Implementation research in patient safety: The next frontier for improving patient care?

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Centre for Implementation Science at the NIHR CLAHRC South London, including King’s Improvement Science
Novel, hybrid sciences

Patient Safety Science
Scientific approach to the prevention, avoidance and amelioration of adverse outcomes or injuries to patients stemming from the healthcare process

Implementation Science
Scientific study of methods to promote the uptake of research findings into routine healthcare in clinical, organisational or policy contexts

...20 years

...10 years
Do we have a problem? If yes, how big?
1 in 10 hospital inpatients suffers an adverse event whilst in hospital
What’s causing it?

Vincent et al, BMJ 1998;316:1154

Developing understanding & theory

- Latent risks
- Small errors or problems that accumulate
- Not all adverse events are the results of human errors; not all human errors lead to adverse events
- ‘High reliability’ organisations
- ‘Work as imagined vs. as done’
- Safety I vs. Safety II

Etc etc…

Table 1: Latent risk factors

<table>
<thead>
<tr>
<th>Latent risk factors</th>
<th>Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment, design, and maintenance</td>
<td>Availability, functioning, standardization design, and maintenance of machines</td>
</tr>
<tr>
<td>Staffing</td>
<td>Adequate staffing, skills</td>
</tr>
<tr>
<td>Communication</td>
<td>Work-directed communication, openness, interrelation, atmosphere</td>
</tr>
<tr>
<td>Training</td>
<td>Training for machines, procedures, team training</td>
</tr>
<tr>
<td>Teamwork and team training</td>
<td>Team performance</td>
</tr>
<tr>
<td>Procedures</td>
<td>Presence of protocols, adherence to protocols</td>
</tr>
<tr>
<td>Situational awareness</td>
<td>Awareness of present situation, own tasks, and future developments</td>
</tr>
<tr>
<td>Incompatible goals</td>
<td>Balance between goals and safety Process of care</td>
</tr>
<tr>
<td>Planning and organization</td>
<td></td>
</tr>
<tr>
<td>Housekeeping</td>
<td>Hygiene</td>
</tr>
</tbody>
</table>

What can we do to address it?

STRONGLY ENCOURAGED INTERVENTIONS:

• Preop & anaesthesia checklists
• Bundles to prevent CLABSI
• Interventions to reduce use of urinary catheters
• Bundles to prevent ventilator associated pneumonia
• Hand hygiene
• ‘Do Not Use’ list of risky abbreviations
• Bundles to reduce pressure ulcers
• Real time US for central line placement
• VTE prophylaxis
Surgical Safety Checklist

Before induction of anaesthesia
(with at least nurse and anaesthetist)
- Has the patient confirmed his/her identity, site, procedure, and consent?
  - Yes
  - Not applicable
- 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.
The first study (2009)

- Major complication rate decreased 36%
- Mortality decreased 47%
- Post-op infection decreased 48%
Within weeks of the publication in England...

- National policy
- All hospitals were asked to implement the checklist within 12 months
- Rate of implementation to be checked via audits and reported by risk-managers
- Hospitals + specialities urged to adapt it to their needs
Further RCT evidence
Largest study to date (2014)

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%
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%

“The likely reason for the failure... is that it was not actually used”

Largest study to date (2014)
Large variations in checklist use

<table>
<thead>
<tr>
<th>Category</th>
<th>One of 5 Trusts</th>
<th>5 Trust average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of time-out in seconds</td>
<td>80 secs</td>
<td>64 secs</td>
</tr>
<tr>
<td>% of Checklist items covered</td>
<td>58%</td>
<td>67%</td>
</tr>
<tr>
<td>% cases all team members present</td>
<td>37%</td>
<td>65%</td>
</tr>
<tr>
<td>% cases with introductions</td>
<td>23%</td>
<td>34%</td>
</tr>
<tr>
<td>% cases all team members paused</td>
<td>19%</td>
<td>30%</td>
</tr>
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</table>
Some poor local implementation

“It just appeared…”

“Our chief exec had a bee in their bonnet and it was ‘no you will do this’…”

“It was sth they were just doing one day”

“There was no discussion or introduction or anything. Typical.”
Behavioural causes of surgical never events

Root Causes of Wrong Site Surgery
(2005)

- Communication
- Orientation/training
- Patient assessment
- Staffing
- Availability of info
- Competency/credentialing
- Procedural compliance
- Environ. safety / security
- Leadership
- Continuum of care
- Care planning
- Organization culture

Intervention: skills training + coaching + standardisation – do we do this routinely…?

