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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. >$5billion
b. $5-10 billion
c. $10-20 billion
d. $20-30 billion
e. >$30 billion

POP QUIZ 1

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

a. >$5billion
b. $5-10 billion
c. $10-20 billion
d. **$20-30 billion**

   (incl $9.1 billion government funding)

e. >$30 billion

(Source: OECD)

WASTE IN RESEARCH

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


THE LANCET

Research: increasing value, reducing waste - January, 2014 www.thelancet.com

"By ensuring that efforts are infused with rigour from start to finish, the research community might protect itself from the sophistry of politicians, disentangle the conflicted motivations of capital and science, and secure real value for money for charitable givers and taxpayers through increased value and reduced waste."

WASTE IN RESEARCH

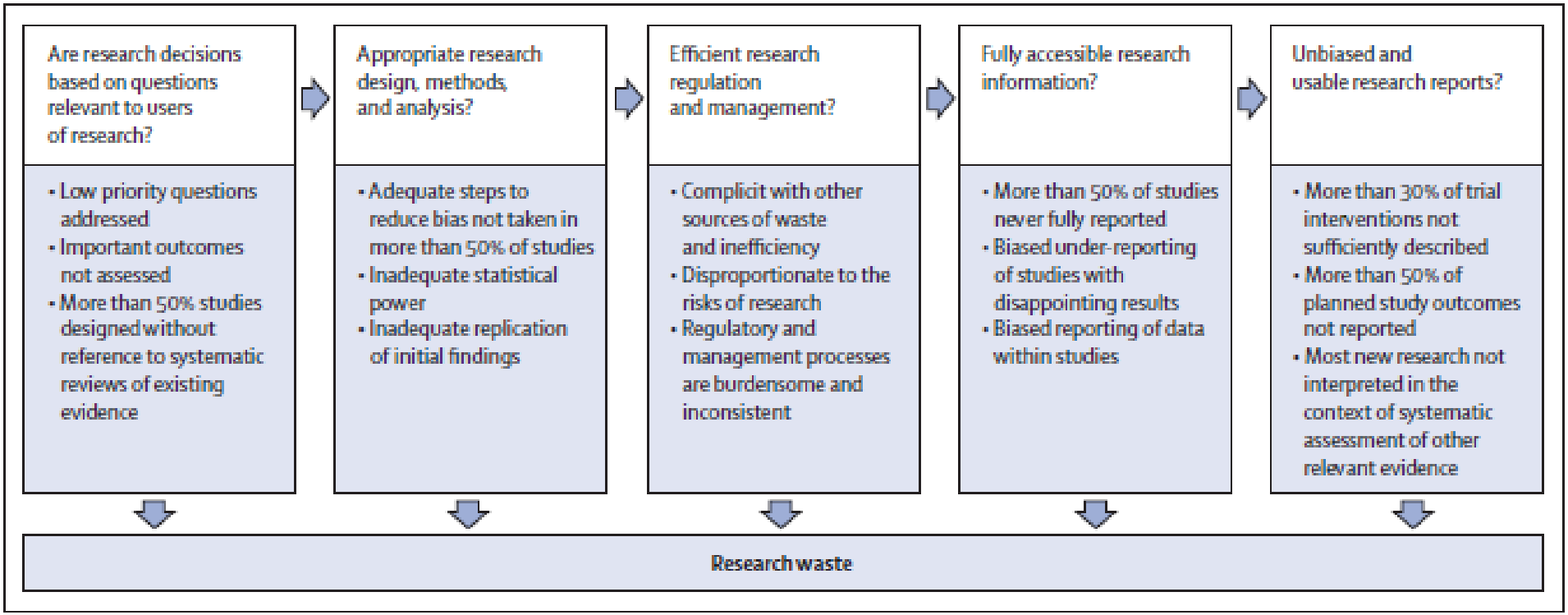

Figure: Avoidable waste or inefficiency in biomedical research

Macleod (2014) Lancet

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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

