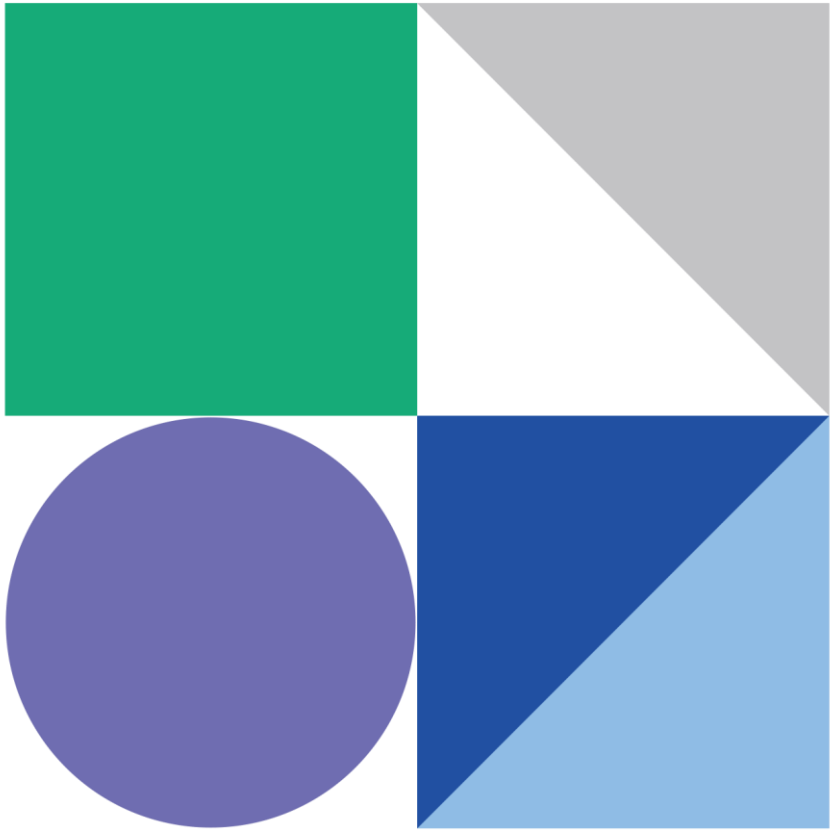
- We wish to offer **an intellectual home** and support **a network of experts** in these phenomena to address questions of scaled implementation of population health and clinical interventions – **in Singapore and beyond**



Evidence and Implementation Summit 2023

9–11 October

Melbourne, Australia | Online



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Thank you

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