INCREASING VALUE AND REDUCING WASTE IN IMPLEMENTATION RESEARCH

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POP QUIZ 1

How much money did Canada spend on R&D in 2013?

a. >$5 billion
b. $5-10 billion
c. $10-20 billion
d. $20-30 billion
e. >$30 billion
POP QUIZ 1

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a. >$5 billion
b. $5-10 billion
c. $10-20 billion
d. $20-30 billion
   (incl $9.1 billion government funding)
e. >$30 billion

(Source: OECD)
In 2009, Chalmers and Glasziou .... estimated that about 85% of research investment—equating to $200 billion of the investment in 2010—is wasted.

Macleod (2014) Lancet
WASTE IN RESEARCH

Are research decisions based on questions relevant to users of research?

- Low priority questions addressed
- Important outcomes not assessed
- More than 50% studies designed without reference to systematic reviews of existing evidence

Appropriate research design, methods, and analysis?

- Adequate steps to reduce bias not taken in more than 50% of studies
- Inadequate statistical power
- Inadequate replication of initial findings

Efficient research regulation and management?

- Complicit with other sources of waste and inefficiency
- Disproportionate to the risks of research
- Regulatory and management processes are burdensome and inconsistent

Fully accessible research information?

- More than 50% of studies never fully reported
- Biased under-reporting of studies with disappointing results
- Biased reporting of data within studies

Unbiased and usable research reports?

- More than 30% of trial interventions not sufficiently described
- More than 50% of planned study outcomes not reported
- Most new research not interpreted in the context of systematic assessment of other relevant evidence

Research waste

Figure: Avoidable waste or inefficiency in biomedical research

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IMPLEMENTATION SCIENCE

- Implementation is a human enterprise that can be studied to understand and improve implementation approaches.

- Implementation science is the scientific study of the determinants, processes and outcomes of implementation.

- Goal is to develop a generalisable empirical and theoretical basis to optimise implementation activities.
POP QUIZ 2

- Research waste in implementation science is:
  - Worse than other areas of health research
  - The same as other areas
  - Better than other areas
  - Don’t know
CURRENT STATE OF IMPLEMENTATION SCIENCE

AUDIT AND FEEDBACK

- Cochrane 2012 review – 140 trials of audit and feedback, median absolute improvement +4%, interquartile range +1% to +16%
- Larger effects were seen if:
  - baseline compliance was low.
  - the source was a supervisor or colleague
  - it was provided more than once
  - it was delivered in both verbal and written formats
  - it included both explicit targets and an action plan

Ivers (2012) Cochrane Library
CURRENT STATE OF IMPLEMENTATION SCIENCE

Cumulative analysis – effect size of audit and feedback interventions over time

CURRENT STATE OF IMPLEMENTATION SCIENCE

Growing Literature, Stagnant Science? Systematic Review, Meta-Regression and Cumulative Analysis of Audit and Feedback Interventions in Health Care

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BACKGROUND: This paper extends the findings of the Cochrane systematic review of audit and feedback on professional practice to explore the estimate of effect over time and examine whether new trials have added to knowledge regarding how optimize the effectiveness of audit and feedback.

METHODS: We searched the Cochrane Central Register of Controlled Trials, MEDLINE, and EMBASE for randomized trials of audit and feedback compared to usual care, with objectively measured outcomes assessing compliance with intended professional practice. Two reviewers independently screened articles and abstracted variables related to the intervention, the context, and trial methodology. The median absolute risk difference in compliance with intended professional practice was determined for each study, and adjusted for baseline performance. The effect size across studies was

DISCUSSION: There is substantial evidence that audit and feedback can effectively improve quality of care, but little evidence of progress in the field. There are opportunity costs for patients, providers, and health care systems when investigators test quality improvement interventions that do not build upon, or contribute toward, extant knowledge.

KEY WORDS: audit and feedback; scientific progress; quality improvement; systematic review; cumulative analysis.

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Figure: Avoidable waste or inefficiency in biomedical research

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ARE RESEARCH QUESTIONS BASED ON QUESTIONS RELEVANT TO USERS OF RESEARCH?

- Balkanization in implementation research
- Poor intervention design
- Failure to plan future research based on current knowledge
BALKANIZATION

‘…the process of fragmentation or division of a region or state into smaller regions or states that are often hostile or non-cooperative with one another.’

