Creating Implementation Laboratories to efficiently advance implementation science and practice

Learning Objectives:

1) to describe how implementation science laboratories may help achieve goals of scientists and healthcare systems
2) to consider barriers and facilitators to development of implementation science laboratories
3) to examine interesting methodological opportunities with implementation science laboratories
4) to discuss the skill sets needed to have productive implementation science laboratories

Who we are

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- noah.ivers@wchospital.ca --- @noahivers

Caveats

Plan for the afternoon

- Session 1 Introduction to implementation science laboratories (60 mins)
- Biobreak (15 mins)
- Session 2 Enhancing the informativeness of trials in Imp Sci Labs (60 mins)
- Biobreak (15 mins)
- Session 3 Case study (20 mins)
- Wrap up

Introduction to implementation Science laboratories

SESSION 1

Defining Implementation Science

•**NIRN:** The **study of factors** that influence the full and effective use of innovations in practice.

•**NIH:** The **study of methods** to promote the integration of research findings and evidence into healthcare policy and practice.

•**IS JOURNAL:** The **scientific study of methods** to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, **to improve the quality and effectiveness of health services**"

Core implementation research activities

- **Knowledge synthesis** (what do we know about the effectiveness of different implementation approaches);
- **Identification of implementation failures**;
- Development of methods to assess **barriers and facilitators** to implementation;
- Development of **implementation interventions**;
- Development of the methods for **optimising implementation interventions**;
- **Evaluations** of the effectiveness and efficiency of implementation interventions;
  - Process, fidelity and outcome evaluation
- **Sustainability and scalability** of implementation interventions;
- Development of implementation science **theory**; and
- Development of implementation science research **methods**.

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- **Sustainability and scalability** of implementation interventions;
- Development of implementation science **theory**; and
- Development of implementation science research **methods**.

Personal example: “Typical” Embedded Evaluation

Desveaux *et al. Implementation Science* (2017) 12:71
DOI 10.1186/s13012-017-0602-z

Implementation Science

RESEARCH Open Access

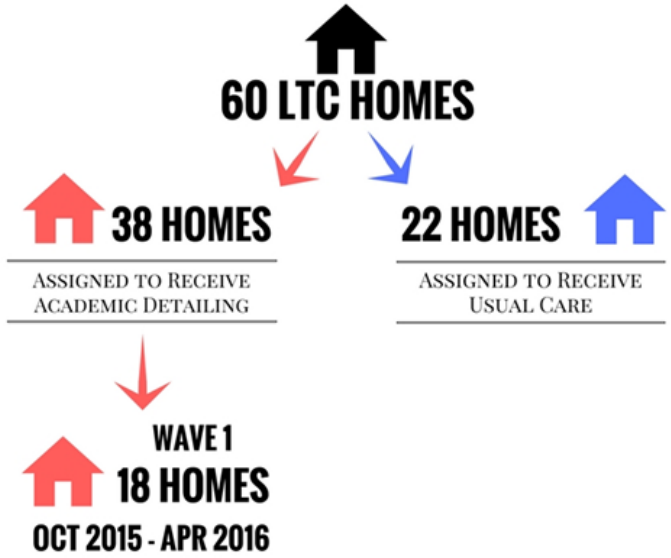
Improving the appropriateness of antipsychotic prescribing in nursing homes: a mixed-methods process evaluation of an academic detailing intervention

L. Desveaux[1*], M. Saragosa[2], J. Rogers[3], L. Bevan[3], H. Loshak[3], A. Moser[3,4], S. Feldman[3,4], L. Regier[3], L. Jeffs[2] and N. M. Ivers[1,5]

Abstract

Background: In 2014, nursing home administration and government officials were facing increasing public and media scrutiny around the variation of antipsychotic medication (APM) prescribing across Ontario nursing homes. In response, policy makers partnered to test an academic detailing (AD) intervention to address appropriate prescribing of APM in nursing homes in a cluster-randomized trial. This mixed-methods study aimed to explore how and why the AD intervention may have resulted in changes in the nursing home context. The objectives were to understand how the intervention was implemented, explore contextual factors associated with implementation, and examine impact of the intervention on prescribing.

Methods: Administrative data for the primary outcome of the full randomized trial will not be available for a minimum of 1 year. Therefore, this paper reports the findings of a planned, quantitative interim trial analysis assessed mean APM dose and prescribing prevalence at baseline and 3 and 6 months across 40 nursing homes (18 intervention, 22 control). Patient-level administrative data regarding prescribing were analyzed using generalized linear mixed effects regression. Semi-structured interviews were conducted with nursing home staff from the intervention group to explore opinions and experiences of the AD intervention. Interviews were analyzed using the framework method, with constructs from the Consolidated Framework for Implementation Research (CFIR) applied as pre-defined deductive codes. Open coding was applied when emerging themes did not align with CFIR



- **PLUS:** 51 qualitative interviews across 17 LTC homes

OUTCOMES

VARIABLE	SOURCE
Primary outcome	
Antipsychotic dispensing	RAI
Secondary prescribing outcomes	
Antipsychotic prescribing	ODB
Mean Antipsychotic dose	ODB
Benzodiazepine (or z-drug) prescribing	ODB
Anti-depressant prescribing	ODB
Acetaminophen prescribing	ODB
Secondary clinical outcomes	
Difficulty in performing activities	RAI
Aggressive behaviour scale	RAI
Pain	RAI
Depression	RAI
Falls	RAI
Secondary health care utilization outcomes	
ER visits	CIHI/NACRS
Hospitalizations	CIHI

“Typical” Challenges and Lessons Learned

- Scientists had no real control of intervention strategy or topic; operations team required adaptation to initial randomization plan
- Delays for final data analysis; process evaluations and interim evaluations helpful, informed next attempts at similar intervention
- One-off “demonstration” project

Evaluating implementation strategies

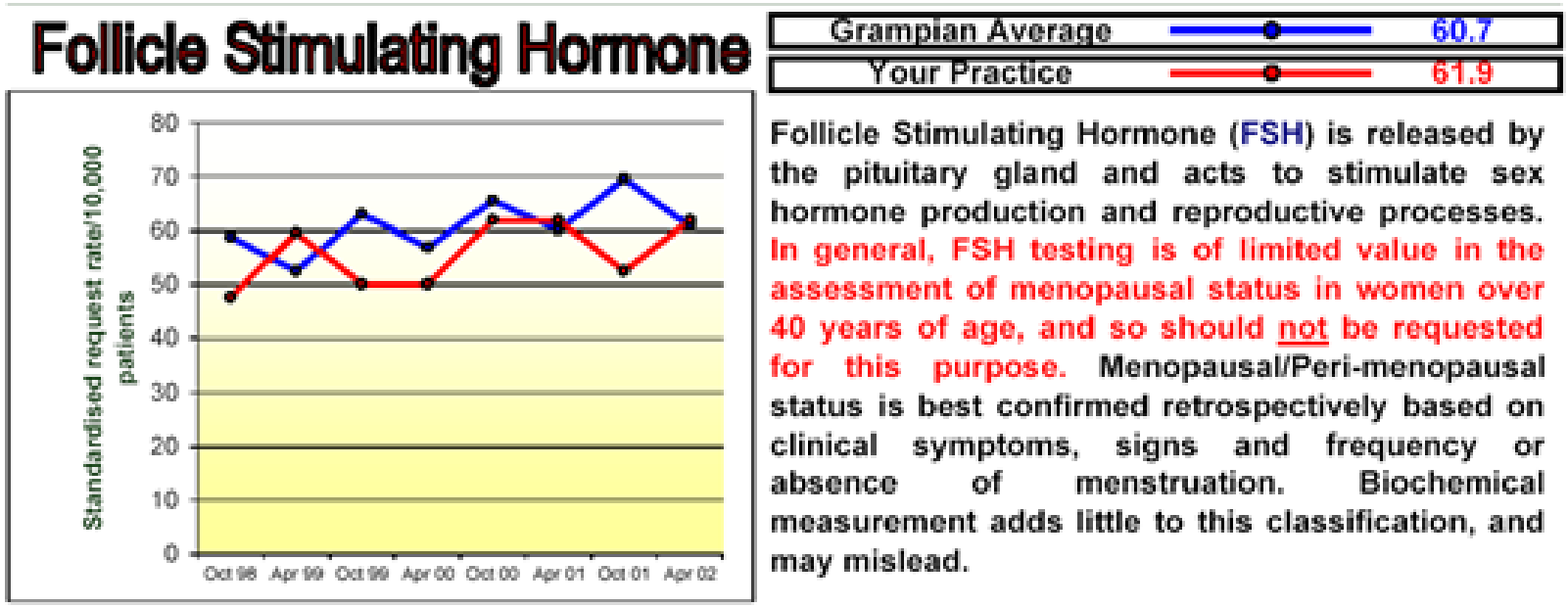
- Mostly one-off projects requiring convening *de novo* research teams
  - seeking project-by-project funding, negotiating access with healthcare systems, conducting study, writing up results, then starting all over again

- Creates problems with:
  - Efficiency (for research team, healthcare system)
  - Failure to maximize learning from individual projects
  - Failure to communicate learning from individual projects
  - Intellectual continuity (fails to develop cumulative knowledge)
  - Promoting interdisciplinarity

Is there another way?

Case study: Audit and Feedback (A&F)

- Any summary of clinical performance of health care over a specified period of time. The summary may also have included recommendations for clinical action.
- Foundational component of many QI activities



Audit and Feedback is generally effective

- 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*

Audit & Feedback science was (is?) stagnant

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.

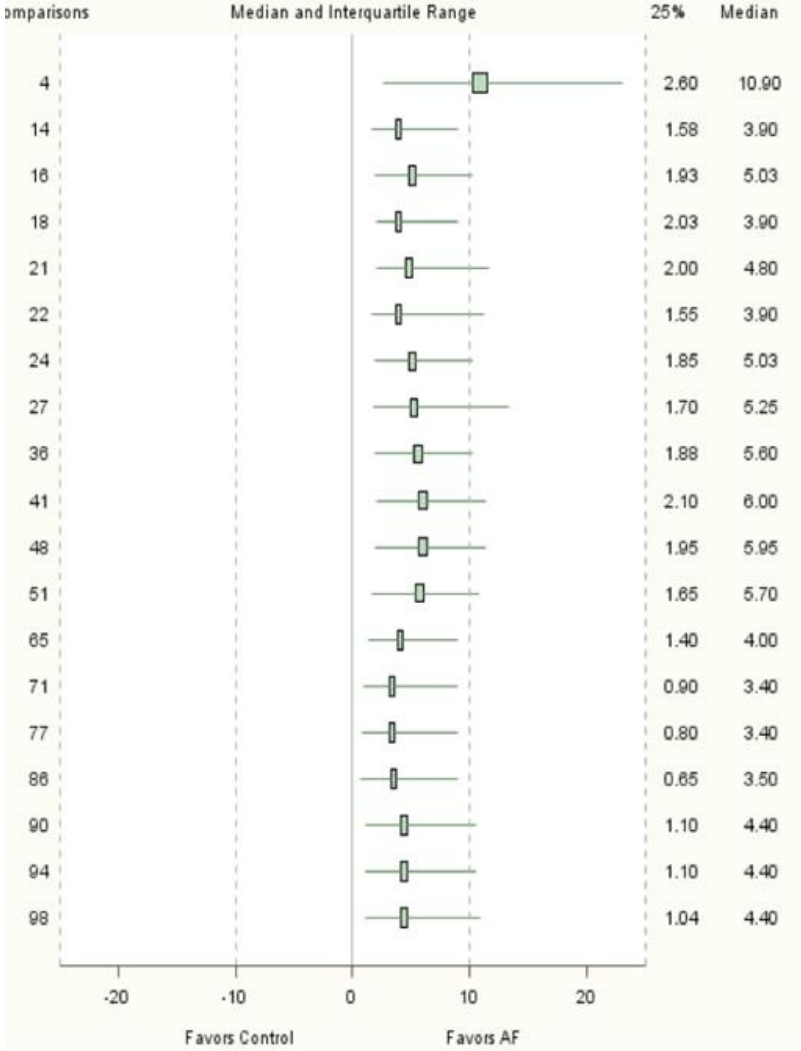
BACKGROUND: This paper extends the findings of the Cochrane systematic review of audit and feedback on professional practice to explore the estimate of effect over time and examine whether new trials have added to knowledge regarding how optimize the effectiveness of audit and feedback.

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

Audit & Feedback science was stagnant



Cumulative analysis – effect size of audit and feedback interventions over time did not change over time

Little evidence of replication - only 6 studies reported testing an intervention from a previous study

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

Remaining uncertainties about how to optimize A&F

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.

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For author affiliations, see end of text.

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Remaining uncertainties about how to optimize A&F

- 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

Colquhoun et al. Implementation Science (2017) 12:117
DOI 10.1186/s13012-017-0646-0

Implementation Science

RESEARCH Open Access

Advancing the literature on designing audit and feedback interventions: identifying theory-informed hypotheses

Heather L. Colquhoun[1*], Kelly Carroll[2], Kevin W. Eva[3], Jeremy M. Grimshaw[2,4], Noah Ivers[5], Susan Michie[6], Anne Sales[7] and Jamie C. Brehaut[2,8]

Abstract

Background: Audit and feedback (A&F) is a common strategy for helping health providers to implement evidence into practice. Despite being extensively studied, health care A&F interventions remain variably effective, with overall effect sizes that have not improved since 2003. Contributing to this stagnation is the fact that most health care A&F interventions have largely been designed without being informed by theoretical understanding from the behavioral and social sciences. To determine if the trend can be improved, the objective of this study was to develop a list of testable, theory-informed hypotheses about how to design more effective A&F interventions.

Methods: Using purposive sampling, semi-structured 60–90-min telephone interviews were conducted with experts in theories related to A&F from a range of fields (e.g., cognitive, health and organizational psychology, medical decision-making, economics). Guided by detailed descriptions of A&F interventions from the health care literature, interviewees described how they would approach the problem of designing improved A&F interventions. Specific, theory-informed hypotheses about the conditions for effective design and delivery of A&F interventions were elicited from th ing independently into themes, and cat

313 theory-informed hypotheses,

Results: We conduc re placed into 30

‘No more business as usual’

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.

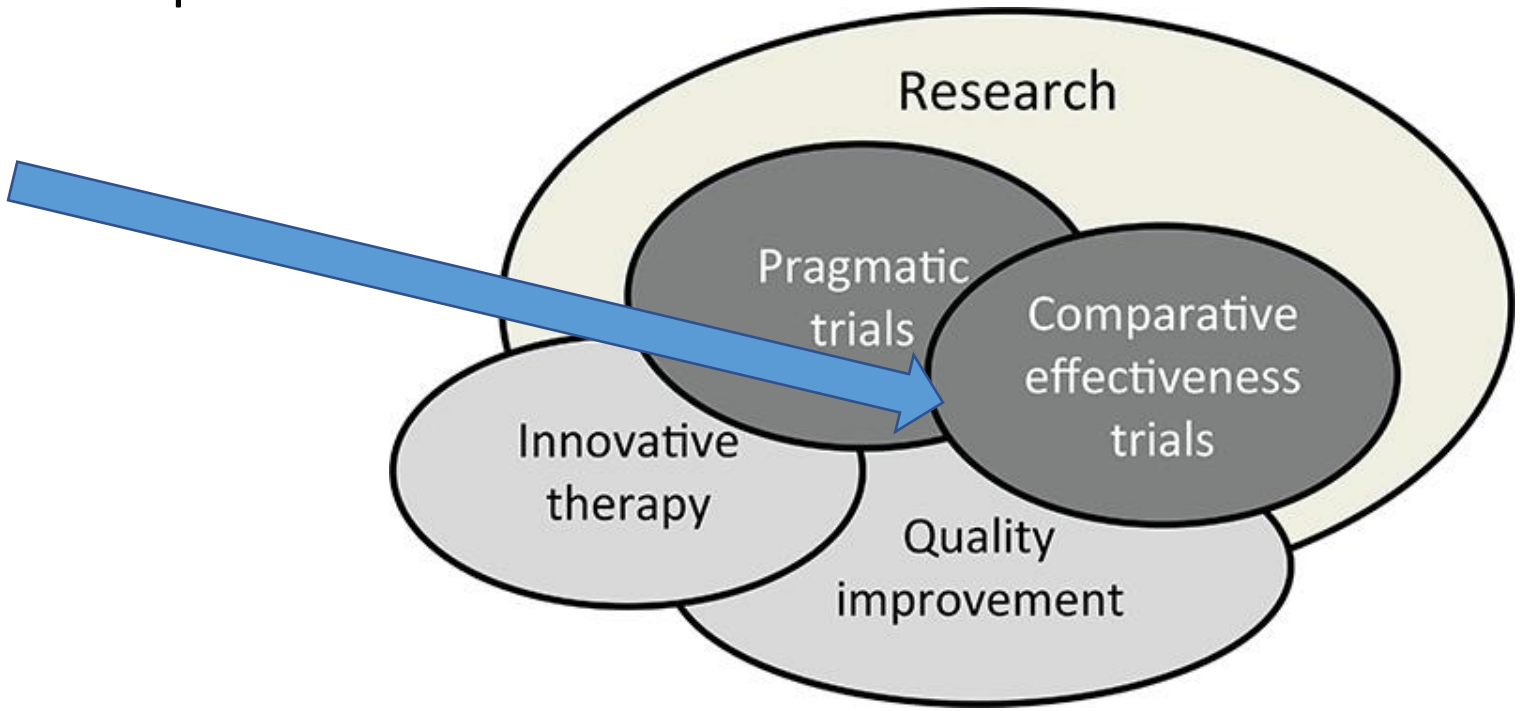
The effectiveness of A&F has been evaluated in the third update of a Cochrane review, which included 140 randomized trials of A&F conducted across many clinical conditions and settings around the world. The review found that A&F leads to a median 4.3% absolute improvement (interquartile range 0.5% to 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

‘No new ideas under the sun’

Comparative effectiveness research is …
comparing different interventions and **strategies...** (to understand) which interventions are most effective for which patients under specific circumstances.