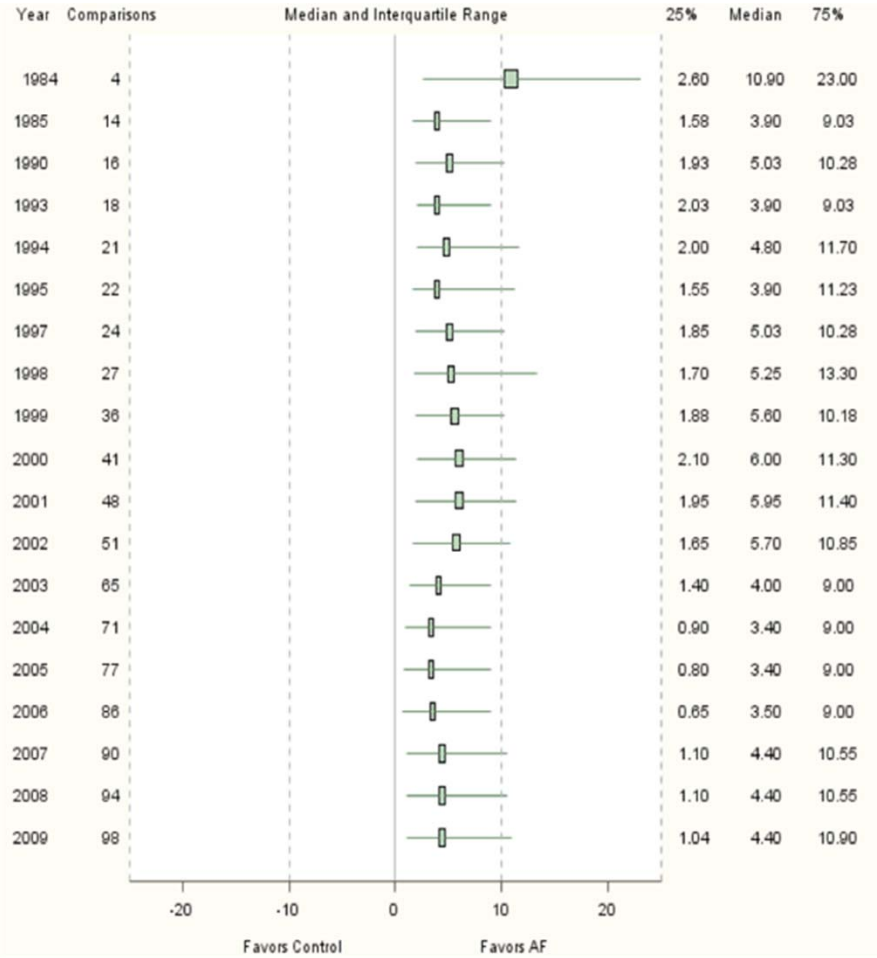
CURRENT STATE OF IMPLEMENTATION SCIENCE

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

Ivers et al (2014) *Journal of General Internal Medicine*

CURRENT STATE OF IMPLEMENTATION SCIENCE

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

Noah M. Ivers, MD, PhD[1], Jeremy M. Grimshaw, PhD[2], Gro Jamtvedt, PT[3], Signe Flottorp, MD[3], Mary Ann O'Brien, PhD[1], Simon D. French, PhD[4], Jane Young, MD[5], and Jan Odgaard-Jensen, PhD[3]

[1]Family Practice Health Centre and Institute for Health Systems Solutions and Virtual Care, Women's College Hospital, Toronto, Ontario, Canada; [2]Clinical Epidemiology Program, Ottawa Hospital Research Institute, Department of Medicine, University of Ottawa, Ottawa, Ontario, Canada; [3]Norwegian Knowledge Centre for the Health Services, Oslo, Norway; [4]School of Rehabilitation Therapy, Faculty of Health Sciences, Queen's University, Kingston, Ontario, Canada; [5]Cancer Epidemiology and Services Research, Sydney School of Public Health, University of Sydney, Sydney, New South Wales, Australia.

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.
J Gen Intern Med
DOI: 10.1007/s11606-014-2913-y

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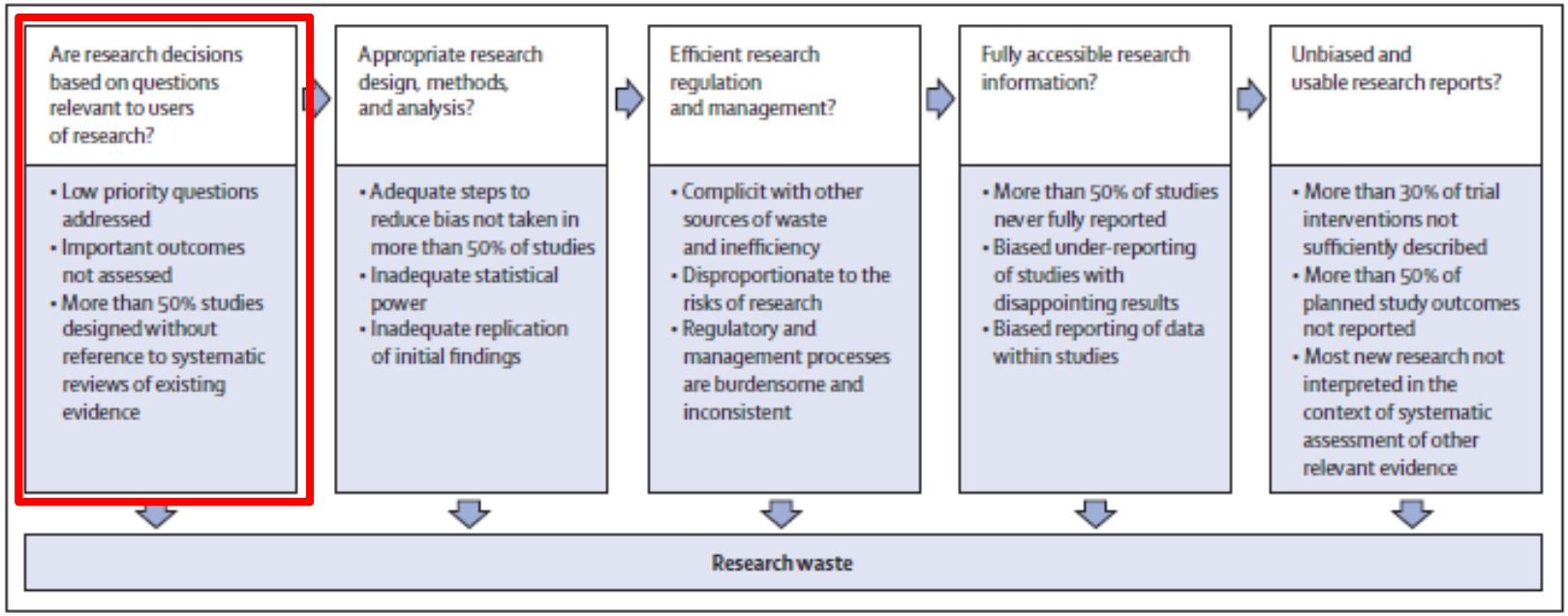