Wikipedia
BALKANIZATION IN IMPLEMENTATION RESEARCH

applied health research  
capacity building  
co-optation - cooperation - competing  
diffusion  
dissemination  
getting knowledge into practice  
impact  
Implementation  
knowledge communication  
knowledge cycle  
knowledge exchange  
knowledge management  
knowledge translation  
knowledge mobilisation  
knowledge transfer  
linkage and exchange  
popularization of research,  
research into practice  
research mediation  
research transfer  
research translation  
science communication  
teaching  
“third mission”  
translational research  
transmission  
utilisation
BALKANIZATION IN IMPLEMENTATION RESEARCH

- Australia Research translation
- Canada Knowledge translation research
- Europe Implementation research
- US Quality improvement research
  Dissemination and implementation research (NIH)
- Global Implementation research
- Other Improvement science
BALKANIZATION IN IMPLEMENTATION RESEARCH

- Related streams of activity include:
  - Knowledge utilisation
  - Diffusion of innovation
  - Technology transfer
  - Social and organisational sciences
  - Quality assurance/quality improvement/patient safety
  - Evidence based medicine (including practice guidelines)
  - Medical education
POOR INTERVENTION DESIGN

ISLAGIATT principle

‘It Seemed Like A Good Idea At The Time’

Martin P Eccles
Failure to build cumulative science - thousands of studies that do not optimally incorporate current state of knowledge when planning new studies

- 142 RCTs of diabetes QI strategies published by 2011 (up from 50 RCTs published by 2006)
  - Most appear local solutions for diabetes management that do not use available evidence to inform design
- 35 systematic reviews of reminders published by Sept 2009
INCREASING VALUE, REDUCING WASTE IN IMPLEMENTATION RESEARCH

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APPROPRIATE RESEARCH DESIGN, METHODS AND ANALYSIS?

Failure to build informative science - thousands of studies that provide flawed or limited information

- Technical – clustering ignored, small numbers of units, unrealistic effect sizes, unit of analysis remain common
- Design – majority are two arm trials (intervention vs control)
- Intervention – little rationale provided for the choice of intervention, few explicitly theory based, insufficient feasibility testing
- Limited efforts to explore causal mechanisms of any observed changes
- Economic evaluation – largely ignored
- Reporting – insufficient details of context, intervention, and methods
Quality improvement needed in quality improvement randomised trials: systematic review of interventions to improve care in diabetes

Noah M Ivers,1 Andrea C Tricco,2 Monica Taljaard,3 Ilana Halperin,4 Lucy Turner,5 David Moher,3 Jeremy M Grimshaw5

ABSTRACT
Objective: Despite the increasing numbers of published trials of quality improvement (QI) interventions in diabetes, little is known about the risk of bias in this literature.

Design: Secondary analysis of a systematic review.

Data sources: Medline, the Cochrane Effective Practice and Organisation of Care (EPOC) database (from inception to July 2010) and references of included studies.

Eligibility criteria: Randomised trials assessing 11 predefined QI strategies or financial incentives targeting health systems, healthcare professionals or patients to improve the management of adult outpatients with diabetes.

Analysis: Risk of bias (low, unclear or high) was assessed for the 142 trials in the review across nine domains using the EPOC version of the Cochrane Risk of Bias Tool. We used Cochrane-Armitage tests for trends to evaluate the improvement

ARTICLE SUMMARY

Article focus
- Reliable quality improvement research is needed to make decisions about initiating or scaling up quality improvement strategies.
- The number of published quality improvement trials has increased rapidly over time.
- The quality of trials published in other areas of health seem to be improving over time but the risk of bias in the quality improvement literature is uncertain.

Key messages
- Nearly half of quality improvement trials for diabetes are at high risk of bias.
- The quality of quality improvement trials does not seem to be improving over time.
- Policy-makers, administrators, clinicians and research funders must carefully scrutinize the
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Macleod (2014) Lancet

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ETHICAL ISSUES

Guidelines and Guidance

The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials

Charles Weijer\textsuperscript{1,2,3}, Jeremy M. Grimshaw\textsuperscript{1,4,5}, Martin P. Eccles\textsuperscript{6}, Andrew D. McRae\textsuperscript{1,3,7}, Angela White\textsuperscript{1}, Jamie C. Brehaut\textsuperscript{4,8}, Monica Taljaard\textsuperscript{1,4,8}, the Ottawa Ethics of Cluster Randomized Trials Consensus Group\textsuperscript{5}

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What is missing from descriptions of treatment in trials and reviews?