‘No new ideas under the sun’

Radical incrementalism

- A deliberate strategy for business operations (particularly in information technology) in which a series of small changes are enacted one after the other, resulting in **radical** cumulative changes in infrastructure.

‘No more business as usual’

- Comparative effectiveness trials of different methods of delivering A&F need large sample sizes that are unlikely to be realized in one off research projects
- Increasingly healthcare systems are providing A&F at scale creating opportunities to embed comparative effectiveness trials into their A&F programs

Opportunities for innovative system-research partnerships

= Implementation Science Laboratories

Imp Sci Labs: a definition (in progress)

Partnership:

Organizations already delivering interventions at scale keen to optimize those interventions

and

Researchers keen to advance generalizable knowledge in implementation

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Comment

Reducing research waste with implementation laboratories

Noah M Ivers, Jeremy M Grimshaw

Published: 06 August 2016

Altmetric 20

DOI: http://dx.doi.org/10.1016/S0140-6736(16)31256-9

Article Info

Summary Full Text Tables and Figures References

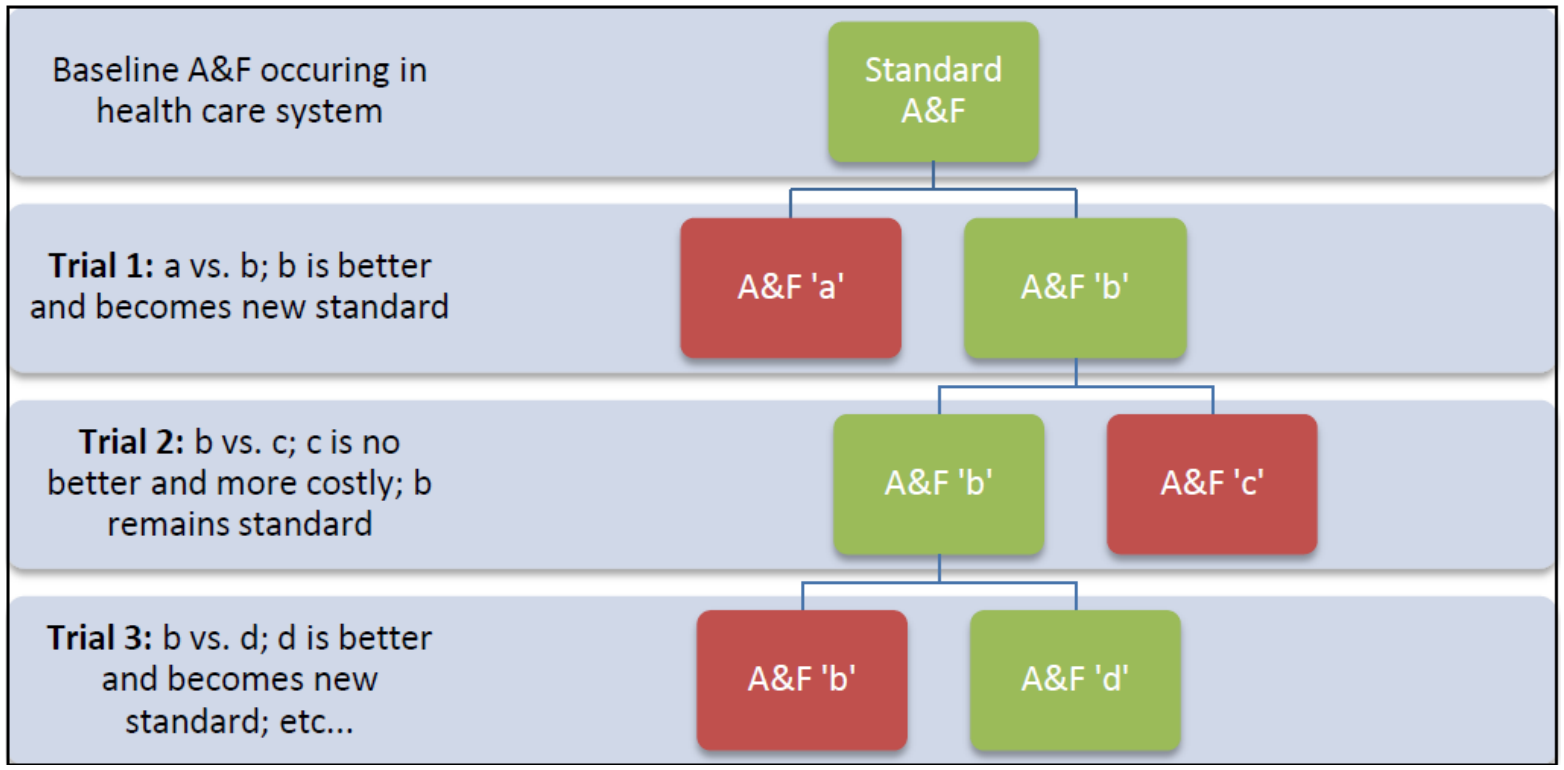
The *Lancet* REWARD (REduce research Waste And Reward Diligence) campaign has encouraged researchers to examine how they work and make efforts to reduce waste and maximise efficiency. Research waste is undermining efforts to improve the effectiveness of health systems. A consistent finding in health services research is inappropriate variations in care and evidence–practice gaps. Implementation science—the study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice[1]—can inform health systems on how to reliably improve care and outcomes.

- **LABORATORY** per Merriam-Webster:

•a place equipped for experimental study in a science or for testing and analysis;

•broadly: a place providing opportunity for experimentation, observation, or practice in a field of study

Imp Sci Labs


Baseline A&F occuring in health care system
Standard A&F
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'

Imp Sci Labs

Role	Health system	Researcher
Develop priorities	X	
Develop prototype A&F	X	X
Delivery of A&F	X	
Data collection	X	
Analysis		X
Interpretation	X	X

Opportunities to seek research funding to cover additional marginal costs of research

Imp Sci Labs

- 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

What (we think) is an IS Lab; what is it not?

IS Labs are both a structure and a process

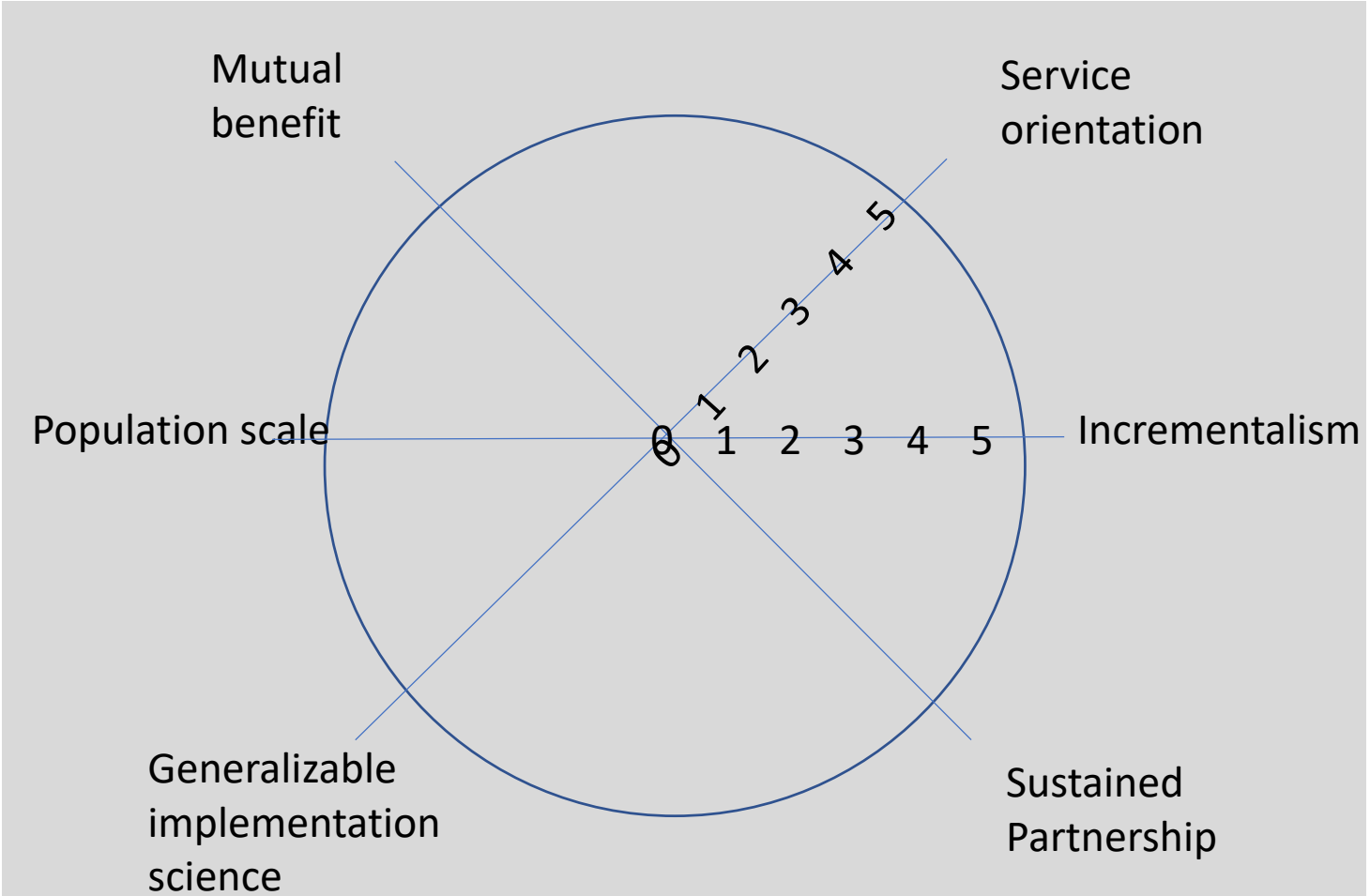
IS Labs are characterized by

- Alignment with partners' service mission
- Sustained partnership between researchers and healthcare organizations
- Commitment to both local improvement and generalizable science via evaluative rigor
- Population-scale impact via incrementalism

What is an IS Lab; what is it not?

	Alignment of scientific and applied goals	Sustained engagement of partners	Generalizable implementation science research	Incremental population-level impact
Implementation Science Laboratory	✔	✔	✔	✔
Learning Health System	✔	✔	?	✔
Learning Collaboratives	✔	?	-	✔
Practice Based Research Network	?	?	✔	-
Embedded Researcher models	✔	-	?	?
Participatory / Action research	?	✔	?	?

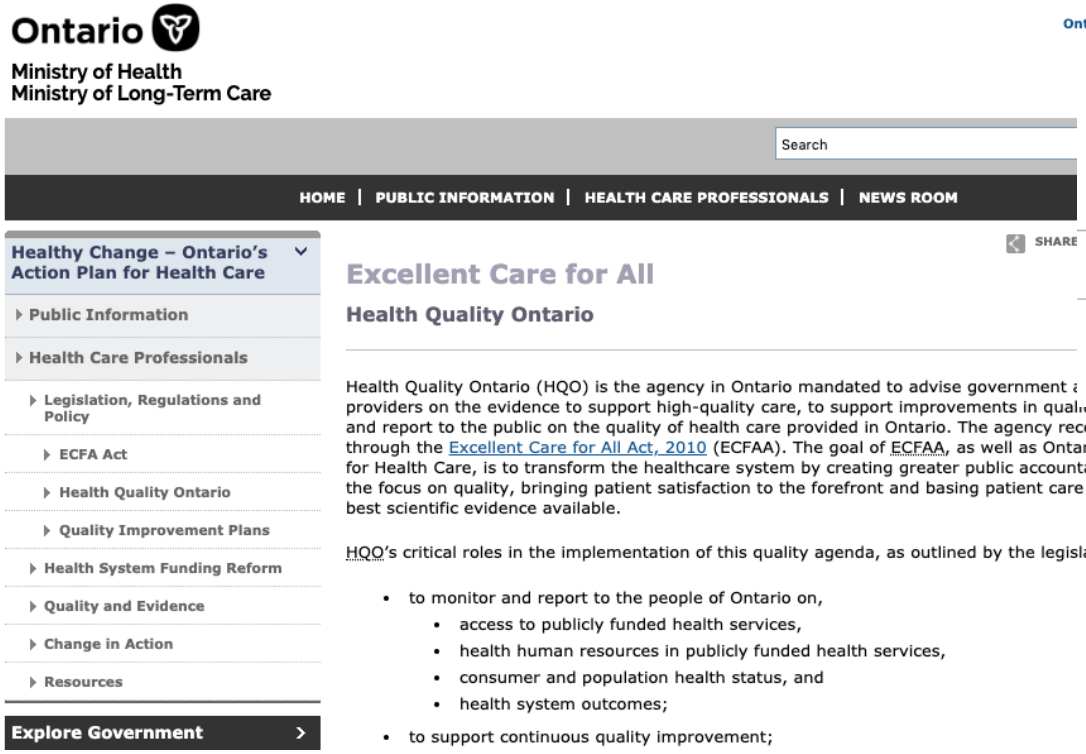
What is an IS Lab; what is it not?

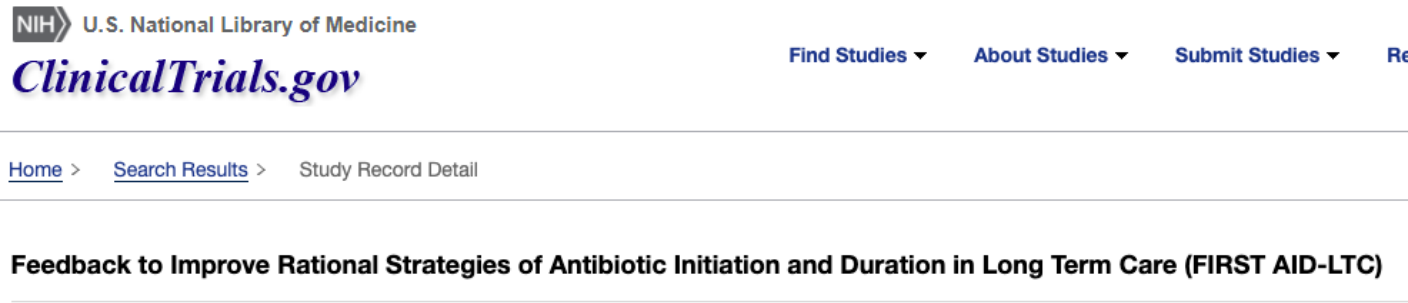


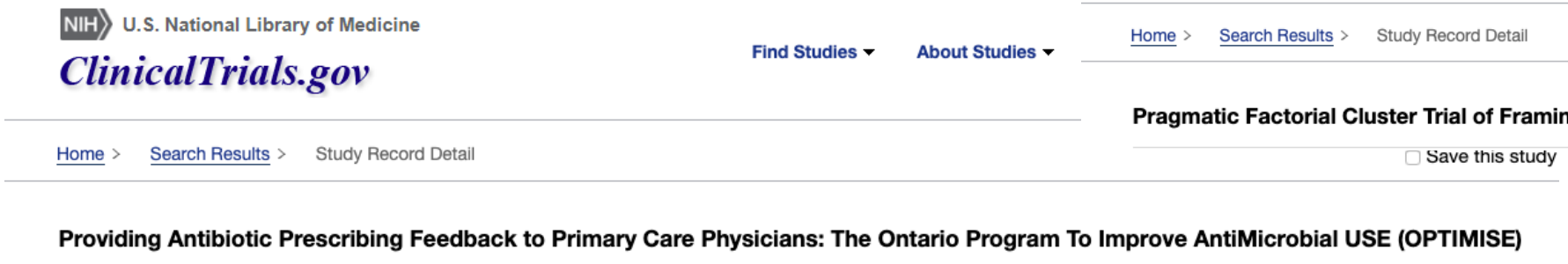
Imp Sci Labs: two ‘types’?