Figure: Avoidable waste or inefficiency in biomedical research

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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

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FAILURE TO PLAN FUTURE RESEARCH BASED ON CURRENT KNOWLEDGE

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

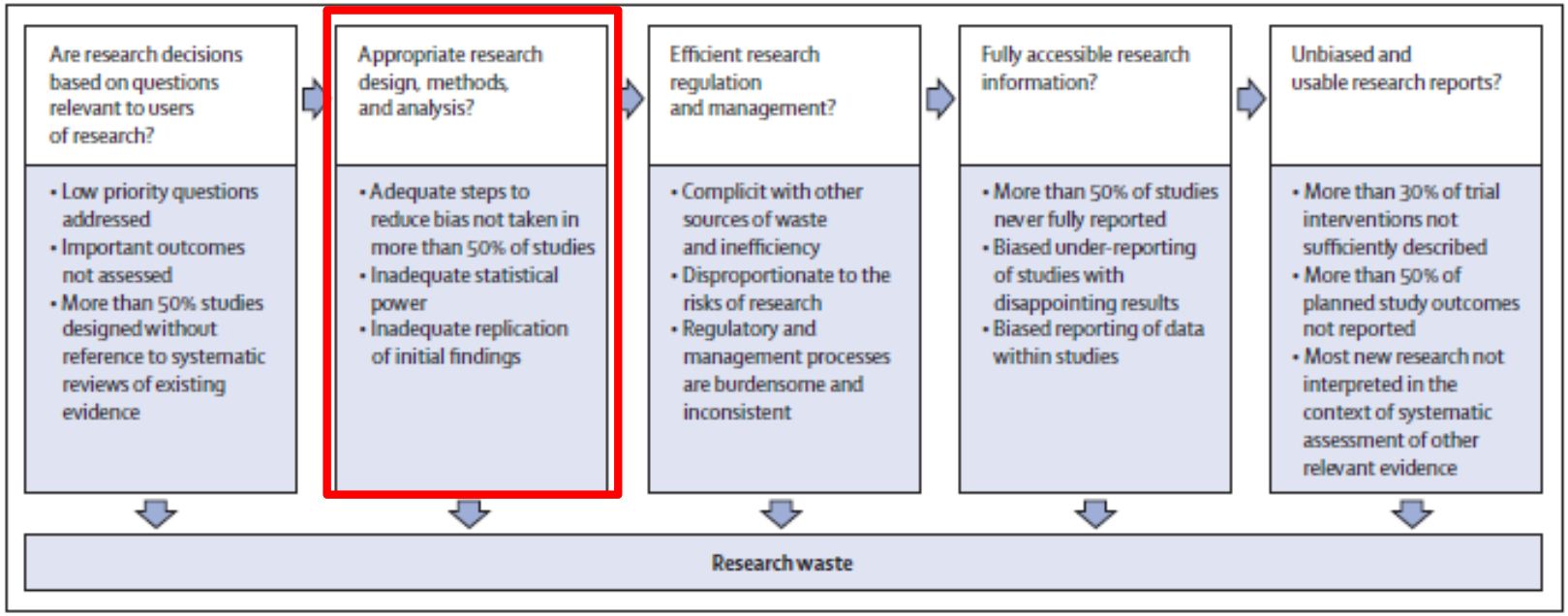

Figure: Avoidable waste or inefficiency in biomedical research

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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

APPROPRIATE RESEARCH DESIGN, METHODS AND ANALYSIS?

Open Access Research

BMJ open accessible medical research

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,[5] Jeremy M Grimshaw[5]

To cite: Ivers NM, Tricco AC, Taljaard M, *et al*. Quality improvement needed in quality improvement randomised trials: systematic review of interventions to improve care in diabetes. *BMJ Open* 2013;**3**:e002727. doi:10.1136/bmjopen-2013-002727

▸ Prepublication history for this paper are available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2013-002727).