### Association Between Implementation of a Medical Team Training Program and Surgical Mortality

<table>
<thead>
<tr>
<th>Author</th>
<th>Position</th>
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<tr>
<td>Julia Neily, RN, MS, MPH</td>
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<tr>
<td>Peter D. Mills, PhD, MS</td>
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<tr>
<td>Yinong Young-Xu, ScD, MA, MS</td>
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<tr>
<td>Brian T. Carney, MD</td>
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<tr>
<td>Priscilla West, MPH</td>
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<tr>
<td>David H. Berger, MD, MHCM</td>
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<tr>
<td>Lisa M. Mazzio, MD</td>
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<tr>
<td>Douglas E. Paull, MD</td>
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<tr>
<td>James P. Bagian, MD, PE</td>
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**Context**: There is insufficient information about the effectiveness of medical team training on surgical outcomes. The Veterans Health Administration (VHA) implemented a formalized medical team training program for operating room personnel on a national level.

**Objective**: To determine whether an association existed between the VHA Medical Team Training program and surgical outcomes.

**Design, Setting, and Participants**: A retrospective health services study with a contemporaneous control group was conducted. Outcome data were obtained from the VHA Surgical Quality Improvement Program (VASQIP) and from structured interviews in fiscal years 2006 to 2008. The analysis included 182,409 sampled procedures from 108 VHA facilities that provided care to veterans. The VHA's nationwide

18% decrease in observed mortality (vs 7% in controls)

(2006-08; 74 vs 34 VA hospitals; N=182,409)

**Substantial training programme**

- 2 months preparation
- Capacity development: 1 day on-site team training session – incl skills, telephone coaching/F-UP for 1 year

October 2010
CONCLUSIONS

1. Cost-effectiveness studies
2. Clinical outcome studies
3. Scaled implementation of evidenced interventions

Some food for thought

- Patient safety science is yet to achieve its full potential impact
- This is partly because the science is yet to move from efficacy to effectiveness studies

Safety intervention efficacy:
Can a patient safety intervention work?

Safety intervention effectiveness:
Does a patient safety intervention work?
Two parallel universes?

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

**Health services**
- Intention to achieve sustainable delivery
- Widespread adoption
- Generalist practitioners, often no further training, no ad hoc measurement
- Service delivery funds (limited)
From evidence to practice
From evidence to practice

“Across most domains in medicine, practice has lagged behind knowledge by at least several years”

David Bates et al, 2003; JAMIA
Time lag between research and practice

17 YEARS

It may have worked in a RCT, but here’s the tricky question….

**Does a patient safety intervention actually work for me, at my hospital, with my staff & my patients…?**
Dissecting effectiveness (i)

Does an intervention actually work...?

Intervention as designed by the researcher vs. as delivered in practice

Fidelity vs. adaptation tension
Does an intervention actually work…?

Patient safety = ‘complex interventions’
Dissecting effectiveness (iii)

Does an intervention actually work...?

For WHOM, HOW EXACTLY, in what CONTEXTS, with what UNINTENDED CONSEQUENCES?
Key point: effectiveness ≠ efficacy

Does an intervention actually work...?

- Intervention as designed by the researcher vs. as delivered in practice
  - Fidelity vs. adaptation tension

- Multiple intervention components
  - Patient safety = ‘complex interventions’

- For WHOM, HOW EXACTLY, in what CONTEXTS, with what UNINTENDED CONSEQUENCES?
Example: Fidelity tensions in the ‘real’ world

With high fidelity

As intended
To ensure effect & causal attribution

Training intervention implementation

Adapted to need
As applicable
To ensure sustainability

Developers & evaluators
Implementors

LOST in TRANSLATION
Implementation science 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
New-ish science, gathering pace
‘Hybrid’ randomised trial (and other) designs

<table>
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<th>Implementation outcome</th>
<th>Definition</th>
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<tr>
<td>Acceptability</td>
<td>Perception amongst stakeholders new intervention is agreeable</td>
</tr>
<tr>
<td>Adoption</td>
<td>Intention to apply or application of new intervention</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Perceived relevance of intervention to a setting, audience, or problem</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Extent to which an intervention can be applied</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Extent to which an intervention gets applied as originally designed / intended</td>
</tr>
<tr>
<td>Implementation costs</td>
<td>Costs of the delivery strategy, including the costs of the intervention itself</td>
</tr>
<tr>
<td>Coverage</td>
<td>Extend to which eligible patients/population actually receive intervention</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Extent to which a new intervention becomes routinely available / is maintained post-introduction</td>
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Example: Hybrid II design: T1 diabetes RCT

### HARPdoc sample measures (1-5 scales)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acceptability</strong></td>
<td></td>
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</tbody>
</table>
| How far do you agree that the HARPdoc course is acceptable (agreeable and satisfactory) in helping you manage hypoglycaemia? | 1. HARPdoc meets my approval  
                             2. HARPdoc is appealing to me  
                             3. I like HARPdoc  
                             4. I welcome HARPdoc |
| **Appropriateness**|                                                         |
| How far do you agree that the HARPdoc course is appropriate (relevant, fit or compatible) in helping you manage hypoglycaemia? | 1. HARPdoc seems fitting  
                             2. HARPdoc seems suitable  
                             3. HARPdoc seems applicable  
                             4. HARPdoc seems like a good match |
| **Feasibility**   |                                                         |
| How far do you agree that the HARPdoc course is feasible (can be successfully used or carried out) in helping you manage hypoglycaemia? | 1. HARPdoc seems implementable  
                             2. HARPdoc seems possible  
                             3. HARPdoc seems doable  
                             4. HARPdoc seems easy to use |
Example: Hybrid III design: WHO checklist implementation in Benin