	+ Sector/Problem Oriented -	
+ Intervention Oriented -	A&F to improve quality in primary care	Optimizing A&F
	Improve quality in primary care	n/a

Personal example: Ontario A&F Implementation Lab







Ivers et al. Implementation Science (2017) 12:86
DOI 10.1186/s13012-017-0615-7

Implementation Science

STUDY PROTOCOL Open Access

Testing feedback message framing and comparators to address prescribing of high-risk medications in nursing homes: protocol for a pragmatic, factorial, cluster-randomized trial

Noah M. Ivers[1,2,3,4*], Laura Desveaux[1], Justin Presseau[5,6,7], Catherine Reis[1], Holly O. Witteman[5,8,9,10,11], Monica K. Taljaard[5,6], Nicola McCleary[5], Kednapa Thavorn[6] and Jeremy M. Grimshaw[5,12]

Abstract

Background: Audit and feedback (AF) interventions that leverage routine administrative data offer a scalable and relatively low-cost method to improve processes of care. AF interventions are usually designed to highlight discrepancies between desired and actual performance and to encourage recipients to act to address such discrepancies. Comparing to a regional average is a common approach, but more recipients would have a discrepancy if compared to a higher-than-average level of performance. In addition, how recipients perceive and respond to discrepancies may depend on how the feedback itself is framed. We aim to evaluate the effectiveness of different comparators and framing in feedback on high-risk prescribing in nursing homes.

Methods: This is a pragmatic, 2 × 2 factorial, cluster-randomized controlled trial testing variations in the comparator and framing on the effectiveness of quarterly AF in changing high-risk prescribing in nursing homes in Ontario, Canada. We grouped homes that share physicians into clusters and randomized these clusters into the four experimental conditions. Outcomes will be assessed after 6 months; all primary analyses will be by intention-to-treat. The primary outcome (monthly number of high-risk medications received by each patient) will be analysed using a general linear mixed effects regression model. We will present both four-arm and factorial analyses. With 160 clusters and an average of 350 beds per cluster, assuming no interaction and similar effects for each intervention, we anticipate 90% power to detect an absolute mean difference of 0.3 high-risk medications prescribed. A mixed-methods process evaluation will explore potential mechanisms underlying the observed effects, exploring targeted constructs including intention, self-efficacy, outcome expectations, descriptive norms, and goal prioritization. An economic analysis will examine cost-effectiveness

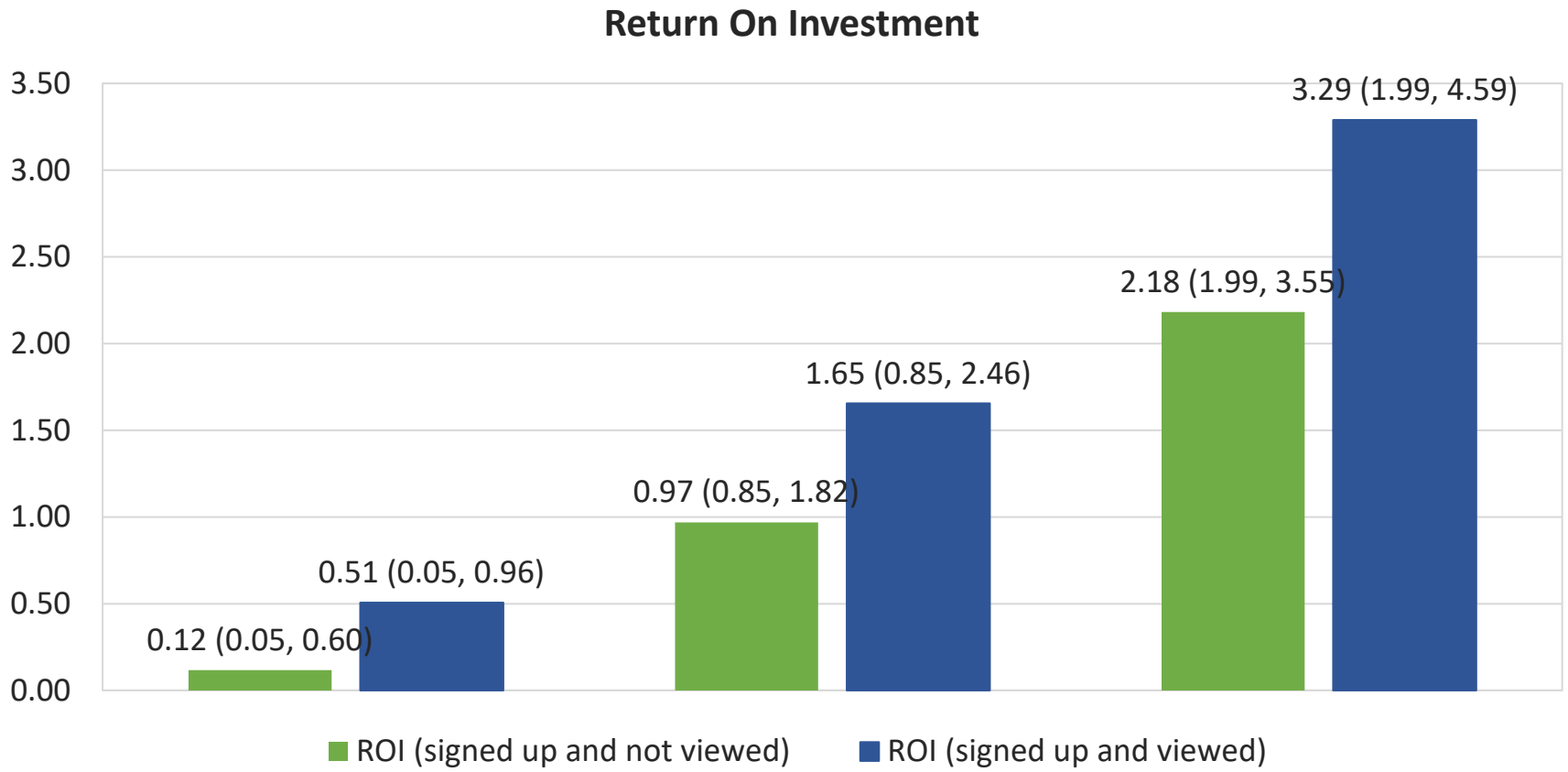
Efficient design: factorial trial

	[90%] **Comparator** [50%]	
[+] **Framing** [-]	**Top** performers and **Positive** Framing	**Median** Performance and **Positive** Framing
	Top performers and **Negative** Framing	**Median** Performance and **Negative** Framing

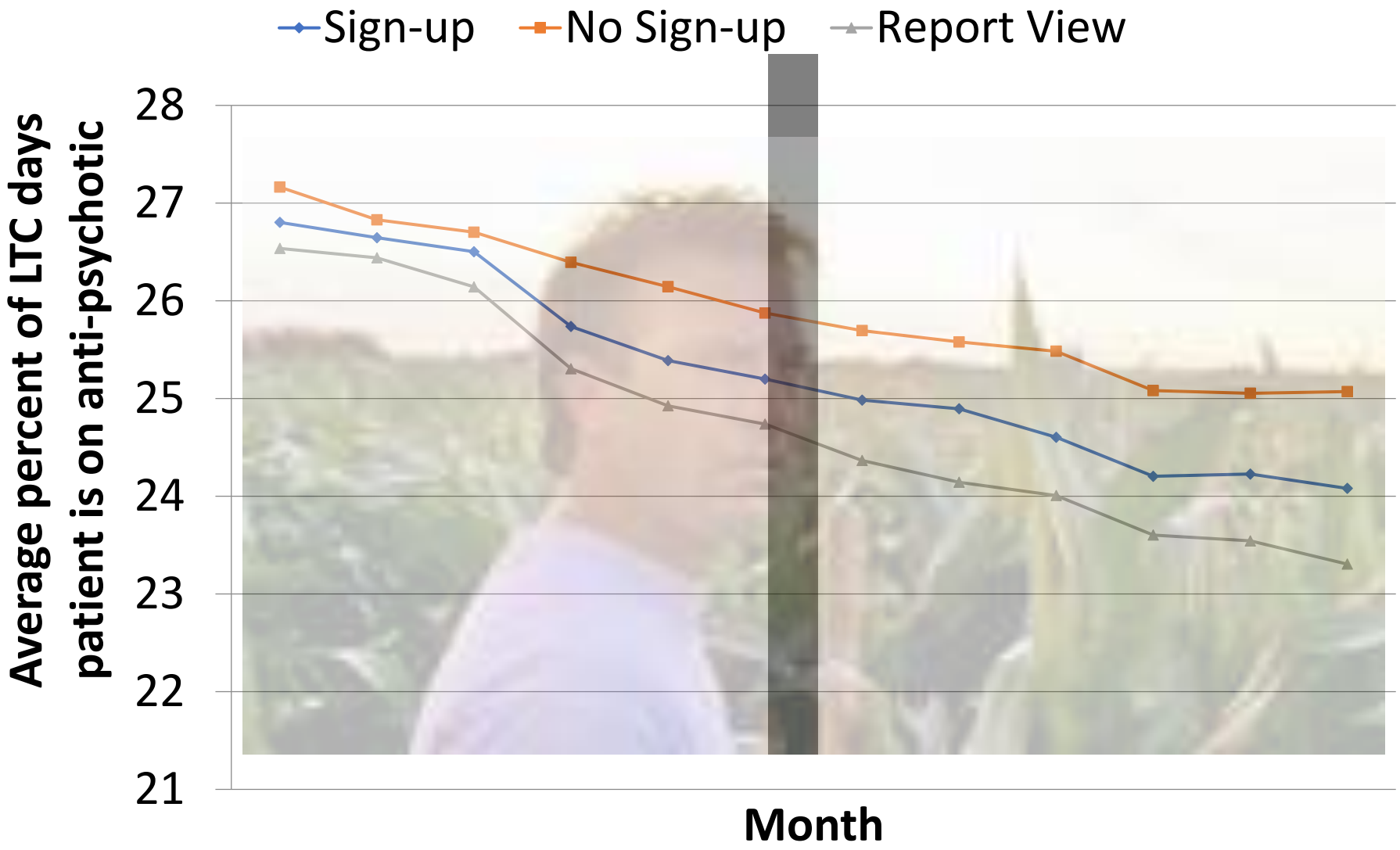
The goal is not for the recipient to 'like' the design, but to create a response that leads to action to benefit patients

Economic analysis (dollars and bodies)

- Estimated set-up and operations costs: $225,000
- Estimated research costs: $65,000



If you build it, will they come?



Testing e-mail content to encourage physicians to access an audit and feedback tool: a factorial randomized experiment

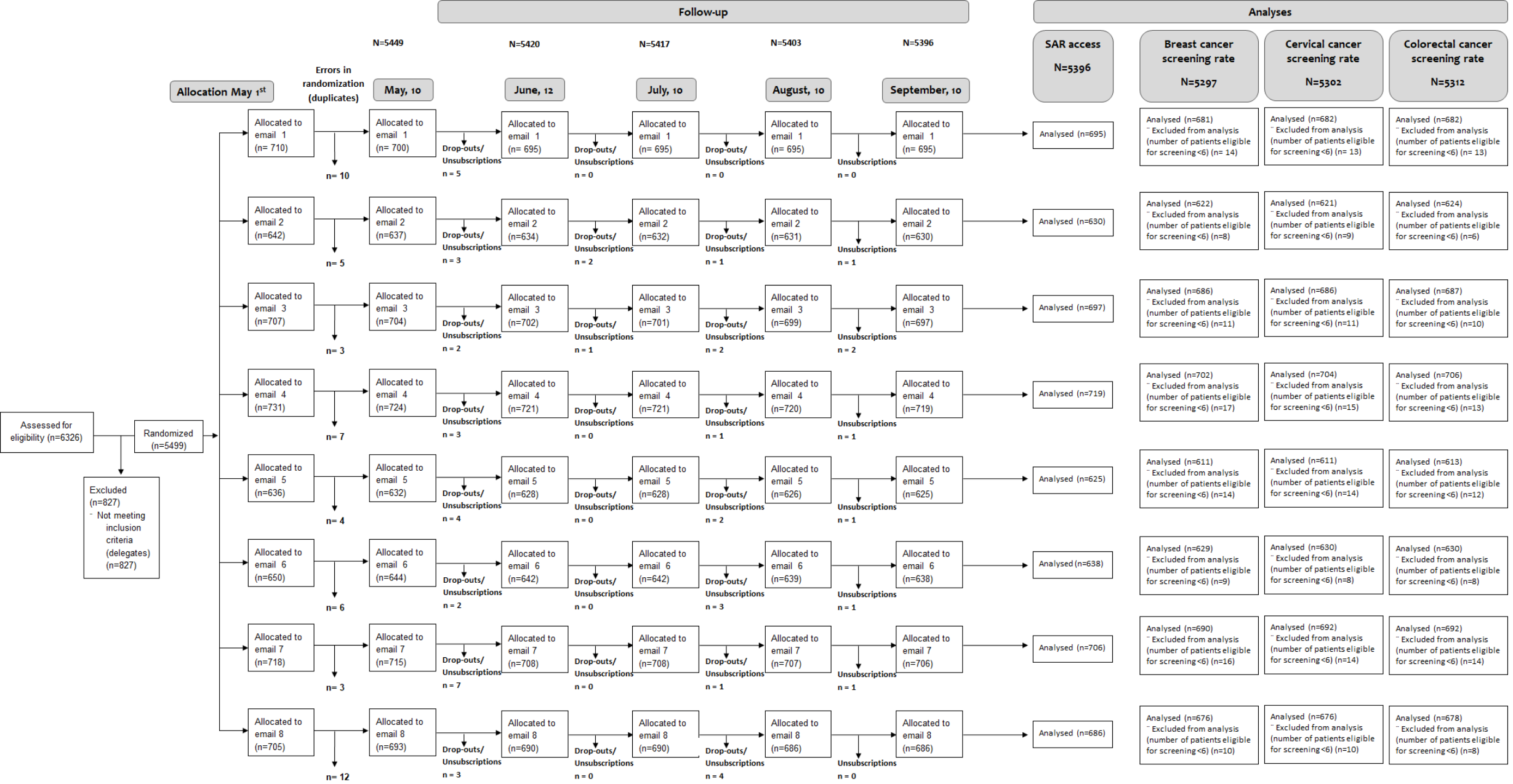
G. Vaisson BSc MSc,* H.O. Witteman PhD,* S. Chipenda-Dansokho PhD,* M. Saragosa RN MN,† Z. Bouck MPH,† C.A. Bravo MSc,† L. Desveaux PhD,† D. Llovet MA PhD,† J. Presseau BA MRes PhD,† M. Taljaard PhD,† S. Umar BA MSc,† J.M. Grimshaw MBChB PhD,† J. Tinmouth MD PhD,† and N.M. Ivers MD PhD†

ABSTRACT

Background In Ontario, an online audit and feedback tool that provides primary care physicians with detailed information about patients who are overdue for cancer screening is underused. In the present study, we aimed to examine the effect of messages operationalizing 3 behaviour change techniques on access to the audit and feedback tool and on cancer screening rates.

Methods During May–September 2017, a pragmatic 2×2×2 factorial experiment tested 3 behaviour change techniques: anticipated regret, material incentive, and problem-solving. Outcomes were assessed using routinely collected administrative data. A qualitative process evaluation explored how and why the e-mail messages did or did not support Screening Activity Report access.

Results Of 5449 primary care physicians randomly allocated to 1 of 8 e-mail messages, fewer than half opened the messages and fewer than 1 in 10 clicked through the messages. Messages with problem-solving content were associated with a 12.9% relative reduction in access to the tool (risk ratio: 0.871; 95% confidence interval: 0.791 to 0.958; $p = 0.005$), but a 0.3% increase in cervical cancer screening (rate ratio: 1.003; 95% confidence interval: 1.001 to 1.006; $p = 0.003$). If true, that association would represent 7568 more patients being screened. No other significant effects were observed.


Follow-up
Analyses
N=5449
N=5420
N=5417
N=5403
N=5396
Allocation May 1st
Errors in randomization (duplicates)
May, 10
June, 12
July, 10
August, 10
September, 10
SAR access N=5396
Breast cancer screening rate N=5297
Cervical cancer screening rate N=5302
Colorectal cancer screening rate N=5312
Assessed for eligibility (n=6326)
Randomized (n=5499)
Excluded (n=827)
- Not meeting inclusion criteria (delegates) (n=827)
Allocated to email 1 (n= 710)
n= 10
Allocated to email 1 (n= 700)
Drop-outs/ Unsubscriptions n = 5
Allocated to email 1 (n= 695)
Drop-outs/ Unsubscriptions n = 0
Allocated to email 1 (n= 695)
Drop-outs/ Unsubscriptions n = 0
Allocated to email 1 (n= 695)
Unsubscriptions n = 0
Allocated to email 1 (n= 695)
Analysed (n=695)
Analysed (n=681) ¨ Excluded from analysis (number of patients eligible for screening <6) (n= 14)
Analysed (n=682) ¨ Excluded from analysis (number of patients eligible for screening <6) (n= 13)
Analysed (n=682) ¨ Excluded from analysis (number of patients eligible for screening <6) (n= 13)
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Analysed (n=678) ¨ Excluded from analysis (number of patients eligible for screening <6) (n=8)

More Challenges and Lessons Learned

- Complex trial designs may be more difficult to explain to partners
- Continuously reflect on which is the ‘right’ implementation question and the shared goal(s) of partners
- Relationships = compromise… in questions, implementation, etc

Imp Sci Labs: two ‘types’?