Received 14 February 2013
Revised 11 March 2013
Accepted 12 March 2013

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 Cochran-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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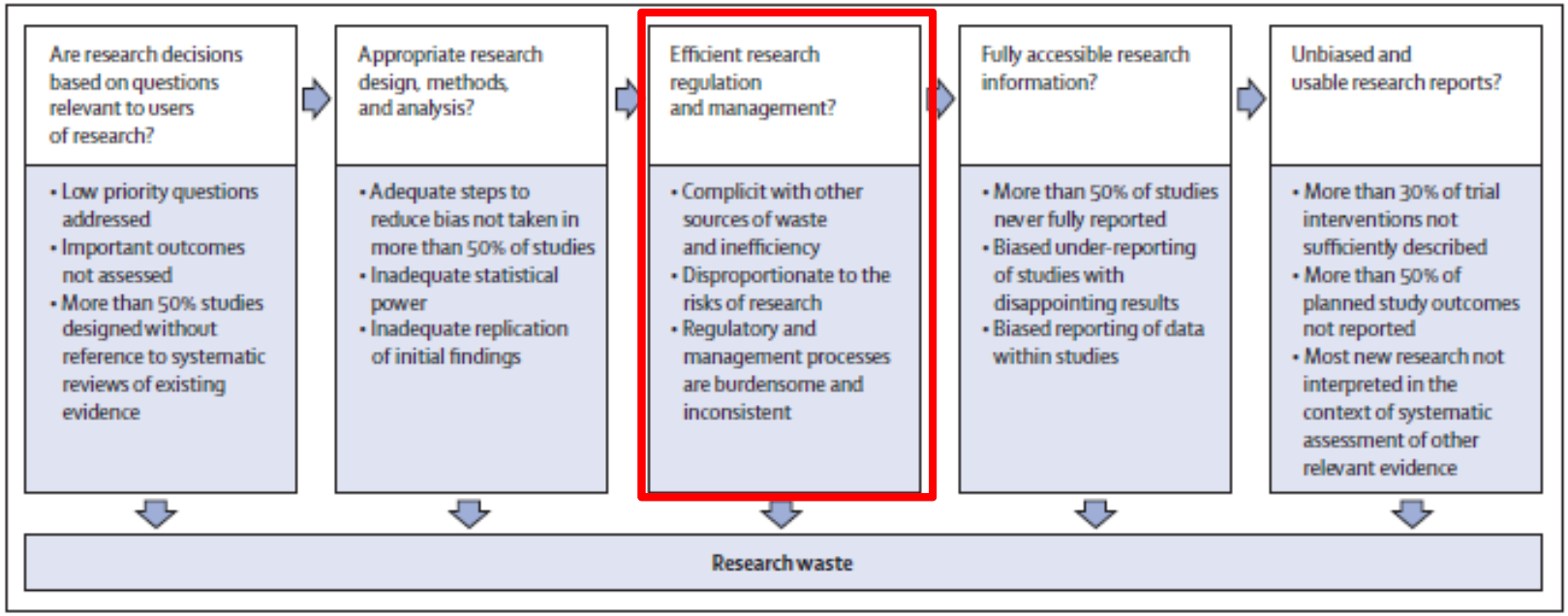

Figure: Avoidable waste or inefficiency in biomedical research

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Macleod (2014) Lancet

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ETHICAL ISSUES

OPEN ACCESS Freely available online

PLOS | MEDICINE

Guidelines and Guidance

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

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

1 Rotman Institute of Philosophy, Department of Philosophy, Western University, London, Ontario, Canada, **2** Department of Medicine, Western University, London, Ontario, Canada, **3** Department of Epidemiology and Biostatistics, Western University, London, Ontario, Canada, **4** Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, **5** Department of Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada, **6** Institute of Health and Society, Newcastle University, Newcastle upon Tyne, United Kingdom, **7** Division of Emergency Medicine, University of Calgary, Foothills Medical Centre, Calgary, Alberta, Canada, **8** Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Ontario, Canada

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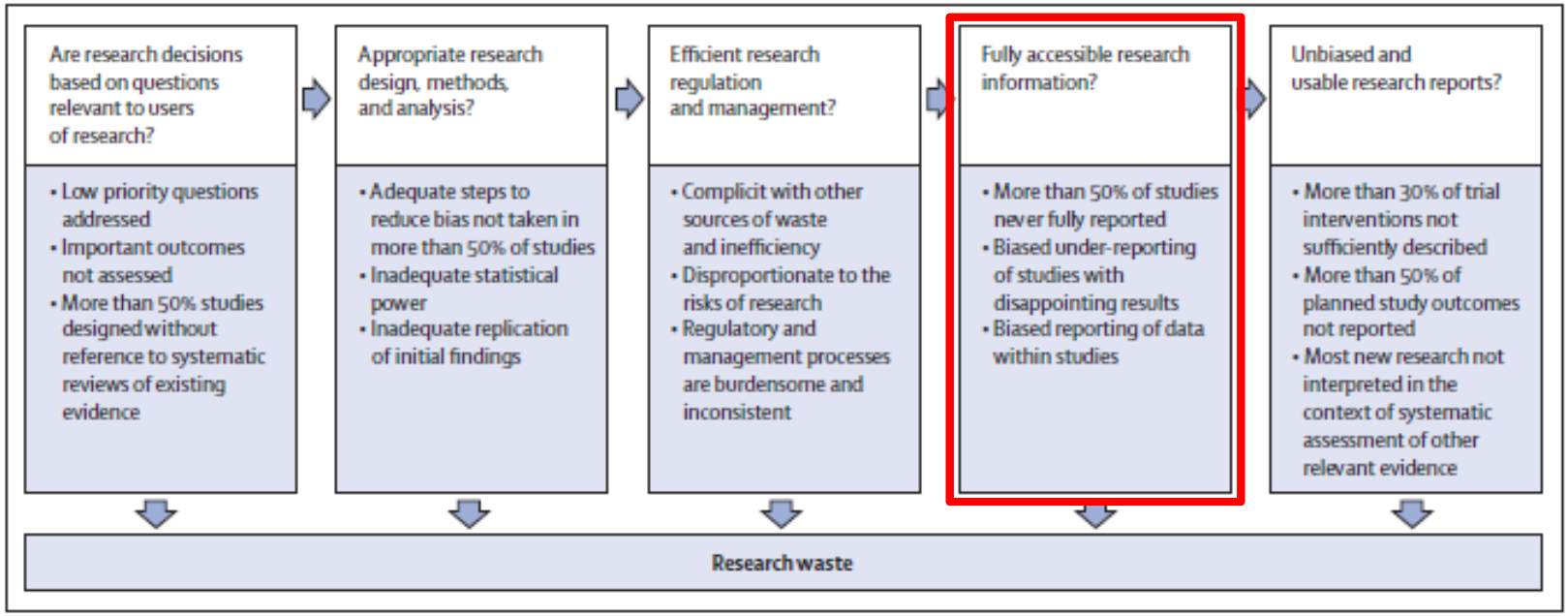