- **Theory**: Consolidated Framework for Implementation Research (CFIR)
- **Intervention**: tailored 3 day MDT training; adapted from Madagascar
- **Timeline**: longitudinal, Jan 2016 to May 2018; evaluation 3M and 12-18M post-intervention
- **Sites & context**: 36 hospitals trained; 17 part of the evaluation
- **Outcomes**: implementation outcomes, WHOBARS (behavioural fidelity), safety surveys and focus groups (qualitative assessment) – no patient level outcomes
- **Stakeholders**: from MoH to frontline providers
- **Summary findings**:
  1. WHO checklist implementation can be improved
  2. The improvement is sustainable over time
  3. Scalable implementation strategy (across countries)
  4. CFIR offers a practical evaluation framework

White et al. *BMJ Global Health* 2018;3(6):e001104
• Development & validation of innovative research design guideline

• To facilitate implementation aspects within applied health research

Hull et al. Implement Sci 2019;under review

Implementation methodology research
Implementation science research development (ImpRes) tool

A practical guide to using the ImpRes tool

Version 1.1
December 2018

Available here: www.kingsimprovementscience.org
4th Global Ministerial Patient Safety Summit

To reduce the 2nd Translational Gap by supporting implementation and sustainable scale-up of patient safety interventions of known efficacy/effectiveness at national and global level

Declaration point 11

Jeddah, March 3rd 2019
Reflections – for discussion

- Producing more ‘can work’ research in patient safety is not an efficient investment; **focus on ‘does work’ research** instead.

- Clinical research is discovering **implementation science to embed evidenced interventions** – patient safety research needs to follow.

- **Implementation parameters need to become primary outcomes** of safety intervention evaluations
  - Fidelity, acceptability, cost and context assessment, etc.

- Significant opportunities for **collaborative work** at the interface of patient safety and implementation sciences!
Join us on July 16\textsuperscript{th} – 18\textsuperscript{th} 2019!

Implementation Science Masterclass 2019

- What is implementation science?
- How can implementation science help ensure services offer the best treatment and care, informed by the latest research?
- What is the best way to plan an effective implementation science project?

This two-day course is for health professionals, researchers, patients and service users, policymakers, commissioners and managers in both the public and private sector who want to ensure clinical practice is evidence-based. The Masterclass includes lectures, group work and guidance to help participants work more effectively on their own implementation projects.

What previous Masterclass delegates said:

- ‘I appreciated the international perspectives of the faculty’
- ‘Exceeded my expectations. Very thorough work. Lots of resources and tips. Excellent!’
- ‘The course reinforced concepts I was familiar with and stretched my thinking about challenges and questions to be answered’
- ‘Clearly key experts in the field; a very impressive panel. Thanks’
- ‘I have come away with lots of ideas and plans and resources to further my implementation science work’

Save the date:
2\textsuperscript{nd} UK annual Implementation Science Research Conference

Thursday 18 July 2019
King’s College London, Denmark Hill Campus

Advancing the science of scaling up

2\textsuperscript{nd} UK Implementation Science Research Conference

Thursday 18 July, King’s College London, Denmark Hill Campus

This one-day annual conference will showcase the latest research in the field of implementation science applied to health and social care. Now in its second year, the 2019 conference will explore the theme: Advancing the science of scaling up: Improving efficiency and effectiveness of implementation strategies in healthcare.

Join applied health researchers, policymakers, clinicians and service user researchers to share how best to implement evidence-based practice and clinical research within health services and systems to improve health outcomes.

The conference will feature presentations from leading international researchers working in the field, oral and poster presentations, and parallel sessions.

The conference is being organised by the Centre for Implementation Science at NIHR CLAHRC South London, a research organisation working to improve health services. It is supported by the UK Implementation Society (UKIS), an independent organisation connecting those working in implementation science, practice and policy.

Call for abstracts:
We welcome submissions from researchers, policymakers, clinicians and service user researchers for an oral or poster presentation. The deadline for abstract submission is: Monday 15 April 2019.

Download the abstract submission form and guidance at www.clahrc-southlondon.nihr.ac.uk/events/2019/implementation-science-research-conference

Cost:
£124.50 (until 1 April 2019). £150 thereafter. Discounts available for NIHR staff working in CLAHRC South London-affiliated organisations / UKIS members / charity and NGC staff / service users, students, and those from low- and middle-income countries.

Register and find out more:
www.clahrc-southlondon.nihr.ac.uk/events/2019/implementation-science-research-conference

If you have any questions, please email clahrcshortcourses@kcl.ac.uk

Find out more about CLAHRC South London
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THANK YOU!