Replicating non-pharmacological treatments in practice depends on how well they have been described in research studies, say Paul Glasziou and colleagues.

Have you ever read a trial or review and wondered exactly how to carry out treatments such as a “behavioural intervention,” “salt reduction,” or “exercise programme”? Although CONSORT and related initiatives have focused on the assessment of validity and presentation of results, less attention has been given to the adequacy of the description of the treatment used. For pharmacological treatments the description would need to include the dose, titration, route, timing, duration, and any monitoring used. For complex treatments the problems are even greater.

Why are full descriptions of treatment important?
The uptake of positive findings from trials is receiving numerous requests for additional details from doctors and patients, the author of a randomised trial on graded exercise for chronic fatigue syndrome subsequently published a supplementary article with a more detailed “prescription.” Similarly, it is not possible to set up a stroke unit, offer low-fat diets, or give smoking cessation advice without sufficient details on the components that were planned and delivered.

Extent of the problem
To assess the extent of problems with descriptions of treatment we prospectively assessed 80 consecutive studies selected for abstraction in the journal Evidence-Based Medicine from October 2005 to October 2006. The journal is aimed specifically at doctors work...
In 2009, Chalmers and Glasziou .... estimated that about 85% of research investment—equating to $200 billion of the investment in 2010—is wasted.

Macleod (2014) Lancet
POP QUIZ 2

Research waste in implementation science is:

- Worse than other areas of health research
- The same as other areas
- Better than other areas
- Don’t know (but no reason to suggest we are doing better than other areas of research!)
INCREASING VALUE, REDUCING WASTE IN IMPLEMENTATION RESEARCH

- Implementation laboratories to test comparative effectiveness of implementation interventions at scale
  - Intervention design and optimisation
- Enhancing informativeness of evaluations of implementation interventions
- Enhancing informativeness of systematic reviews of implementation interventions
IMPLEMENTATION LABORATORIES TO TEST COMPARATIVE EFFECTIVENESS AT SCALE

Implementation Research Laboratories

- Research teams integrated into healthcare systems undertaking program(s) of research directly relevant to healthcare systems’ priorities
- Reduces problems relating to convening *de novo* research teams, seeking project by project funding, negotiating access with healthcare systems, conducting study, writing up (usually out of funding period)
- Opportunities for formal and informal linkages of mutual advantage to research team and healthcare system
- More explicitly recognise relatives roles and responsibilities of research team and healthcare system
Back to Audit and Feedback

Head-to-head arm trials evaluating:

- alternative ways of designing and/or delivering audit and feedback
- audit and feedback vs audit and feedback plus co-interventions
- audit and feedback versus alternative interventions
Practice Feedback Interventions: 15 Suggestions for Optimizing Effectiveness

Jamie C. Brehaut, PhD; Heather L. Colquhoun, PhD; Kevin W. Eva, PhD; Kelly Carroll, MA; Anne Sales, PhD; Susan Michie, PhD; Noah Ivers, MD, PhD; and Jeremy M. Grimshaw, MD, PhD

Electronic practice data are increasingly being used to provide feedback to encourage practice improvement. However, evidence suggests that despite decades of experience, the effects of such interventions vary greatly and are not improving over time. Guidance on providing more effective feedback does exist, but it is distributed across a wide range of disciplines and theoretical perspectives.

Through expert interviews; systematic reviews; and experience with providing, evaluating, and receiving practice feedback, 15 suggestions that are believed to be associated with effective feedback interventions have been identified. These suggestions are intended to provide practical guidance to quality improvement professionals, information technology developers, educators, administrators, and practitioners who receive such interventions. Designing interventions with these suggestions in mind should improve their effect, and studying the mechanisms underlying these suggestions will advance a stagnant literature.