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UNBIASED AND USABLE RESEARCH REPORTS?

ANALYSIS

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,[1 2] 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[6] subsequently published a supplementary article with a more detailed "prescription."[7] 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.[8]

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-

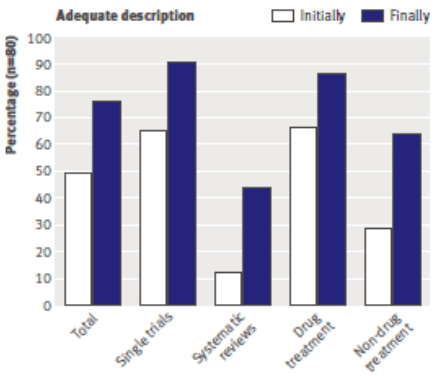

Fig 2 | Percentage of studies with sufficient description of treatment initially (based only on the published paper) and after supplementary information was obtained

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INCREASING VALUE, REDUCING WASTE IN THE RESEARCH ENTERPRISE

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

Macleod (2014) Lancet


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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

Ivers *et al. Implementation Science* 2014, **9**:14
http://www.implementationscience.com/content/9/1/14

IMPLEMENTATION SCIENCE

DEBATE **Open Access**

No more 'business as usual' with audit and feedback interventions: towards an agenda for a reinvigorated intervention

Noah M Ivers[1*], Anne Sales[2], Heather Colquhoun[3], Susan Michie[4], Robbie Foy[5], Jill J Francis[6] and Jeremy M Grimshaw[7]

Abstract

Background: Audit and feedback interventions in healthcare have been found to be effective, but there has been little progress with respect to understanding their mechanisms of action or identifying their key 'active ingredients.'

Discussion: Given the increasing use of audit and feedback to improve quality of care, it is imperative to focus further research on understanding how and when it works best. In this paper, we argue that continuing the 'business as usual' approach to evaluating two-arm trials of audit and feedback interventions against usual care for common problems and settings is unlikely to contribute new generalizable findings. Future audit and feedback trials should incorporate evidence- and theory-based best practices, and address known gaps in the literature.

Summary: We offer an agenda for high-priority research topics for implementation researchers that focuses on reviewing best practices for designing audit and feedback interventions to optimize effectiveness.

Keywords: Audit and feedback, Synthesis, Best practice, Implementation, Optimization

Background

Audit and feedback (A&F) involves providing a recipient with a summary of their performance over a specified period of time and is a common strategy to promote the implementation of evidence-based practices. A&F is used widely in healthcare by a range of stakeholders, including research funders and health system payers, delivery organizations, professional groups and researchers, to monitor and change health professionals' behaviour, both to increase accountability and to improve quality of care. A&F is an improvement over self-assessment [1] or self-monitoring [2] as it can provide objective data regarding discrepancies between current practice and target performance, as well as comparisons of performance to other health professionals. The recognition of suboptimal performance can act as a cue for action, encouraging those who are both motivated and capable to take action to reduce the discrepancy.

The effectiveness of A&F has been evaluated in the third update of a Cochrane review, which included 140 randomized trials of A&F conducted across many clinical conditions and settings around the world. The review found that A&F leads to a median 4.3% absolute improvement (interquartile range 0.5% to 16%) in provider compliance with desired practice [3]. One-quarter of A&F interventions had a relatively large, positive effect on quality of care, while another quarter had a negative or null effect. The challenge of identifying factors that differentiate more and less successful A&F interventions is exacerbated by poor reporting of both intervention components and contextual factors in the literature [4]. Furthermore, most A&F interventions tested in RCTs are designed without explicitly building on previous research or extant theory [5,6]. As a result, there has been little progress with respect to identifying the key ingredients for a successful A&F intervention or understanding the mechanisms of action of effective A&F interventions

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

AUDIT AND FEEDBACK – POTENTIAL EFFECT MODIFIERS

Annals of Internal Medicine

ACADEMIA AND THE PROFESSION

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.

Ann Intern Med. doi:10.7326/M15-2248 **www.annals.org**
For author affiliations, see end of text.
This article was published at www.annals.org on 23 February 2016.