	+ Sector/Problem Oriented -	
+ Intervention Oriented -	A&F to improve community dentistry	Optimizing A&F
	Community dentistry	n/a

Hunter New England Population Health Laboratory

ELSEVIER

CrossMark

Journal of Clinical Epidemiology 85 (2017) 3–11

Journal of Clinical Epidemiology

COMMENTARIES

Embedding researchers in health service organizations improves research translation and health service performance: the Australian Hunter New England Population Health example

Luke Wolfenden[a,b,c,*], Sze Lin Yoong[a,b,c], Christopher M. Williams[a,b,c], Jeremy Grimshaw[d], David N. Durrheim[a,b,c], Karen Gillham[a,b,c], John Wiggers[a,b,c]

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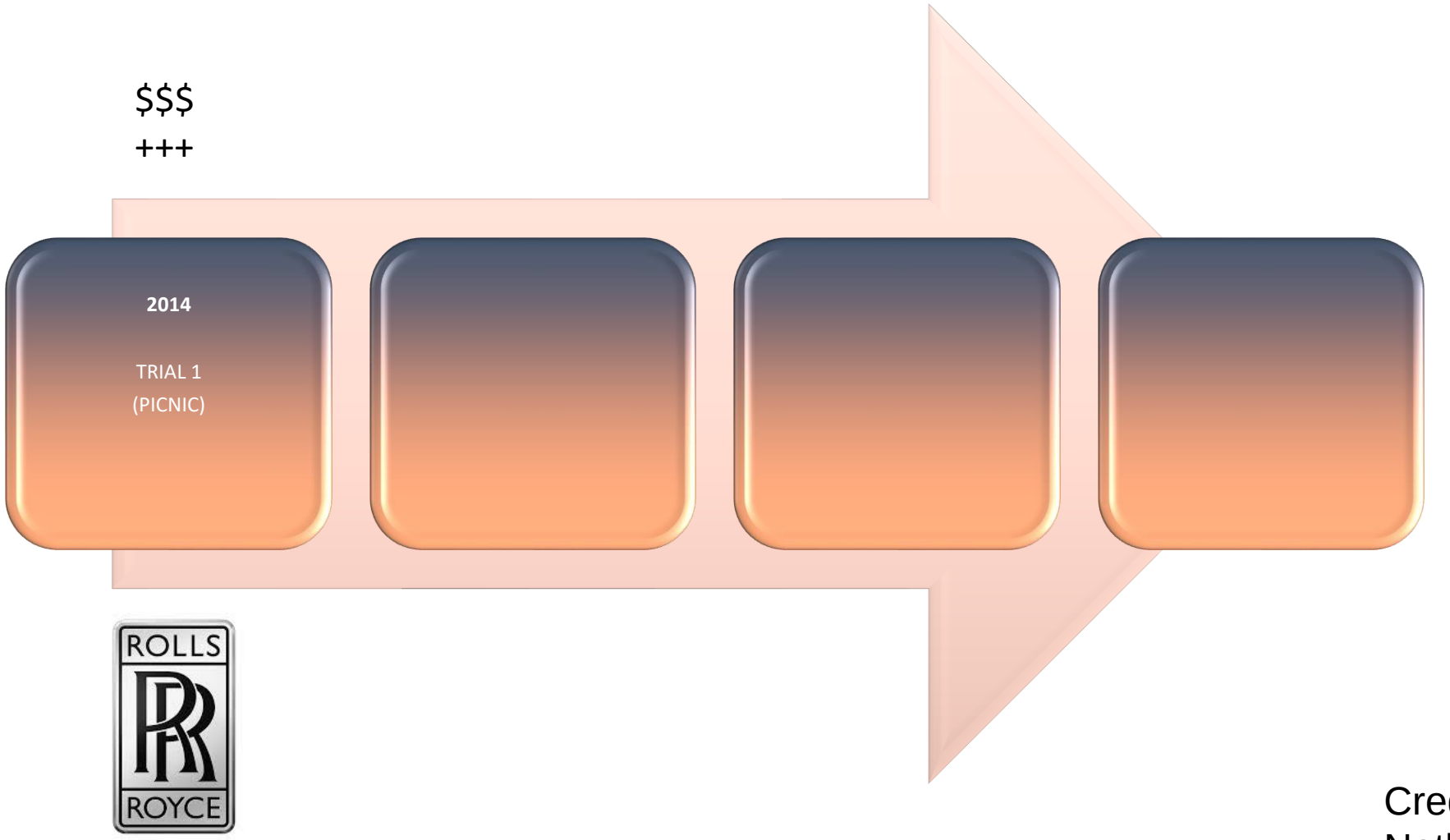
Increasing Australian schools' implementation of a mandatory state-wide school healthy food policy

- Implementation of healthy food guidelines in schools is often poor.
- Limited evidence of strategies to increase school implementation of guidelines (unsure if we could)
- Research needed to identify strategies that are effective in supporting schools' implementation of healthy food guidelines

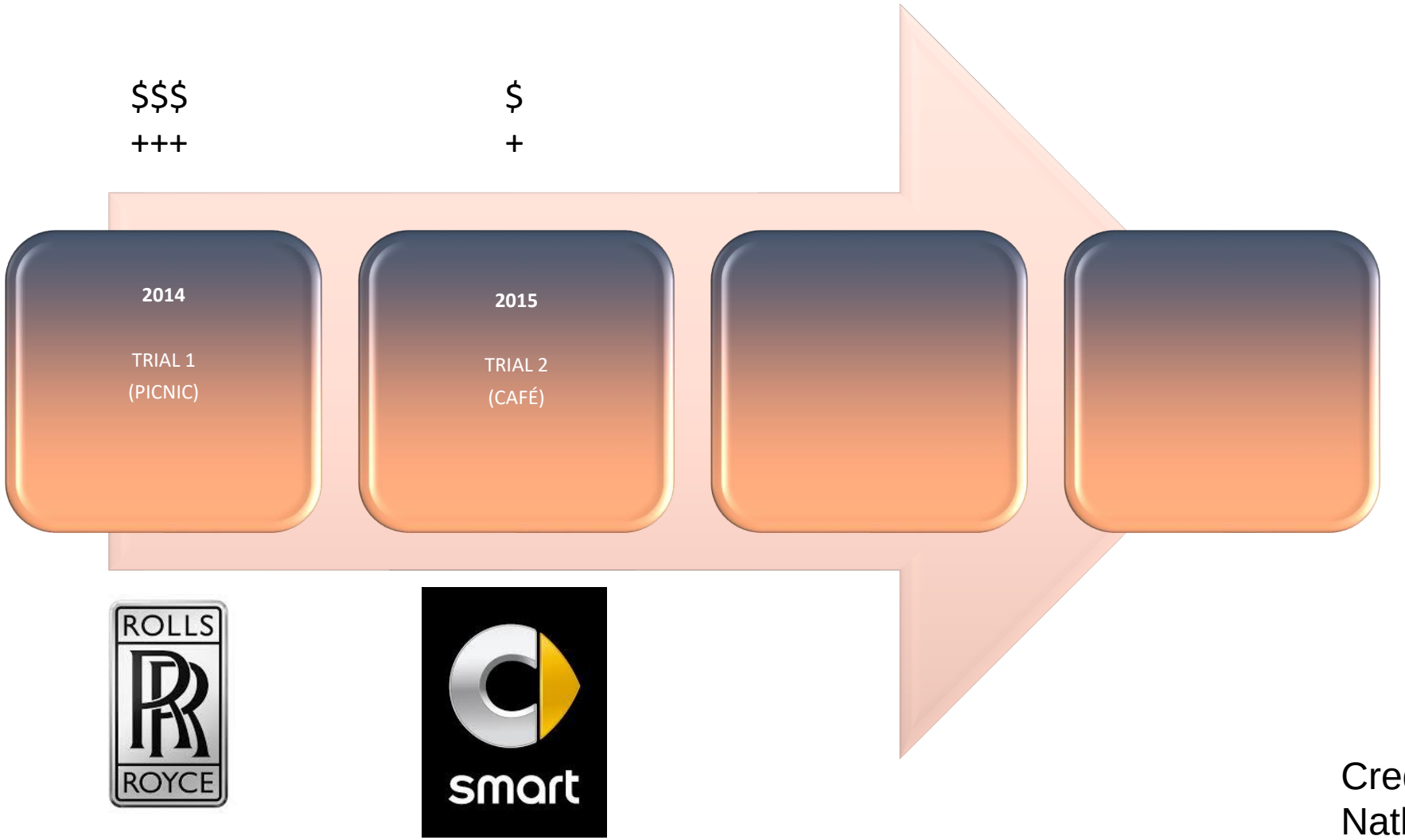
Credit: Nicole Nathan, Luke Wolfenden

Hunter New England Population Health Laboratory



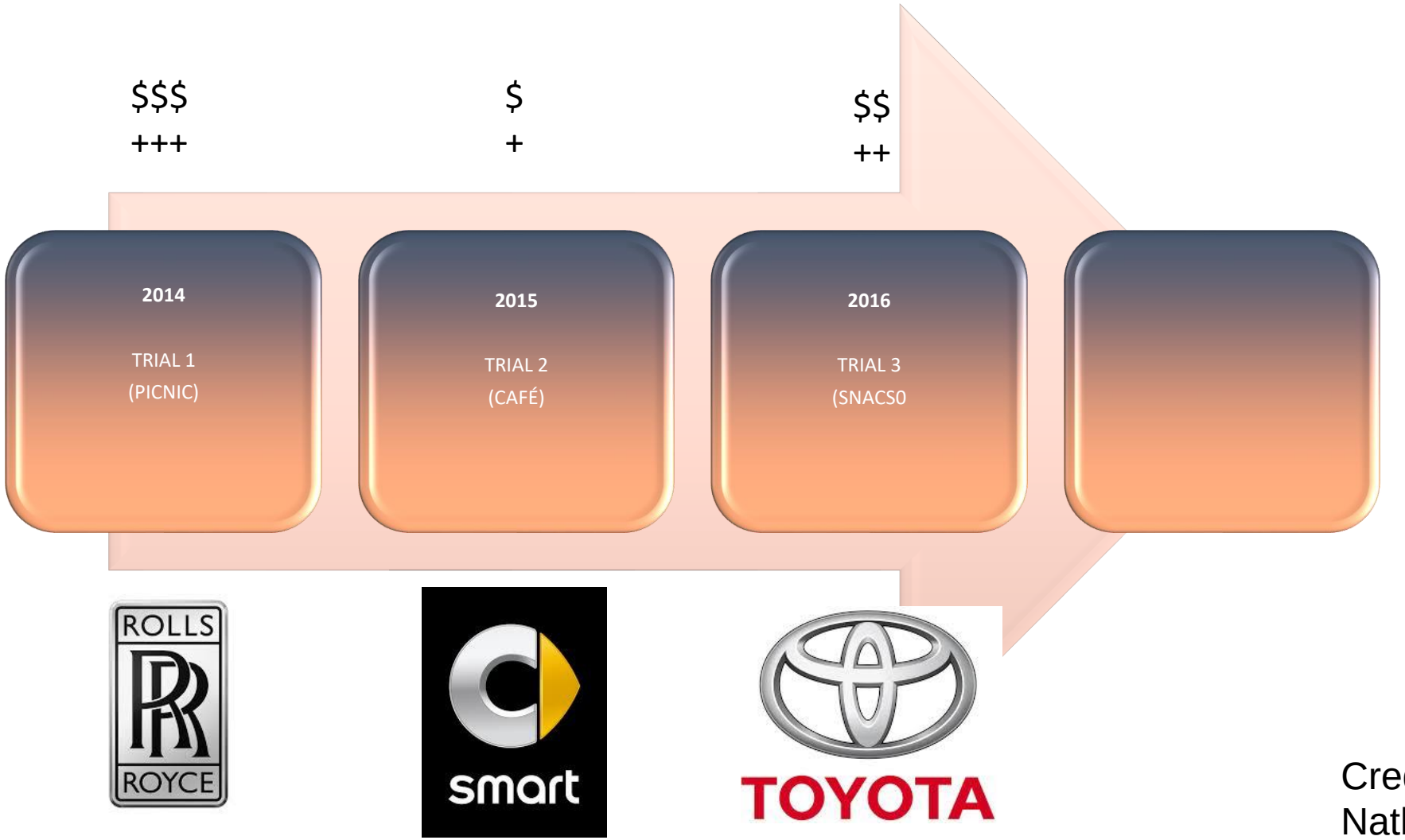
Credit: Nicole Nathan, Luke Wolfenden

Hunter New England Population Health Laboratory



Credit: Nicole Nathan, Luke Wolfenden

Hunter New England Population Health Laboratory



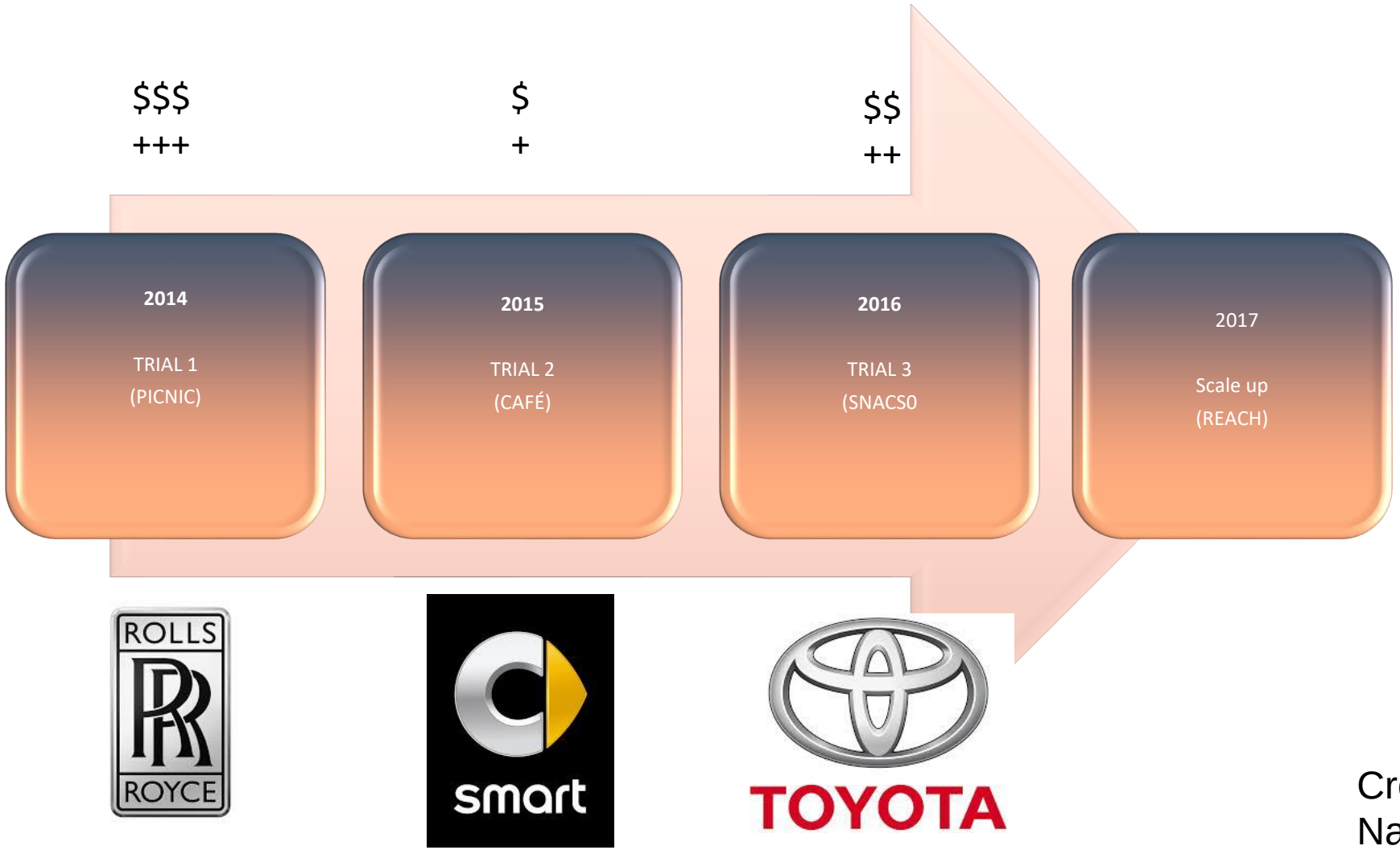
Credit: Nicole Nathan, Luke Wolfenden

Hunter New England Population Health Laboratory

- SNACS (i.e. Trial 3) became the model for service delivery for remaining schools
- Delivered to >160 schools
- Primary outcome
  - At f/up 35% of schools compared to 17% at baseline (OR = 2.8 (1.6–4.7), p = < 0.001) had menus compliant with the state healthy canteen policy
  - Maintained at 6 months f/up

Credit: Nicole Nathan, Luke Wolfenden

Hunter New England Population Health Laboratory



Credit: Nicole Nathan, Luke Wolfenden

Translation Research in A Dental Setting (TRiADS)

Clarkson *et al. Implementation Science* 2010, **5**:57
http://www.implementationscience.com/content/5/1/57

IMPLEMENTATION SCIENCE

STUDY PROTOCOL **Open Access**

The translation research in a dental setting (TRiaDS) programme protocol

Jan E Clarkson[1*], Craig R Ramsay[2], Martin P Eccles[3], Sandra Eldridge[4], Jeremy M Grimshaw[5], Marie Johnston[6], Susan Michie[7], Shaun Treweek[8], Alan Walker[9], Linda Young[10], Irene Black[9], Debbie Bonetti[1], Heather Cassie[1], Jill Francis[2], Gillian MacKenzie[10], Lorna MacPherson[11], Lorna McKee[2], Nigel Pitts[1], Jim Rennie[12], Doug Stirling[10], Colin Tilley[13], Carole Torgerson[14], Luke Vale[2]

Abstract

Background: It is well documented that the translation of knowledge into clinical practice is a slow and haphazard process. This is no less true for dental healthcare than other types of healthcare. One common policy strategy to help promote knowledge translation is the production of clinical guidance, but it has been demonstrated that the simple publication of guidance is unlikely to optimise practice. Additional knowledge translation interventions have been shown to be effective, but effectiveness varies and much of this variation is unexplained. The need for researchers to move beyond single studies to develop a generalisable, theory based, knowledge translation framework has been identified.