For author affiliations, see end of text.
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AUDIT AND FEEDBACK – POTENTIAL EFFECT MODIFIERS

- Be provided multiple times
- Present feedback as soon as possible
- Provide individual rather than general data
- Include clear comparators that reinforce desired behaviour change
- Support an action perceived to be a priority for recipients
- Recommend actions that can improve and are under control of the recipient
- Recommend a specific action
- Tailor feedback interventions based on situation-specific barriers

- Closely link visual display and summary message
- Be presented in multiple ways
- Minimize cognitive load
- Address barriers that prevent use of the feedback
- Provide short, actionable messages followed by more detail
- Address credibility of the information
- Increase motivation to change practice
- Encourage social construction of feedback rather than passive delivery
‘NO MORE BUSINESS AS USUAL’

- Testing comparative effectiveness of different ways of delivering audit and feedback needs large sample sizes that are unlikely to be realised in one-off research projects.
- Increasing delivery of large scale audit and feedback programs within healthcare systems.
- Opportunities to collaborate with these programs to efficiently advance implementation science about how to optimise audit and feedback.
IMPLEMENTATION LABORATORIES TO OPTIMISE AUDIT AND FEEDBACK

Baseline A&F occurring in health care system

Trial 1: a vs. b; b is better and becomes new standard
- A&F 'a'
- A&F 'b'

Trial 2: b vs. c; c is no better and more costly; b remains standard
- A&F 'b'
- A&F 'c'

Trial 3: b vs. d; d is better and becomes new standard; etc...
- A&F 'b'
- A&F 'd'
IMPLEMENTATION LABORATORIES TO OPTIMISE AUDIT AND FEEDBACK

- Benefits for health system – learning organisation; demonstrable improvements in its quality improvement activities; linkages to academic experts
- Benefits for implementation science – ability to test important (but potentially subtle) variations in audit and feedback that may be important effect modifiers
IMPLEMENTATION LABORATORIES TO OPTIMISE AUDIT AND FEEDBACK

- UK NIHR funded 5 year research program
- 2x2 factorial trial testing different ways of designing and delivering blood utilisation audits
- Randomising 152 UK hospitals
IMPLEMENTATION LABORATORIES

- Ontario Healthcare Implementation Laboratory
- 4 sequential trials embedded into routine feedback to family practices (n=\(~140\)) and long term care homes (\(~80\))
META-LABORATORIES

- Shared learning across studies and laboratories
- Shared expertise
- Opportunities for planned replication to explore replicability and outer context issues
- Building international community of health care system organisations with shared interests
Explicit process for developing intervention based upon understanding of:

- determinants of problem
- perceived mechanism of action of proposed intervention
- logistics
- practicalities

French (2011) Imp Sci
ENHANCING INFORMATIVENESS OF EVALUATIONS OF IMPLEMENTATION INTERVENTIONS

- Rigorous quantitative designs allow strong causal inferences to be made about the effects of a program (causal description)
- They provide relatively little information about the mechanisms through which a program operates (causal explanation)
- Better understanding of causal explanation likely to improve understanding about generalisability of study findings
ENHANCING INFORMATIVENESS OF EVALUATIONS OF IMPLEMENTATION INTERVENTIONS

- Design elements
- Process evaluations
  - Qualitative
  - Quantitative
  - Theory based
- Temporal evaluations
Seeing the forests and the trees—innovative approaches to exploring heterogeneity in systematic reviews of complex interventions to enhance health system decision-making: a protocol

Noah Ivers¹, Andrea C Tricco², Thomas A Trikalinos³, Issa J Dahabreh³, Kristin J Danko⁴, David Moher⁴, Sharon E Straus², John N Lavis⁶, Catherine H Yu², Kaveh Shojania⁷, Braden Manns⁸, Marcello Tonelli¹⁰, Timothy Ramsay⁴,⁵, Alun Edwards⁹, Peter Sargious⁹, Alison Paprica¹¹, Michael Hillmer¹¹,¹²
ENHANCING INFORMATIVENESS OF SYSTEMATIC REVIEWS OF IMPLEMENTATION INTERVENTIONS

- Bayesian hierarchical multivariate meta-regression
- Combinatorial meta-analyses

Multiple, complex, and possibly interacting intervention components

- Impact of contextual factors on intervention components and their effects

- Poor reporting of intervention characteristics and contextual factors (as well as outcomes)

- Difficulties in characterizing complex intervention components

- Exploration of alternative categorisation systems (e.g., behaviour change techniques)

- Author surveys
- Annual updates
- Enriched study registers
Implementation research is about improving health outcomes and the quality of health services.

Substantive evidence base on the effects of different implementation interventions; good news is that it is possible to change stakeholder decisions and behaviours!

However current evidence base provides little practical guidance for health care systems about which interventions to use and how to optimise them.
SUMMARY

- Likely substantial waste in implementation research (as in other health research fields)
- Opportunities to add value and reduce waste
- Requires action from multiple stakeholders (funders/sponsor, institution, researchers etc)
- Significant risks if we do not grasp the nettle.