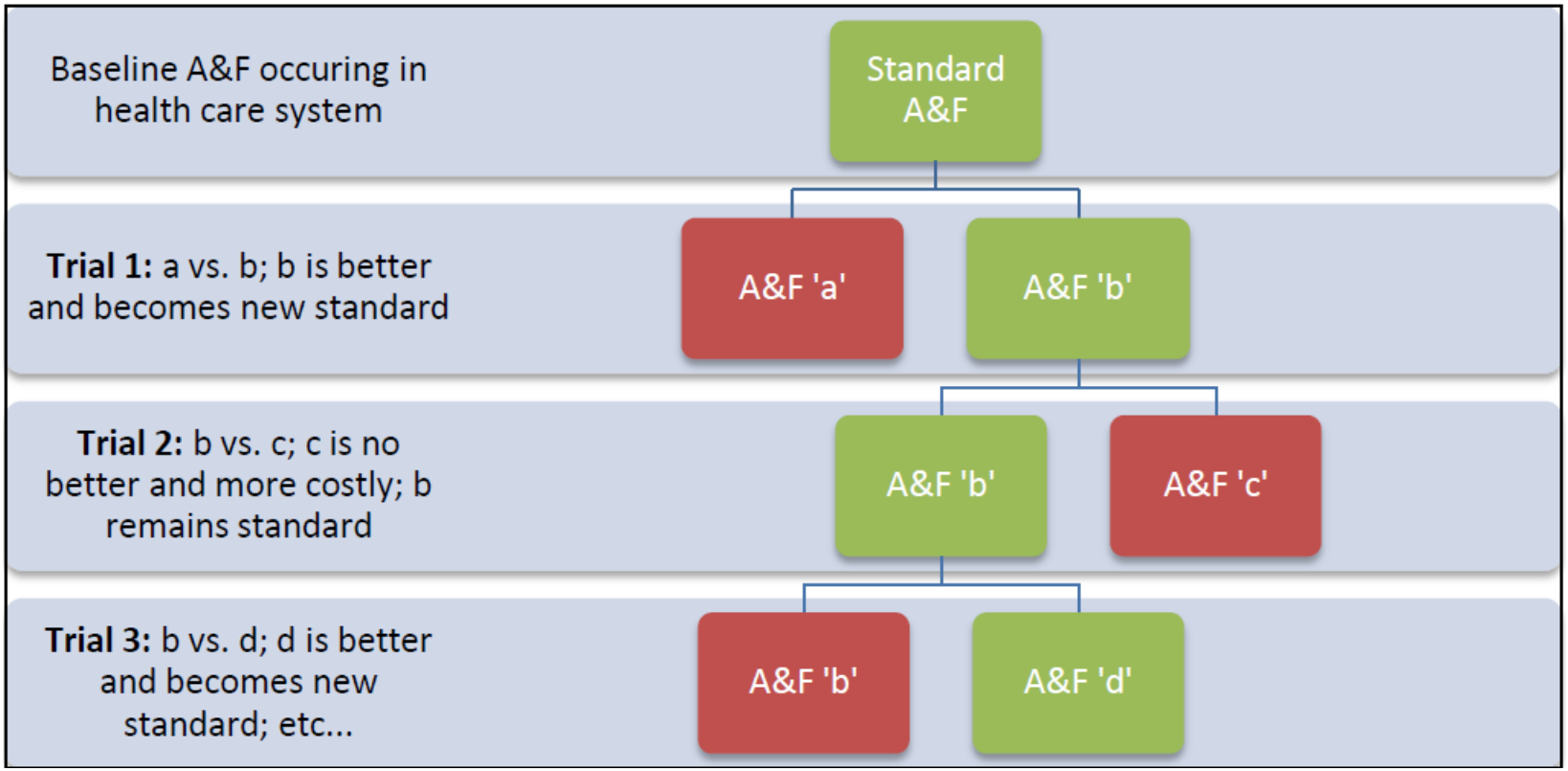
AUDIT AND FEEDBACK – POTENTIAL EFFECT MODIFIERS

- 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



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

Affinite

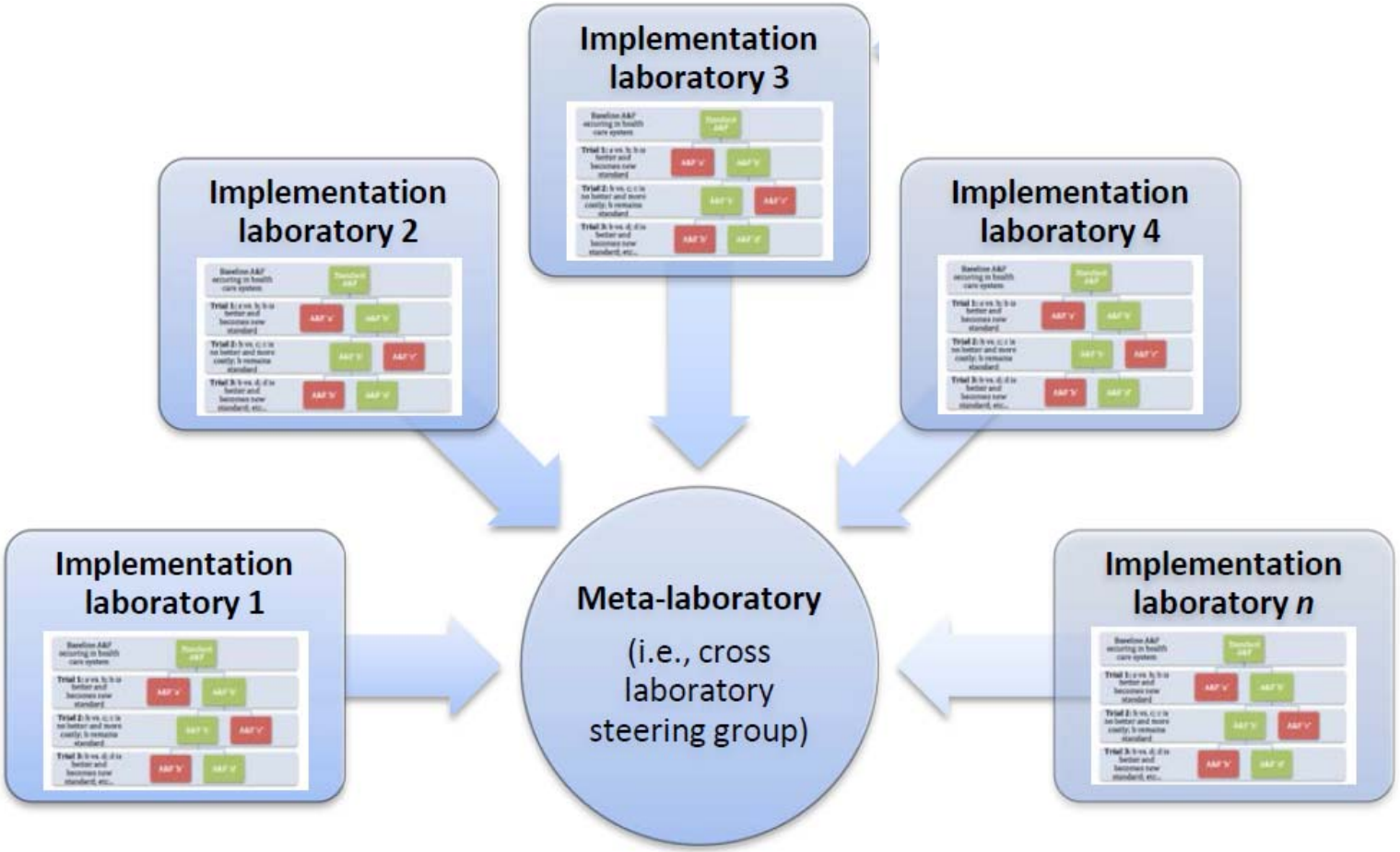