For dentistry in Scotland, the production of clinical guidance is the responsibility of the Scottish Dental Clinical Effectiveness Programme (SDCEP). TRiaDS (Translation Research in a Dental Setting) is a multidisciplinary research collaboration, embedded within the SDCEP guidance development process, which aims to establish a practical evaluative framework for the translation of guidance and to conduct and evaluate a programme of integrated, multi-disciplinary research to enhance the science of knowledge translation.

Methods: Set in General Dental Practice the TRiaDS programmatic evaluation employs a standardised process using optimal methods and theory. For each SDCEP guidance document a diagnostic analysis is undertaken alongside the guidance development process. Information is gathered about current dental care activities. Key recommendations and their required behaviours are identified and prioritised. Stakeholder questionnaires and

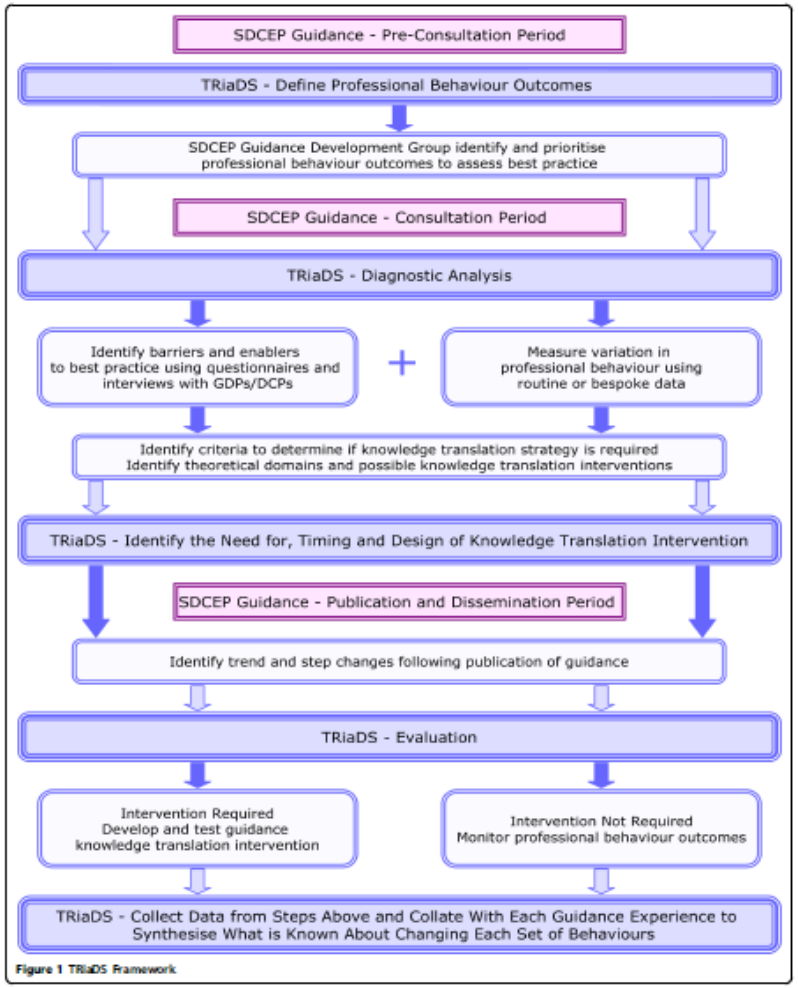


Figure 1 TRiaDS Framework

Imp Sci Labs: opportunities

IMPACT:

- Relationships: sharing of tacit and explicit knowledge
- Sustainability: evidence-based policy and results-oriented organizations
- Scale: system-wide implementation

METHODS:

- Causal attribution: advanced trial methods
- Causal explanation: embedded process evaluations
- Sequential studies

Imp Sci Labs: challenges

HEALTH SYSTEM PARTNERS:

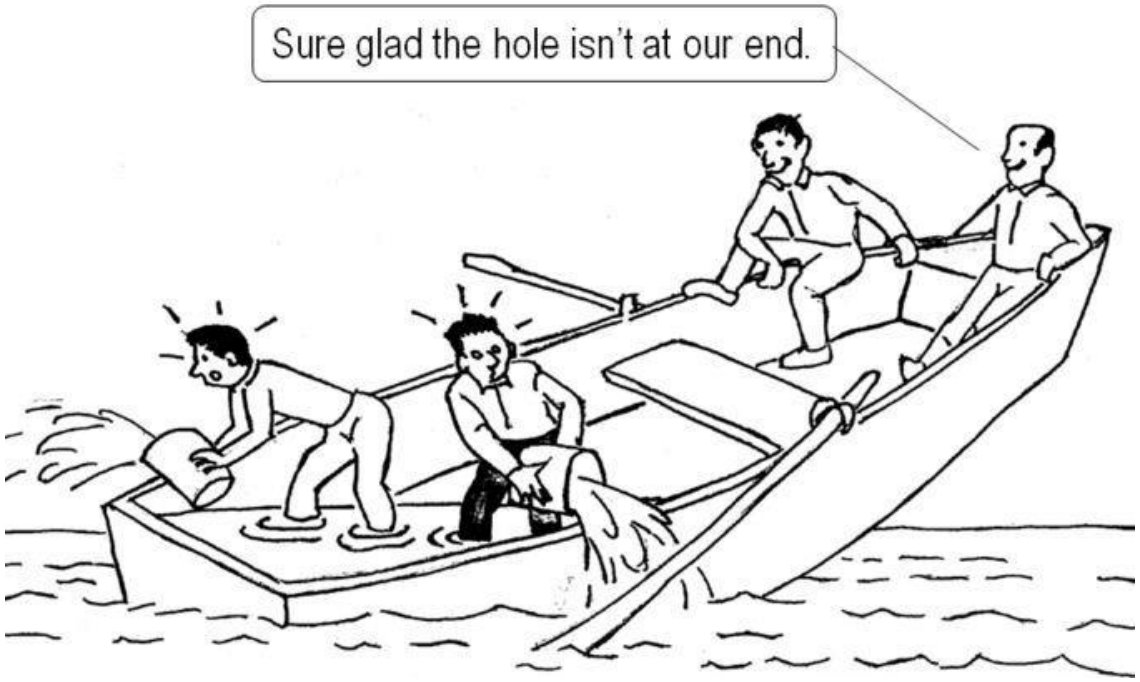
- Willingness to acknowledge arbitrariness of decisions
- Ability to respond to emerging evidence
- Compromise

RESEARCH PARTNERS:

- Lack of control over topic and outcomes and timing
- Scientific effort as a means to an end
- Compromise

Vision for Imp Sci Lab Partnerships

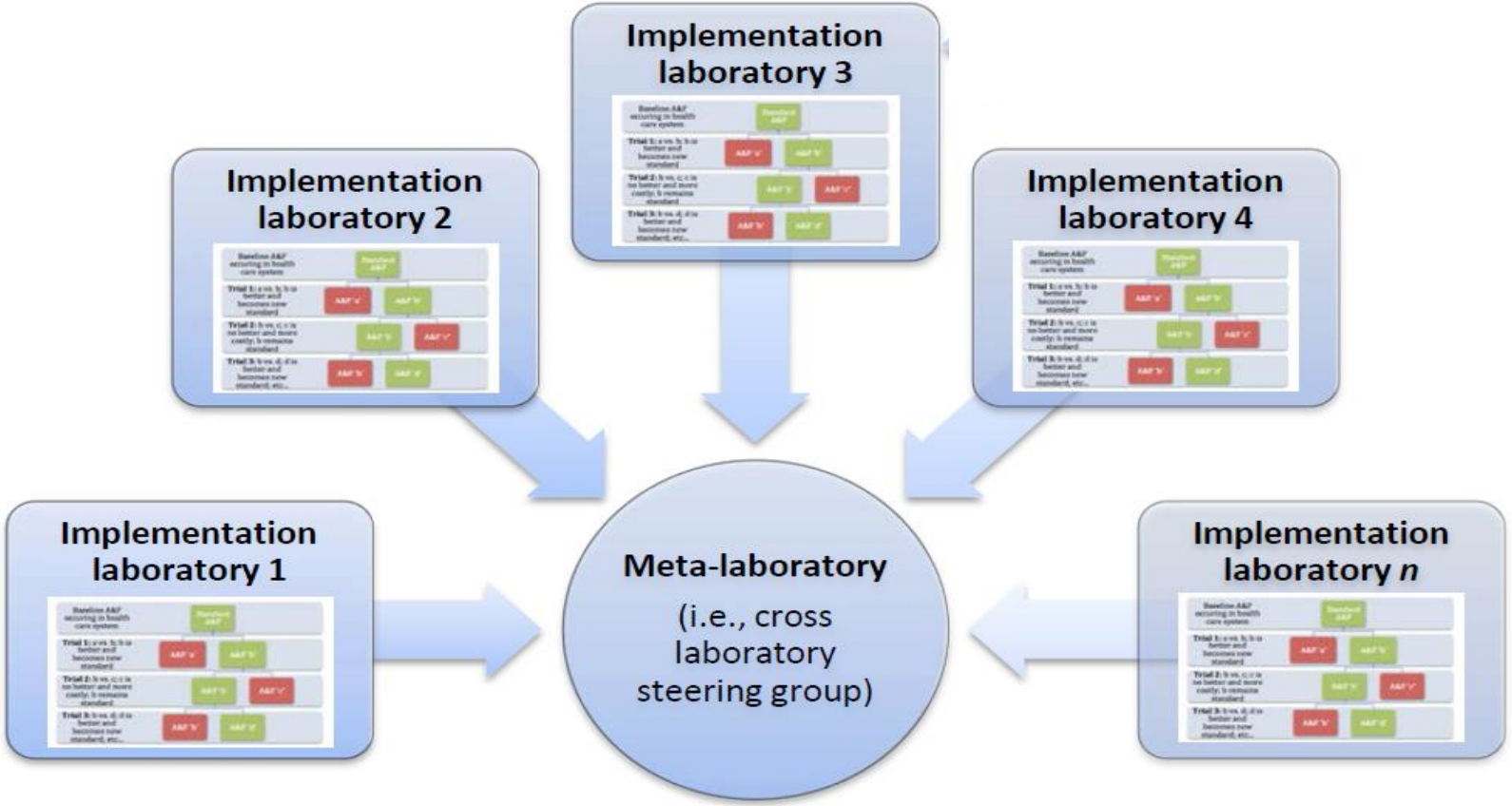
- Mutually beneficial
- Sustainable
- Scalable



‘Meta’ Implementation Labs

Creates opportunities to:

- Compare role of inner context prospectively within a lab
- Compare role of outer context across labs

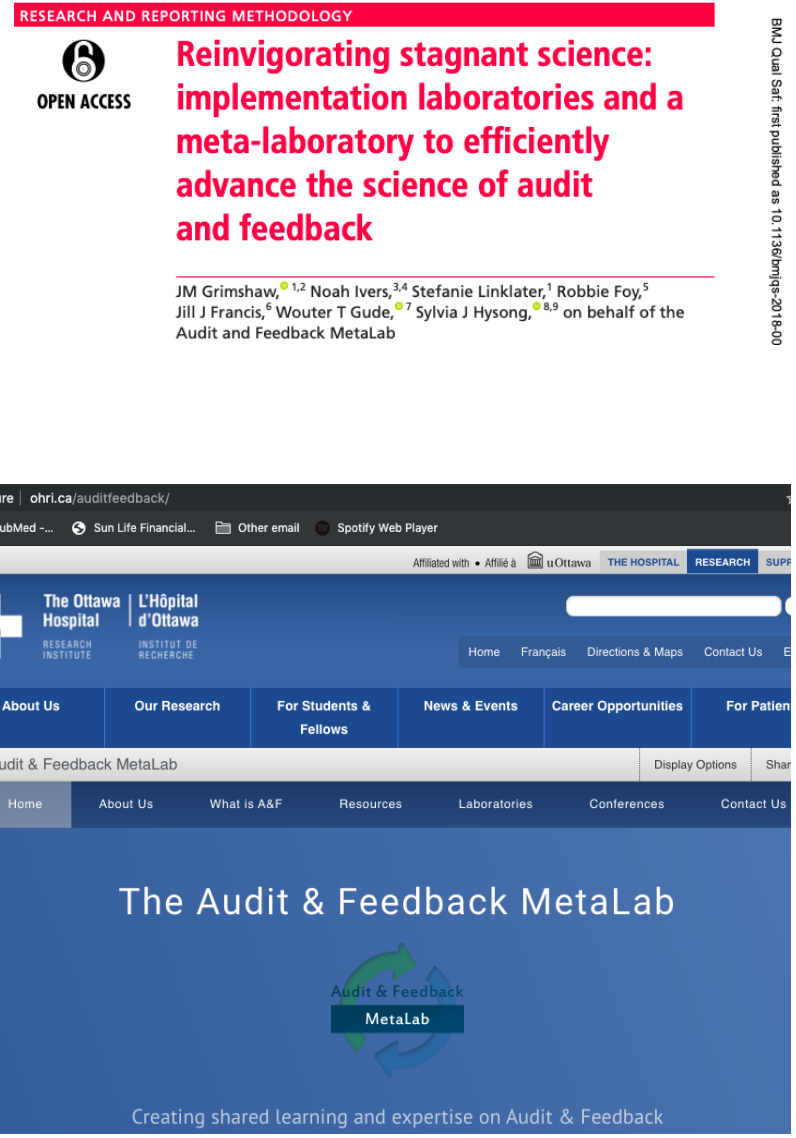


A&F MetaLab

A global community of science and practice

- 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

- http://www.ohri.ca/auditfeedback/
- @afMetaLab



Audience participation

In small groups please discuss (10 mins):

1. Potential advantages of IS Lab approach for your work
2. Barriers and facilitators to partnership-based research in your context
3. Short and long-term strategies to overcome barriers

Audience participation

FEEDBACK

BIOBREAK

(15 MINS)

Enhancing the informativeness of trials in imp sci labs

SESSION 2

Background

Rigorous evaluations (mainly cluster RCTs) of implementation interventions are required because:

- the effects are modest
- limited understanding of likely confounders/effect modifiers
- opportunity costs if ineffective or inefficient interventions recommended to health care systems

Background

- 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

Methods for enhancing informativeness

- (Better intervention design)
- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Methods for enhancing informativeness

- (Better intervention design)
- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Qualitative
  - Theory based
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Two arm RCTs

Two arm RCT

	Time
Sites	1
1	
…	
…	
…	
…	
N	

A&F intervention

No intervention

Pre-post two arm RCT

	Time	
Sites	1	2
1		
…		
…		
…		
…		
N		

Intervention

Control

Two arm RCTs

Advantages

- Simple
- Relatively straight forward to operationalise
- Maximises power

Disadvantages

- *Versus control*: no information on relative effectiveness of different interventions
- *Versus other intervention*: no control information

Multi arm RCTs

Three arm trial

	Time
Sites	1
1	
…	
…	
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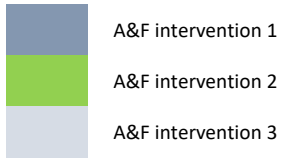
…	
N	



Multi arm RCTs – TIGER trial

Epilepsia, **45**(1):28–34, 2004
Blackwell Publishing, Inc.