NHS Blood and Transplant

- 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-IMPLEMENTATION LABORATORIES



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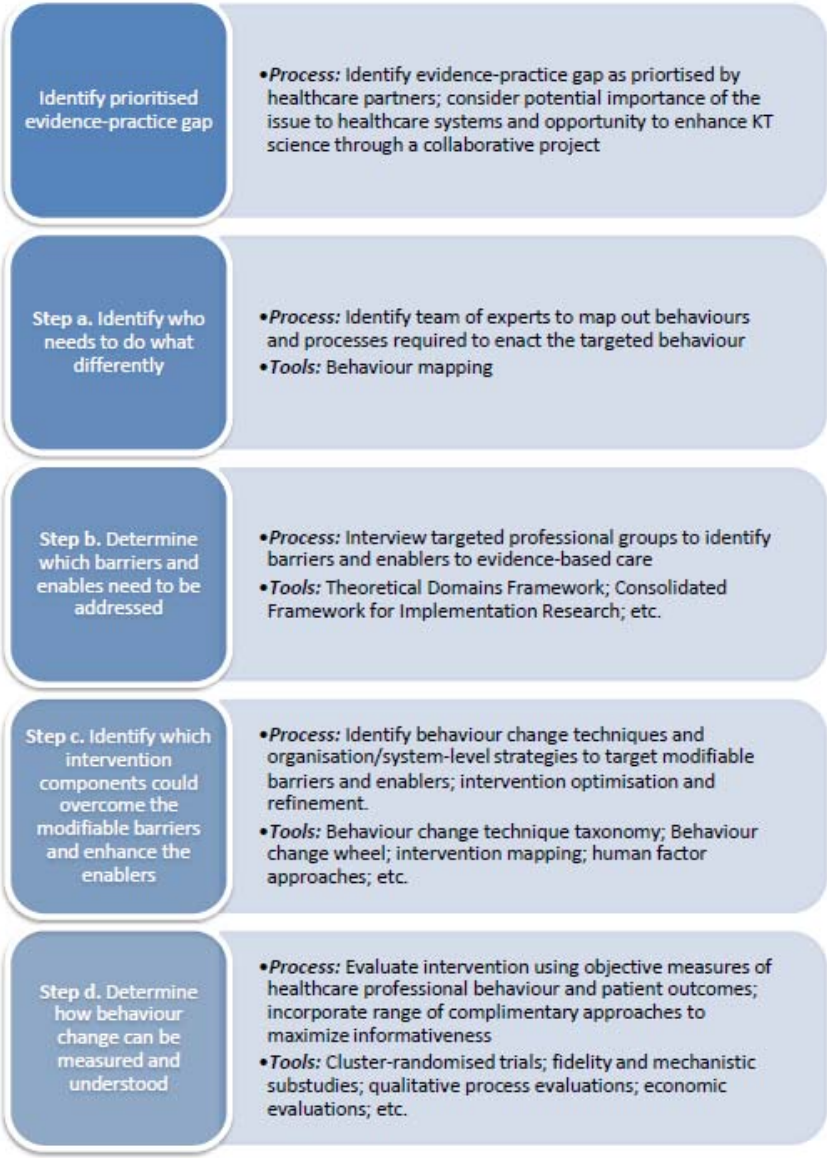
META-LABORATORIES