Implementation Strategies for a Scottish National Epilepsy Guideline in Primary Care: Results of the Tayside Implementation of Guidelines in Epilepsy Randomized (TIGER) Trial

*Julian Davis, †Richard Roberts, †D. L. W. Davidson, ‡Angela Norman, *Simon Ogston, §Jeremy M. Grimshaw, ‖Peter Davey, ¶James Grant, and *Danny Ruta

*Department of Epidemiology & Public Health, University of Dundee, †Department of Neurology, Ninewells Hospital & Medical School, and ‡Ryehill Health Centre, Dundee, Scotland; §Ottawa Health Research Unit, University of Ottawa, Ottawa, Ontario, Canada; ‖Medicines Monitoring Unit, University of Dundee; and ¶St Margaret's Health Centre, Auchterarder, Scotland

Summary: *Purpose:* To determine the effectiveness of two dissemination and implementation strategies to implement a national guideline for epilepsy management in primary care settings.

Methods: Three-arm cluster-randomized controlled trial. The participants were general practitioners from 68 practices in Tayside, Scotland, and 1,133 of their patients with self-reported epilepsy treated with antiepileptic medications (AEDs). Practices were randomized blind to a control, intermediate, or intensive intervention. Control: Postal dissemination of a nationally developed clinical guideline. Intermediate intervention: Postal dissemination of the guideline supported by interactive, accredited workshops, and dedicated, structured protocol documents. Intensive intervention: Intermediate intervention plus a nurse specialist who supported and educated practices in the establishment of epilepsy review clinics. The primary outcome was the SF-36 health-related quality-of-life instrument. Secondary measures were a battery of prevalidated epilepsy-specific quality-of-life instruments. These were administered at baseline and after the intervention phase. Process of care was assessed by case-note review on number of review meetings and counseling sessions for epilepsy before and after the interventions.

Results: None of the intervention groups showed any change in the primary or secondary outcome measures or process-of-care measures.

Conclusions: None of the intervention strategies led to improvements in patient quality of life or quality of epilepsy care. Further research is needed to discover why the interventions failed, to identify barriers to adoption of guidelines, and to develop strategies that might improve implementation and uptake in the future. **Key Words:** Guidelines—Implementation—Epilepsy—Primary care—Quality of life.

Multi arm RCTs – TIGER trial

- TIGER trial 3 arm RCT testing three levels of intervention to improve epilepsy care in primary care:
  - A – mailed dissemination of guidelines (low level)
  - B – A plus mailed dissemination of guidelines, interactive educational workshop and practice support tools (intermediate)
  - C – B plus epilepsy care liaison nurse (intensive)

Multiple arm RCTs

Advantages

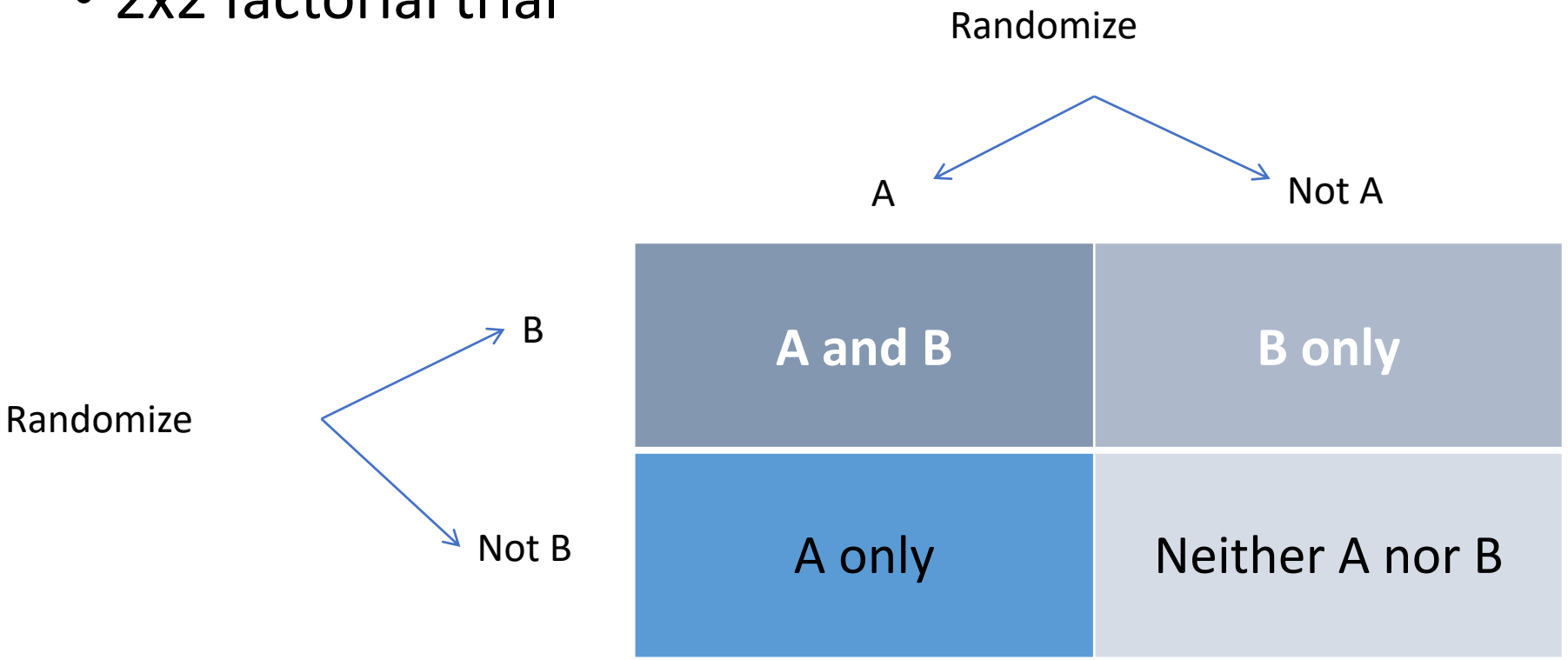
- Simple
- Relatively straight forward to operationalise
- Allows comparison of multiple interventions or levels of intervention under similar circumstances

Disadvantages

- Rapidly lose power
- Rarely have power to detect small but significant differences between different interventions

Factorial trials

- 2x2 factorial trial



Factorial trials - NEXUS

ARTICLES

Effect of audit and feedback, and reminder messages on primary-care radiology referrals: a randomised trial

Martin Eccles, Nick Steen, Jeremy Grimshaw, Lois Thomas, Paul McNamee, Jennifer Soutter, John Wilsdon, Lloyd Matowe, Gillian Needham, Fiona Gilbert, Senga Bond

Summary

Background Radiological tests are often used by general practitioners (GPs). These tests can be overused and contribute little to clinical management. We aimed to assess two methods of reducing GP requests for radiological tests in accordance with the UK Royal College of Radiologists' guidelines on lumbar spine and knee radiographs.

Methods We assessed audit and feedback, and educational reminder messages in six radiology departments and 244 general practices that they served. The study was a before-and-after, pragmatic, cluster randomised controlled trial with a 2×2 factorial design. A random subset of GP patients' records were examined for concordance with the guidelines. The main outcome measure was number of radiograph requests per 1000 patients per year. Analysis was by intention to treat.

Findings The effect of educational reminder messages (ie, the change in request rate after intervention) was an absolute change of −1·53 (95% CI −2·5 to −0·57) for lumbar spine and of −1·61 (−2·6 to −0·62) for knee radiographs, both relative reductions of about 20%. The effect of audit and feedback was an absolute change of −0·07 (−1·3 to 0·9) for lumbar spine of 0·04 (−0·95 to 1·03) for knee radiograph requests, both relative reductions of about 1%. Concordance between groups did not differ significantly.

Interpretation 6-monthly feedback of audit data is ineffective but the routine attachment of educational reminder messages to radiographs is effective and does not affect quality of referrals. Any department of radiology that handles referrals from primary care could deliver this intervention to good effect.

Introduction

General practitioners (GPs) can overuse radiological tests, particularly lumbar spine[1,2] and knee radiographs.[3] Such tests are frequently of little clinical use. Guidelines for use of these investigations are in the UK Royal College of Radiologists' publication *Making the best use of a radiology department*.[4] However, few studies have been done of interventions designed to change GPs' behaviour. Although these studies showed that GPs altered their use of radiological tests, they were badly designed,[5,6] used inappropriate analysis,[7] had short duration of follow-up,[8] or omitted cost considerations.[9] Grol[10] and Lomas[11] have summarised the theory of how to change doctors' behaviour, and Oxman and colleagues[12] have reviewed the effectiveness of interventions. Specific prompts at the time of consultation are a powerful strategy[13] and have been shown to alter GPs' behaviour—eg, when referring patients for infertility investigations[14]—but the effect of the widely-used strategy of audit and feedback is not so certain.[15,16]

We assessed two methods (audit and feedback, and educational messages) of reducing GPs' requests for radiological tests in accordance with the UK Royal College of Radiologists' guidelines. Our hypothesis was that either intervention alone would be more effective than a control and that both interventions together would be more effective than either alone.

Methods

Study design

The study was based in six radiology departments in the north-east of England and Scotland and in GPs' surgeries (practices) that referred patients exclusively to them. The study was a before-and-after, pragmatic, cluster randomised controlled trial, with a 2×2 factorial design—practices were the units of randomisation and analysis.[17] Randomisation, stratified by radiology department and practice size, was done by the study

Factorial trials - NEXUS

- NEXUS trial evaluated effects of brief educational messages appended to x-ray reports and feedback on referral rates on family practitioners' x-ray referral patterns
- 2 x 2 factorial design allowed comparison of two interventions and potential synergies/disynergies

Factorial trials

Advantages

- Comparison of multiple interventions or levels of intervention under similar circumstances
- Possibility of detecting interaction effects
- Maximises power
- Efficient (two RCTs for the price of one)

Disadvantages

- Complex to conduct and analyse
- Rarely sufficient power to detect interaction effects
- Power diminished if interaction between the interventions

More advanced trial designs

- SMART (sequential multiple assignment randomized trial) designs
- MOST (multiphase optimization strategy)
- Adaptive designs

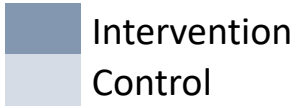
•See http://www.ohri.ca/auditfeedback/resources-webinars/ for presentations from the 2018 Society for Clinical Trials Scientific meeting.

Side bar: Policy-friendly designs

- Stepped wedge designs
- Balanced incomplete block designs

Stepped wedge designs

	Time					
Groups	1	2	3	4	5	6
1						
2						
3						
4						
5						



- All sites start in control and end in intervention condition
- Sites cross to intervention sequentially and in random order
- Outcomes are assessed repeatedly in each site over time

- Policy friendly because everyone gets the intervention (eventually)!

Stepped wedge designs

The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting

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[1]University of Birmingham, Birmingham B15 2TT, UK
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[3]University of Warwick, Coventry CV4 7AL, UK

Correspondence to:
K Hemming k.hemming@bham.ac.uk

Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/BMJ.h391)

Cite this as: *BMJ* 2015;350:h391
doi: 10.1136/bmj.h391

Accepted: 24 November 2014

The stepped wedge cluster randomised controlled trial is a relatively new study design that is increasing in popularity. It is an alternative to parallel cluster trial designs, which are commonly used for the evaluation of service delivery or policy interventions delivered at the level of the cluster. The design includes an initial period in which no clusters are exposed to the intervention. Subsequently, at regular intervals (the "steps") one cluster (or a group of clusters) is randomised to cross from the control to the intervention under evaluation. This process continues until all clusters have crossed over to be exposed to the intervention. At the end of the study there will be a period when all clusters are exposed. Data collection continues throughout the study, so that each cluster contributes observations under both control and intervention observation periods. It is a pragmatic study design, giving great potential for robust scientific evaluations that might otherwise not be possible.

Brief history of the stepped wedge cluster randomised trial

The stepped wedge cluster randomised trial has been implementations." The Gambia hepatitis intervention study (example 1) is probably the earliest and most widely known stepped wedge study.[1]

Two systematic reviews, determining the number and breadth of stepped wedge studies, have recently been conducted.[2 3] These reviews reveal that the use of this study design is on the increase and that areas of use are diverse and include HIV, cancers, healthcare associated infections, social policy, and criminal justice.

In 2007 Hussey and Hughes[4] first described methods to determine statistical power available when using a stepped wedge design. However, there is a dearth of literature on the more general methodological aspects, such as the rationale for, and conduct of, stepped wedge studies. In this article we illustrate how this new study design differs from the conventional parallel design and its variations. We also give several examples and consider several design and methodological issues, including rationale, sample size, and efficiency compared with competing designs, and highlight some important reporting and analysis considerations.

Balanced incomplete block designs

- Each participating doctor experiences both the new intervention and the status quo simultaneously for two or more clinical conditions

- ‘everyone gets something’

Balanced incomplete block design

	Condition 1	*Condition 2*
Group 1	**Intervention**	Control
Group 2	Control	**Intervention**

Balanced incomplete block design: URGE

Family Practice Vol. 20, No. 6 © Oxford University Press 2003, all rights reserved. Printed in
Doi: 10.1093/fampra/cmg605, available online at www.fampra.oupjournals.org

Cluster randomized trial of a guideline-based open access urological investigation service

RE Thomas[a], JM Grimshaw[a,b], J Mollison[c], S McClinton[d], E McIntosh[e], H Deans[f] and J Repper[g,h]

Thomas RE, Grimshaw JM, Mollison J, McClinton S, McIntosh E, Deans H and Repper J. Cluster randomized trial of a guideline-based open access urological investigation service. *Family Practice* 2003; **20:** 646–654.

Background. Out-patient services are trying to achieve effective and efficient health care in overcrowded, busy clinic settings. 'One stop' and 'open access' clinics have been advocated as a way of improving out-patient services.

Objectives. Our aim was to evaluate the effectiveness and efficiency of a guideline-based open access urological investigation service.

Methods. General practices were randomized to receive either referral guidelines and access to the investigation service for lower urinary tract symptoms (LUTS) or referral guidelines and access to the investigation service for microscopic haematuria (MH). The study population comprised 66 general practices in the Grampian region of Scotland referring 959 patients. The outcome measures were compliance with guidelines (number of recommended investigations completed), number of general practice consultations, the number and case mix of referrals,

Balanced incomplete block designs: URGE

- 2 x 2 balanced incomplete block design to evaluate guideline based open access urological investigation service in UK family practice
- 76 family practices randomised
- Two study conditions – haematuria and prostatism
- Effects evaluated on process and outcome of care

Balanced incomplete block design: URGE

	Prostatism	*Microscopic haematuria*
Group 1	**Intervention**	Control
Group 2	Control	**Intervention**

Audience participation

In small groups please discuss (10 mins):

- how to feature both formative and outcome evaluations to ensure benefit for organizational partner and for science?

Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Design philosophy

- Pragmatic trials with broad inclusion criteria (allowing exploration of whether variations in subjects modifies effects), and variation in how intervention is delivered (allowing exploration of whether variations in method of deliver modifies effects)

Design philosophy - NEXUS

- Pragmatic trial
- Intervention delivered by 6 radiology departments across wide range of settings
- Intervention embedded into routine reporting systems in 4 departments, stickers manually placed in 2 departments
- 20-30% relative reduction in x-ray requests. No difference in effects across radiology departments in different settings or by method of delivery

Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Guidance and recommendations

Process evaluation of complex interventions: Medical Research Council guidance

Graham F Moore,[1] Suzanne Audrey,[2] Mary Barker,[3] Lyndal Bond,[4] Chris Bonell,[5] Wendy Hardeman,[6] Laurence Moore,[7] Alicia O'Cathain,[8] Tannaze Tinati,[3] Daniel Wight,[7] Janis Baird[3]

Process evaluation is an essential part of designing and testing complex interventions. New MRC guidance provides a framework for conducting and reporting process evaluation studies

experience and expertise in evaluating complex interventions was assembled to produce the guidance. In line with the principles followed in developing earlier MRC guidance documents, draft guidance was produced drawing on literature reviews, process evaluation case studies, workshops, and discussions at conferences and seminars. It was then circulated to academic, policy, and practice stakeholders for comment.

Fidelity process evaluations

Was the intervention poorly designed or implemented?

Key components
• Design fidelity • Implementation fidelity • Dose • Adaptations • Reach

Methods
• Interviews • Observation • Document analysis • Surveys • Routine data

Fidelity process evaluations - COGENT

Effect of computerised evidence based guidelines on management of asthma and angina in adults in primary care: cluster randomised controlled trial

Martin Eccles, Elaine McColl, Nick Steen, Nikki Rousseau, Jeremy Grimshaw, David Parkin, Ian Purves

Abstract

Objective To evaluate the use of a computerised support system for decision making for implementing evidence based clinical guidelines for the management of asthma and angina in adults in primary care.

Design A before and after pragmatic cluster randomised controlled trial utilising a two by two incomplete block design.

Setting 60 general practices in north east England.

Participants General practitioners and practice nurses in the study practices and their patients aged 18 or over with angina or asthma.

Main outcome measures Adherence to the guidelines, based on review of case notes and patient reported generic and condition specific outcome measures.

Results The computerised decision support system had no significant effect on consultation rates, process of care measures (including prescribing), or any patient reported outcomes for either condition. Levels of use of the software were low.