- 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

INTERVENTION DESIGN AND OPTIMISATION

- 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

ENHANCING INFORMATIVENESS OF SYSTEMATIC REVIEWS OF IMPLEMENTATION INTERVENTIONS

Ivers *et al. Systematic Reviews* 2014, **3**:88
http://www.systematicreviewsjournal.com/content/3/1/88

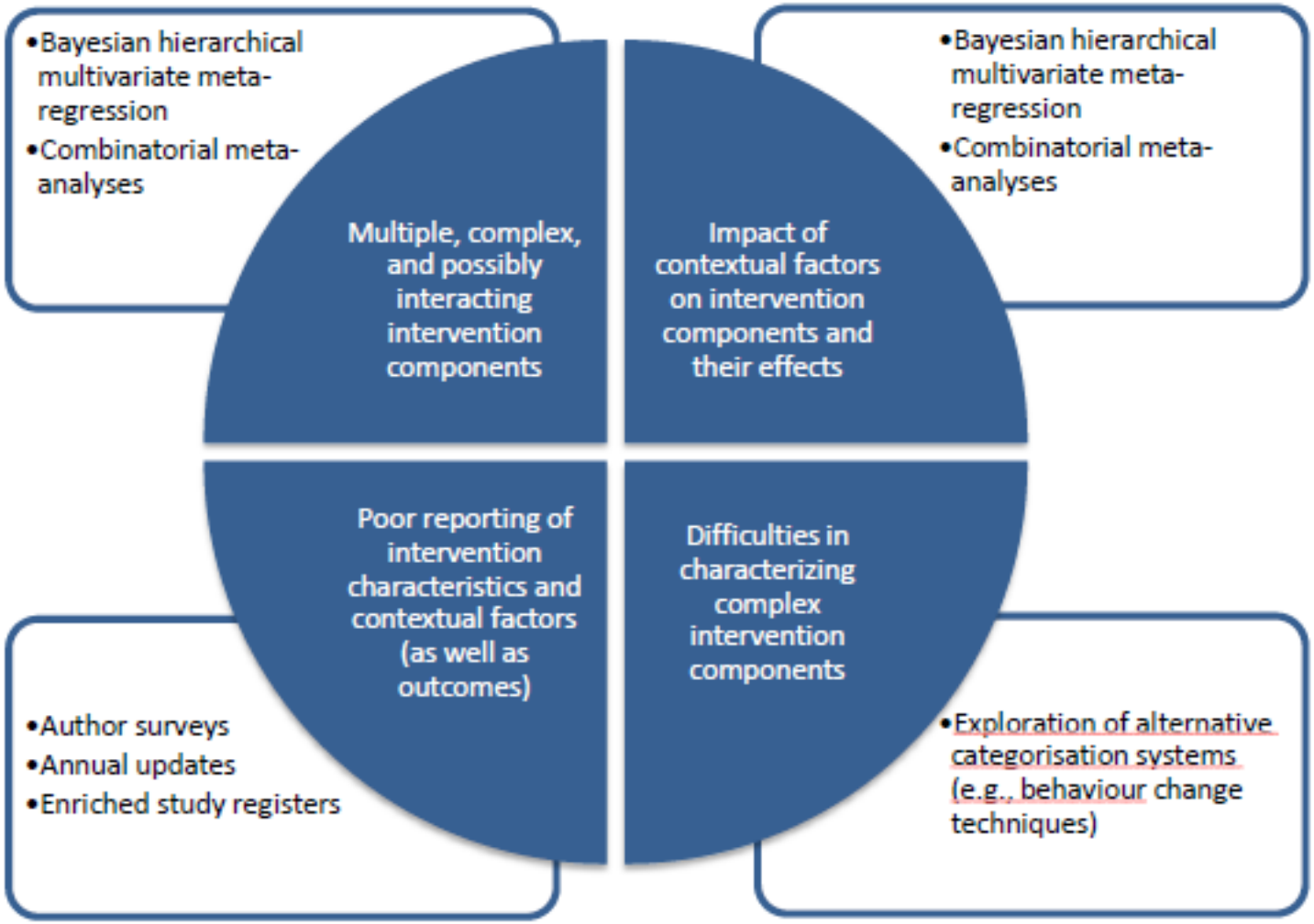
SYSTEMATIC REVIEWS

PROTOCOL Open Access

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 Ivers[1], Andrea C Tricco[2], Thomas A Trikalinos[3], Issa J Dahabreh[3], Kristin J Danko[4], David Moher[4,5], Sharon E Straus[2], John N Lavis[6], Catherine H Yu[2], Kaveh Shojania[7], Braden Manns[8,9], Marcello Tonelli[10], Timothy Ramsay[4,5], Alun Edwards[9], Peter Sargious[9], Alison Paprica[11], Michael Hillmer[11,12] and

ENHANCING INFORMATIVENESS OF SYSTEMATIC REVIEWS OF IMPLEMENTATION INTERVENTIONS



SUMMARY

- 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.

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