Conclusions No effect was found of computerised evidence based guidelines on the management of asthma or angina in adults in primary care. This was probably due to low levels of use of the software, despite the system being optimised as far as was technically possible. Even if the technical problems of producing a system that fully supports the management of chronic disease were solved, there remains the challenge of integrating the systems into clinical encounters where busy practitioners manage patients with complex, multiple conditions.

recent systematic review of 68 controlled trials examined the effectiveness of such systems.[3] They were shown to be beneficial: nine of 15 trials of systems to improve drug dosing; one of five trials evaluating diagnostic aids; 14 of 19 trials evaluating systems to improve preventive care; and 19 of 26 trials evaluating "other" medical care such as the management of disease in hospital and ordering tests. Improvements were found in six of the 14 studies measuring patient outcomes. However, the authors reported that most of the studies had flaws in design or analysis so that the findings should be interpreted with caution. Moreover, no studies were identified in the management of chronic disease in primary care or in computerised decision support systems integrated into routine computer systems in primary care.

We undertook a pragmatic cluster randomised controlled trial of a computerised decision support system to implement clinical guidelines for the management of asthma and angina in adults in primary care.

Methods

Our study methods are reported in detail elsewhere.[4 5] We chose as chronic illnesses angina and asthma in adults; these diseases are predominantly cared for in primary care and are important because of their morbidity and mortality. We developed evidence based guidelines for the two conditions.[6 7] Our study was approved by the appropriate multicentre research ethics committee.

Study general practices

We chose the study practices because their computer

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Fidelity process evaluations - COGENT

- COGENT trial evaluated computerised decision support for chronic disease management in UK family practice
- No effects observed on process or outcome of care
- Nested case study – 6 family practices receiving intervention
- 19 semi structured interviews with 13 key informants

Fidelity process evaluations - COGENT

Practice based, longitudinal, qualitative interview study of computerised evidence based guidelines in primary care

Nikki Rousseau, Elaine McColl, John Newton, Jeremy Grimshaw, Martin Eccles

Abstract

Objective To understand the factors influencing the adoption of a computerised clinical decision support system for two chronic diseases in general practice.
Design Practice based, longitudinal, qualitative interview study.
Setting Five general practices in north east England.
Participants 13 respondents (two practice managers, three nurses, and eight general practitioners) gave a total of 19 semistructured interviews. 40 people in practices included in the randomised controlled trial (34 doctors, three nurses) and interview study (three doctors, one previously interviewed) gave feedback.
Results Negative comments about the decision support system significantly outweighed the positive or neutral comments. Three main areas of concern among clinicians emerged: timing of the guideline trigger, ease of use of the system, and helpfulness of the content. Respondents did not feel that the system fitted well within the general practice context. Experience of "on-demand" information sources, which were generally more positively viewed, informed the comments about the system. Some general practitioners suggested that nurses might find the guideline content more clinically useful and might be more prepared to use a computerised decision support system, but lack of feedback from nurses who had experienced the system limited the ability to assess this.
Conclusions Significant barriers exist to the use of complex clinical decision support systems for chronic disease by general practitioners. Key issues include the relevance and accuracy of messages and the flexibility to respond to other factors influencing decision making in primary care.

questions about why systems are or are not effective. Models of implementation of guidelines and other innovations emphasise the importance of pre-existing attitudes and the context of the intervention, as well as the nature of the intervention itself, in the successful adoption of an intervention.[5-7] We conducted a randomised controlled trial of a computerised decision support system for the primary care management of two common chronic diseases, which is reported in detail elsewhere and summarised in box 1.[8-10] In this paper we report a qualitative interview study conducted in parallel in order to illuminate trial findings.[11 12]

Methods

Design

We designed a practice based, longitudinal, qualitative interview study to enable us to examine attitudinal and contextual influences on the use of the computerised decision support system.[5-7] Interviews in clinicians' consultation rooms allowed a detailed discussion of their usual practice in relation to the index conditions and a demonstration of how the system interacted with these consultations. We considered observing clinicians interacting with the system but judged this to be

Box 1: Details of associated randomised controlled trial

Design—Before and after pragmatic cluster randomised controlled trial with a two by two incomplete block design
Setting—Sixty general practices in the north of England. Practices were eligible to participate if at least

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Health Services Research Unit, University of Aberdeen, Aberdeen
Jeremy Grimshaw *professor of health services research*
Correspondence to: M Eccles martin.eccles@ncl.ac.uk

bmj.com 2003;326:314

Fidelity process evaluations - COGENT

Interviewees were largely enthusiastic and optimistic about the benefits of computing.

BUT…

- System was felt by most general practitioners to be difficult to use and unhelpful clinically.
- System did not activate at an appropriate time within the general practice consultation.

Fidelity process evaluations - AFFINITIE

Lorencatto *et al. Implementation Science* (2016) 11:163
DOI 10.1186/s13012-016-0528-x

Implementation Science

STUDY PROTOCOL Open Access

A multidimensional approach to assessing intervention fidelity in a process evaluation of audit and feedback interventions to reduce unnecessary blood transfusions: a study protocol

Fabiana Lorencatto[1*], Natalie J. Gould[1], Stephen A. McIntyre[1], Camilla During[1], Jon Bird[2], Rebecca Walwyn[3], Robert Cicero[3], Liz Glidewell[3], Suzanne Hartley[3], Simon J. Stanworth[4], Robbie Foy[3], Jeremy M. Grimshaw[5], Susan Michie[6], Jill J. Francis[1] and for the AFFINITIE programme

Fidelity process evaluations

Implementation research trials tend to be pragmatic

We expect imperfect intervention fidelity

Attempts to improve or enhance fidelity should be seen as part of the intervention (with implications if scale up is desirable)

- Measuring intervention fidelity facilitates interpretation of a trial result
  - With fidelity x, our intervention led to y% improvement. We assume that if similar (or greater) levels of fidelity can be achieved in other settings, then similar (or greater) benefits might ensue.
  - With fidelity a, our intervention did not lead to practice improvements. We cannot rule out that if we had achieved fidelity >a that practice may have improved (but likely more resources will be required to improve fidelity).

Mechanistic process evaluations

Why did it work (or not) and can it be replicated?

Key components	Methods
• Mediators • Moderators • Interactions • Unexpected pathways	• Interviews • Observation • Document analysis • Survey • Routine data

Mechanistic process evaluation

Collect data on theoretical construct(s) alongside randomised trials to explore possible causal mechanisms

- Wherever possible:
  - build from *a priori* intervention program theory
    - micro-level theories
    - mid-level theories
  - standard measures (or standard measurement approaches) for mid-level theories
  - collect data pre and post intervention
  - minimise data collection to reduce risk of it acting as co-intervention
- (Note these are not mutually compatible!!!)

Mechanistic process evaluation – DRAM

Effect of enhanced feedback and brief educational reminder messages on laboratory test requesting in primary care: a cluster randomised trial

Ruth E Thomas, Bernard Lewis Croal, Craig Ramsay, Martin Eccles, Jeremy Grimshaw

Lancet 2006; 367: 1990–96

Health Services Research Unit, University of Aberdeen, Aberdeen, UK (R E Thomas PhD); Department of Clinical Biochemistry, NHS Grampian, Aberdeen, UK (B L Croal MD); Health Services Research Unit, University of Aberdeen, Aberdeen, UK (C Ramsay PhD); Centre for Health Services Research, School of Population and Health Sciences, University of Newcastle upon Tyne

Summary

Background Laboratory services play an important part in screening, diagnosis, and management of patients within primary care. However, unnecessary use of laboratory tests is increasing. Our aim was to assess the effect of two interventions on the number of laboratory tests requested by primary-care physicians.

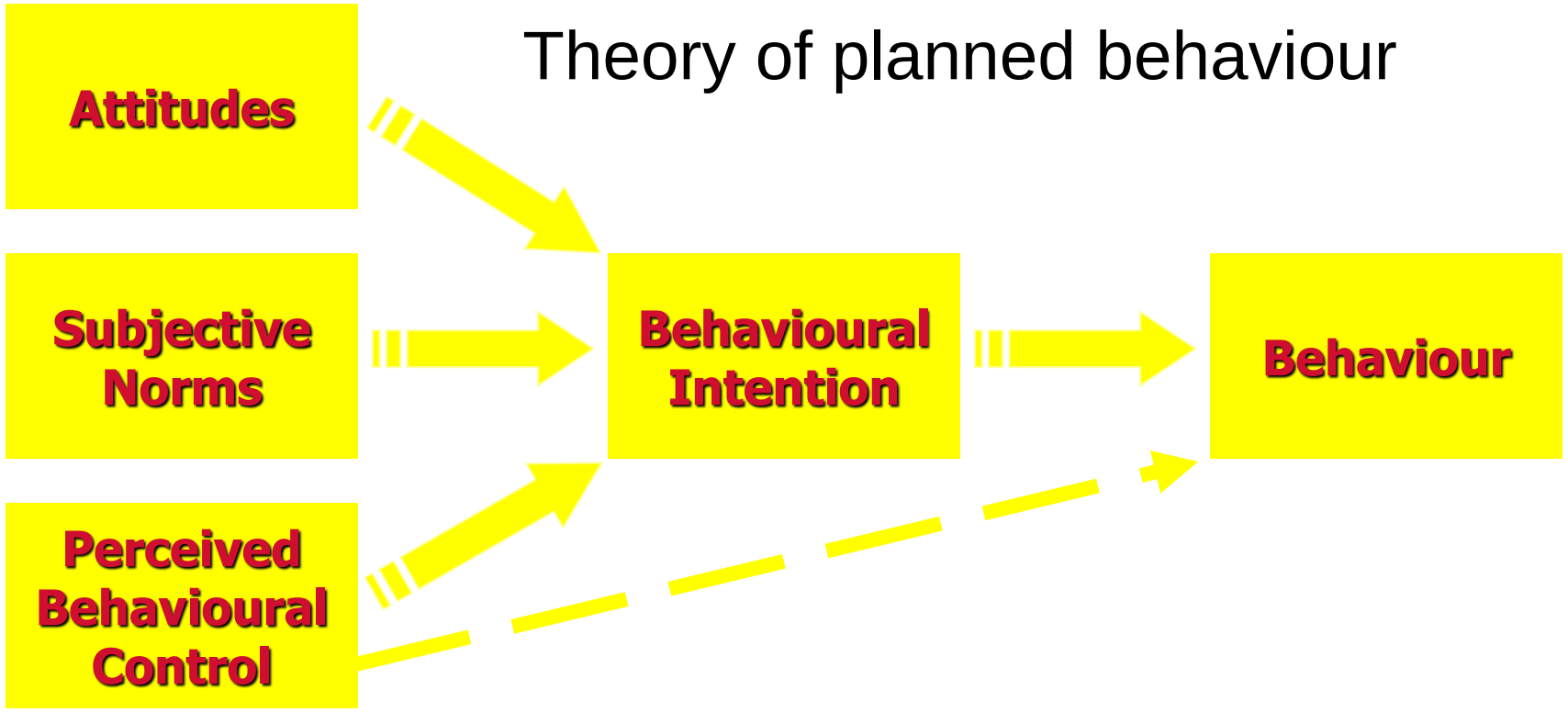
Methods We did a cluster randomised controlled trial using a 2×2 factorial design, involving 85 primary-care practices (370 family practitioners) that request all laboratory tests from one regional centre. The interventions were quarterly feedback of practice requesting rates for nine laboratory tests, enhanced with educational messages, and brief educational reminder messages added to the test result reports for nine laboratory tests. The primary outcome was the number of targeted tests requested by primary-care practices during the 12 months of the intervention. This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN06490422.

Mechanistic process evaluation – DRAM

DRAM trial evaluated effects of brief educational messages and audit and feedback on family practitioners' laboratory test ordering on 9 tests

- Improvements observed across majority of tests for both interventions (e.g. FSH), no benefit in post eradication H Pylori testing
- Intervention hypothesized to work by enhancing intention through improved attitudes and social norms

Mechanistic process evaluation – DRAM



Ajzen & Madden, (1986), *Journal of Experimental Social Psychology*, 22, 453

Mechanistic process evaluation – DRAM

Ramsay *et al. Implementation Science* 2010, **5**:71
http://www.implementationscience.com/content/5/1/71

IMPLEMENTATION SCIENCE

RESEARCH ARTICLE Open Access

Using the theory of planned behaviour as a process evaluation tool in randomised trials of knowledge translation strategies: A case study from UK primary care

Craig R Ramsay[1*], Ruth E Thomas[1], Bernard L Croal[2], Jeremy M Grimshaw[3], Martin P Eccles[4]

Mechanistic process evaluation – DRAM

Results - FSH

	Intention (1-7)	Attitudes (1-7)	Social norms (1-7)	PBC (1-7)
Control	4.3	4.2	4.2	2.0
Feedback only	5.6	5.2	4.9	1.5
Educational messages	6.0	5.5	5.2	1.5
Feedback and messages	6.0	5.7	5.2	1.5

Mechanistic process evaluation – DRAM

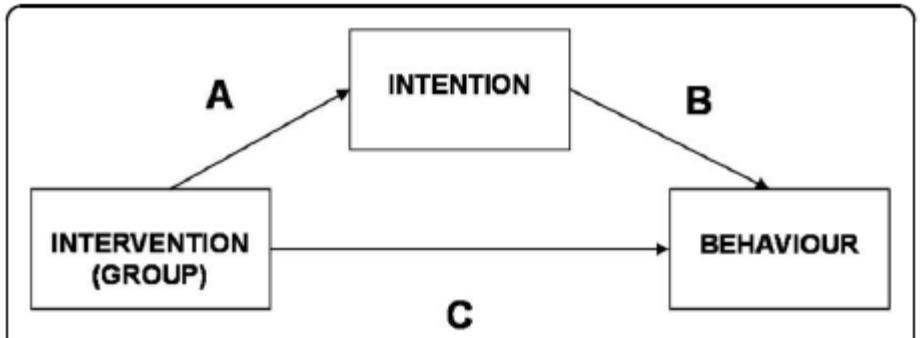


Figure 2 Mediation Model - Intervention group as the predictor of behaviour, intention as the mediator. The direct effect of the intervention allocation on behaviour is the coefficient **C** in the path diagram above. The indirect effect (often called the mediated effect) hypothesises that the observed intervention effect is due to a causal relationship whereby the intervention allocation "causes" the mediator variable (intention) to change and that in turn "causes" the behaviour to change. The indirect effect is therefore the product of the coefficients **A** and **B** in the statistical model and the direct effect is **C**. The strength of the mediation is determined by the difference between the direct minus indirect effect.

Mechanistic process evaluation – DRAM

Table 6 Mediational analysis of intentions on trial result

	Ferritin	FSH	HPS
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
Main effect:			
Reminders			
Direct effect	-1.33 (-6.78, 4.11)	-1.11 (-3.35, 1.12)	-1.37 (-4.87, 2.13)
Indirect effect	-0.39 (-2.70, 1.22)	-0.86 (-2.53, 0.19)	0.21 (-.44, 1.47)
Percentage effect mediated by intentions	29%	77%	0%
Enhanced Feedback			
Direct effect	-4.57 (-9.85, 0.70)	-0.66 (-2.91, 1.60)	1.55 (-1.94, 5.05)
Indirect effect	-1.31 (-3.66, 0.16)	-0.15 (-1.19, 0.50)	-0.10 (-1.44, 0.83)
Percentage effect mediated by intentions	28%	23%	0%

Mechanistic process evaluation

Implementation Science

BioMed Central

Study protocol

Open Access

Looking inside the black box: a theory-based process evaluation alongside a randomised controlled trial of printed educational materials (the Ontario printed educational message, OPEM) to improve referral and prescribing practices in primary care in Ontario, Canada

Jeremy M Grimshaw*[†1,2], Merrick Zwarenstein[†3,4], Jacqueline M Tetroe[†1,6,12], Gaston Godin[†5], Ian D Graham[†1,6,12], Louise Lemyre[†2,7], Martin P Eccles[†8], Marie Johnston[†9], Jillian J Francis[†10], Jan Hux[†3], Keith O'Rourke[†1], France Légaré[†11] and Justin Presseau[†7]

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Mechanistic process evaluation

	Process evaluation +	**Process evaluation -**
Trial result +	• Intervention changed behavior through hypothesized mediators	• Intervention changed behavior through other (non measured) mediators • Measures used not sensitive predictors of behavior change • Selection bias (responders to mechanistic study nor representative of whole population)
Trial result -	• Intervention led to changes in mediators but not sufficient for behavior change • Selection bias (responders to mechanistic study nor representative of whole population)	• Intervention did not activate mediators or change behavior

Audience participation

In small groups please discuss (5 mins):

- Which methods might be viable how to make your lab as informative as possible for partners (and for other labs)?
- What resources and skills sets are available and which are needed to use those methods?

Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Temporal analyses

- Implementation interventions may take time to ‘bed down’ in a specific setting (‘learning effects’)
- Implementation interventions may decay over time (‘decay effects’)
- If we evaluate the average effect of an intervention over a period of time we may underestimate its effects if learning effect or overestimate its effects/substainability if decay effects

Depending on outcome data, it may be possible to collect data over defined period times to allow exploration of learning and decay effects

Temporal analyses - NEXUS

- NEXUS trial evaluated effects of brief educational messages and audit and feedback on family practitioners' x-ray referral patterns
- Educational messages - 20-30% relative reduction in x-ray requests
- Audit and feedback - no effect

Temporal analyses - NEXUS

Clinical Radiology (2003) **58**: 319–321
doi:10.1016/S0009-9260(02)00524-X, available online at www.sciencedirect.com

Assessing the Long-term Effect of Educational Reminder Messages on Primary Care Radiology Referrals

C. R. RAMSAY*, M. ECCLES†, J. M. GRIMSHAW‡, N. STEEN†

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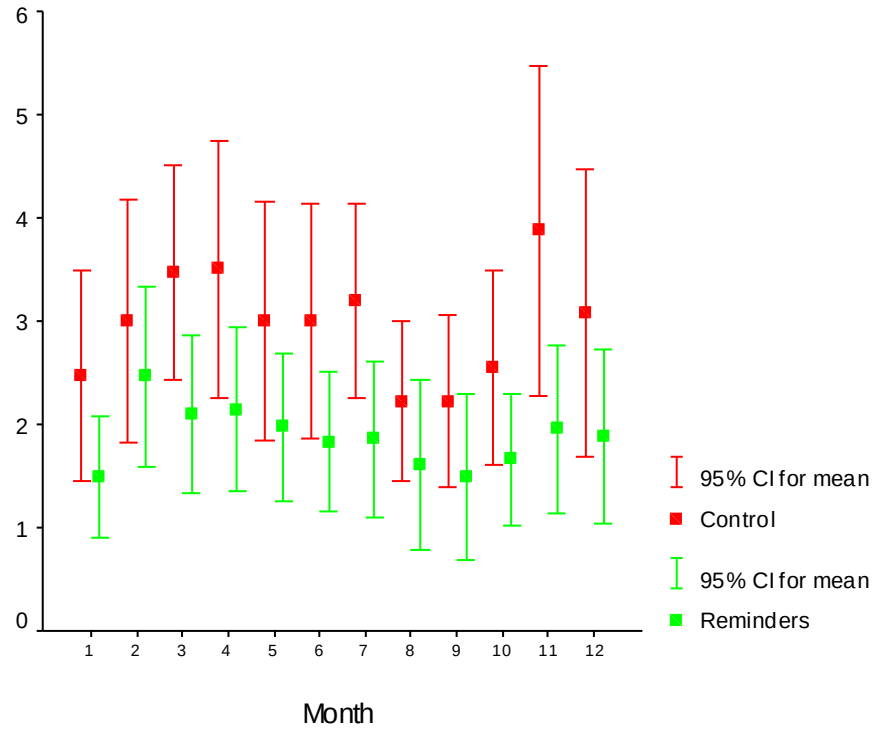
Received: 9 July 2002 Revised: 28 October 2002 Accepted: 7 November 2002

AIM: To investigate whether the effect of educational reminder messages for knee and lumbar spine radiographs varied over a 12 month period.
MATERIALS AND METHODS: In a previous randomized, controlled trial, educational reminder messages attached to x-ray reports were shown to be effective in reducing the number of radiograph requests by general practitioners for knee and lumbar spine radiographs. In this study, all radiology departments from the previous trial were asked for monthly referral records for the 12 month intervention period for knee and lumbar spine radiographs for each general practice. Poisson regression was used to test for a change over time in the number of referrals between control and intervention practices.
RESULTS: Data were obtained for 66% of the general practices in the main trial. The number of referrals for both knee and lumbar spine radiographs remained consistently and statistically significantly lower in the educational reminder messages group compared with the control group (relative risk = 0.65 and 0.64, respectively). There was no evidence that this difference increased or decreased throughout the 12 month period.
CONCLUSIONS: The effect of educational reminder messages was produced as soon as the intervention was delivered and maintained throughout the intervention period. There was no evidence of the effect of the intervention wearing off. Ramsay C. R. *et al.* (2003). *Clinical Radiology* **58**, 319–321.

Temporal analyses - NEXUS

- The effect of educational reminder messages was produced as soon as the intervention was delivered and maintained throughout the intervention period.
- There was no evidence of the effect of the intervention wearing off.

Mean number of knee x-rays by month

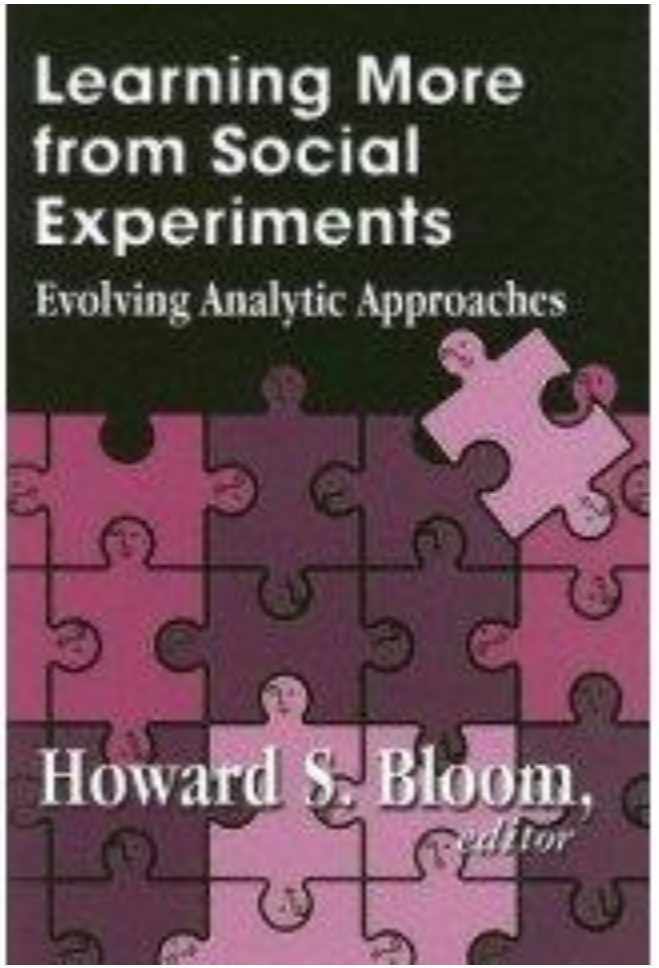


Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Analytical approaches

- Bloom HS (ed) (2005) Learning more from social experiments. Evolving analytical Approaches. Sage Publications



Analytical approaches

- Pragmatic multisite trials usually involve some variation in context of intervention sites, of intervention implementation and of intervention effectiveness across sites
- Bloom suggests that using hierarchical approaches to analyzing data that make use of these natural variations will provide greater insight into mediators and moderators of interventions

Analytical approaches

- Factors influencing the effectiveness of complex interventions include:
  - The way the program is implemented
  - Specific content (activities and services) of the program
  - The socio-economic environment
  - Types of people it serves

Analytical approaches

Worked example – targeting low income parents who qualify for cash welfare to increase enrollees' employment and earnings

- Larger effects of programs that:
  - Emphasized quick job entry
  - Emphasized personalized attention
  - Had smaller staff caseload
  - Had agreement on program goals between staff and supervisors
  - Did not include basic education
  - Were not in lowest unemployment areas

Analytical approaches

Worked example – targeting low income parents who qualify for cash welfare to increase enrollees' employment and earnings

- Larger effects of programs that targeted clients with:
  - High school graduate or had a GED
  - Three or more children
  - More welfare dependent (upon welfare continuously for 12 months)

Analytical approaches

Conditions for successful application of approach:

- Adequacy of model as conceptual and theoretical framework
- Quality and consistency of data
- Appropriateness of analyses
- Statistical properties of model

Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

Development of Ex Post Program theory

THE MILBANK QUARTERLY
A MULTIDISCIPLINARY JOURNAL OF POPULATION HEALTH AND HEALTH POLICY

Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program

MARY DIXON-WOODS, CHARLES L. BOSK, EMMA LOUISE AVELING, CHRISTINE A. GOESCHEL, and PETER J. PRONOVOST

University of Leicester; University of Pennsylvania; Johns Hopkins University

Methods for enhancing informativeness

- Design elements
- Design philosophy
- Process evaluations
  - Intervention fidelity
  - Intervention mechanisms
- Temporal evaluations
- Analytical approaches
- Ex post program theory
- Economic evaluation

BIOBREAK

(15 MINS)

CASE STUDY

SESSION 3

Case study: The RAPID study

PLOS | MEDICINE

RESEARCH ARTICLE

An Audit and Feedback Intervention for Reducing Antibiotic Prescribing in General Dental Practice: The RAPiD Cluster Randomised Controlled Trial

Paula Elouafkaoui[1,2], Linda Young[1]*, Rumana Newlands[3], Eilidh M. Duncan[3], Andrew Elders[4], Jan E. Clarkson[1,2], Craig R. Ramsay[3], Translation Research in a Dental Setting (TRiaDS) Research Methodology Group[¶]

1 NHS Education for Scotland (NES), Dundee Dental Education Centre, Frankland Building, Dundee, United Kingdom, **2** Dental Health Services Research Unit (DHSRU), University of Dundee, Park Place, Dundee, United Kingdom, **3** Health Services Research Unit (HSRU), University of Aberdeen, Health Sciences Building, Foresterhill, Aberdeen, United Kingdom, **4** NMAHP Research Unit, Glasgow Caledonian University, Cowcaddens Road, Glasgow, United Kingdom

¶ Membership of the Translation Research in a Dental Setting (TRiaDS) Research Methodology Group is provided in the Acknowledgments.
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OPEN ACCESS

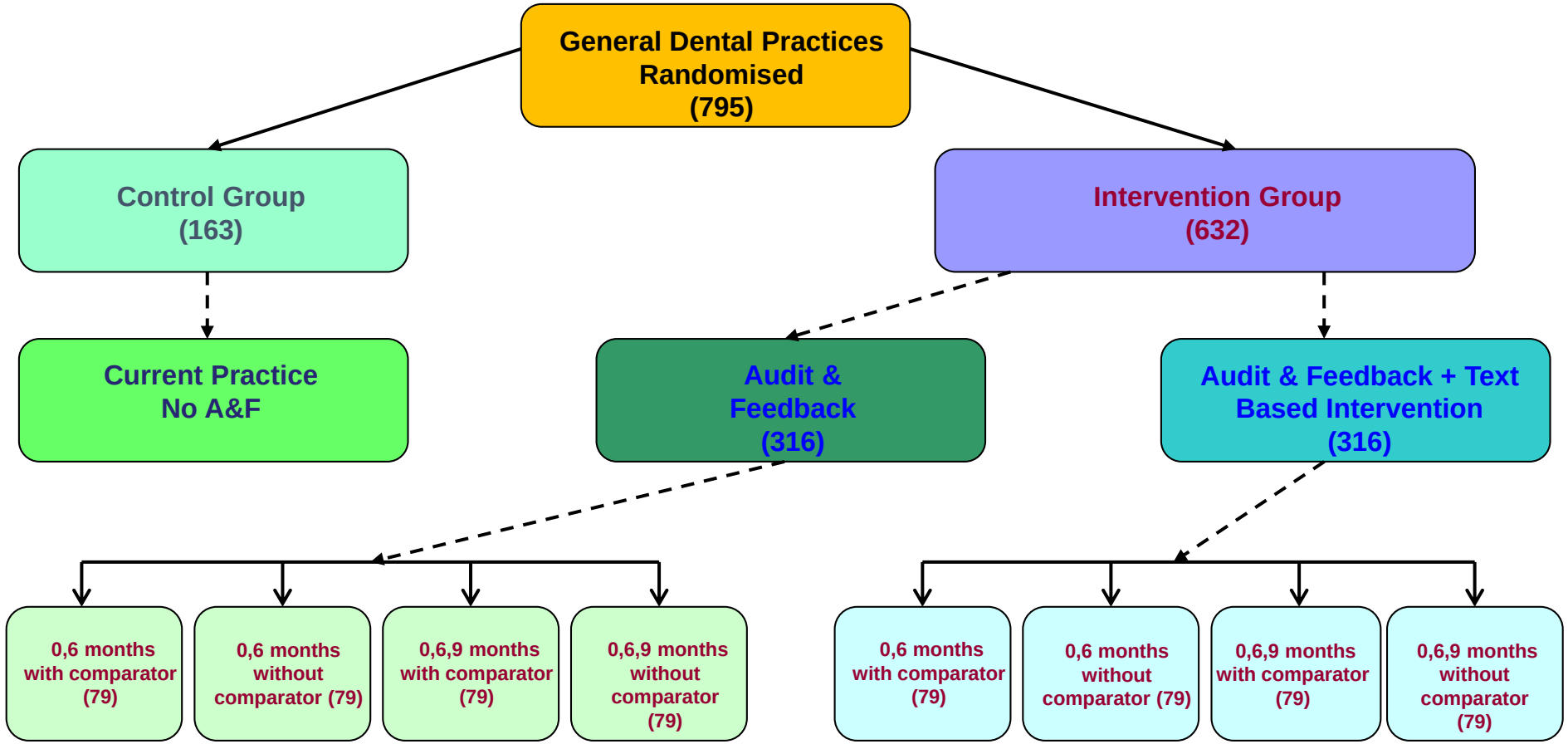
Citation: Elouafkaoui P, Young L, Newlands R,

Case study: The RAPID study

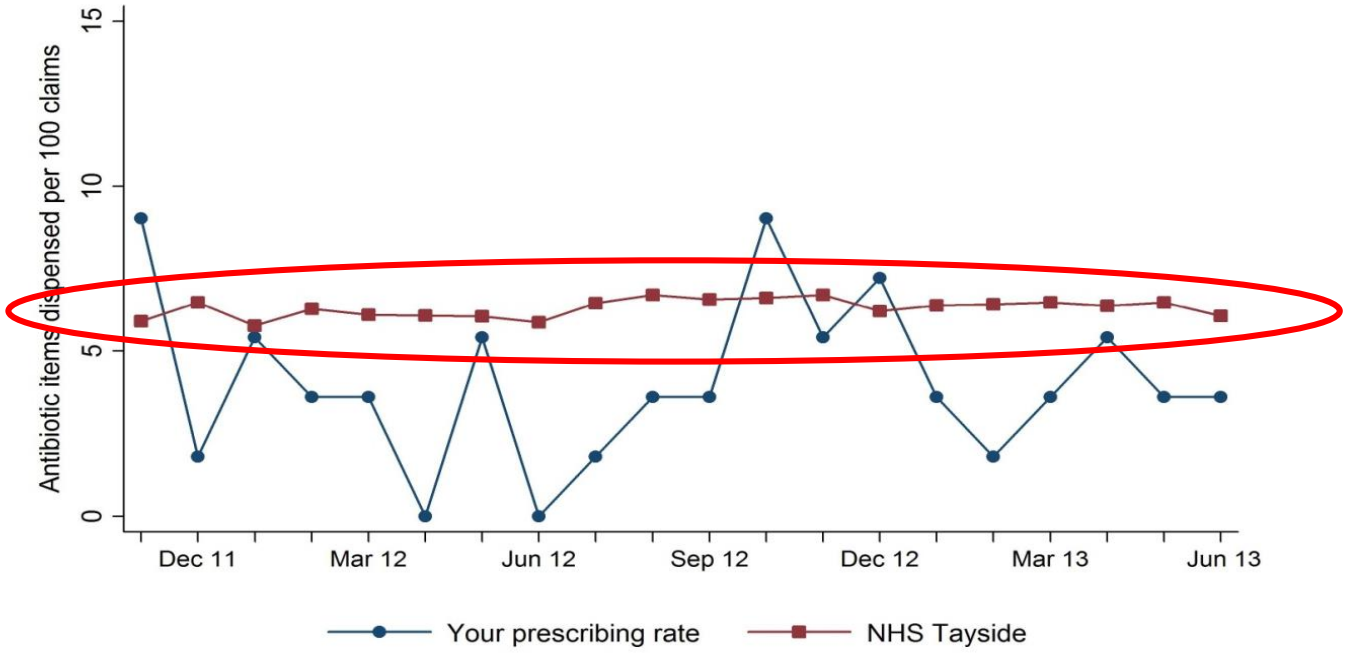
Dental healthcare mostly provided via public insurance (National Health Service, NHS)

- 1000 NHS primary care dental practices
  - 3,200 dentists
- The RAPiD study aimed to assess the impact of individualised audit and feedback (A&F) interventions on dentists' antibiotic prescribing rates
- May 2013: Launched A&F intervention
  - Routine prescribing data updated monthly

Case study: The RAPID study



Antibiotic Prescribing Rate
Mr A N Other



Your prescribing rate is your monthly number of antibiotic items dispensed multiplied by 100 and divided by the average monthly number of claims made on your ordinary lists at this practice between November 2011 and June 2013. The health board rate is the overall ordinary list prescribing rate for current dentists in non-salaried practices in NHS Tayside. (Source: ISD Scotland. Data as at October 2013)

Prescribing courses of antibiotic treatment can encourage the development of antimicrobial resistance and therefore must be kept to a minimum.

As a first step in the treatment of bacterial infections, use local measures. For example, drain pus if present in dental abscesses by extraction of the tooth or through root canals, and attempt to drain any soft-tissue pus by incision.

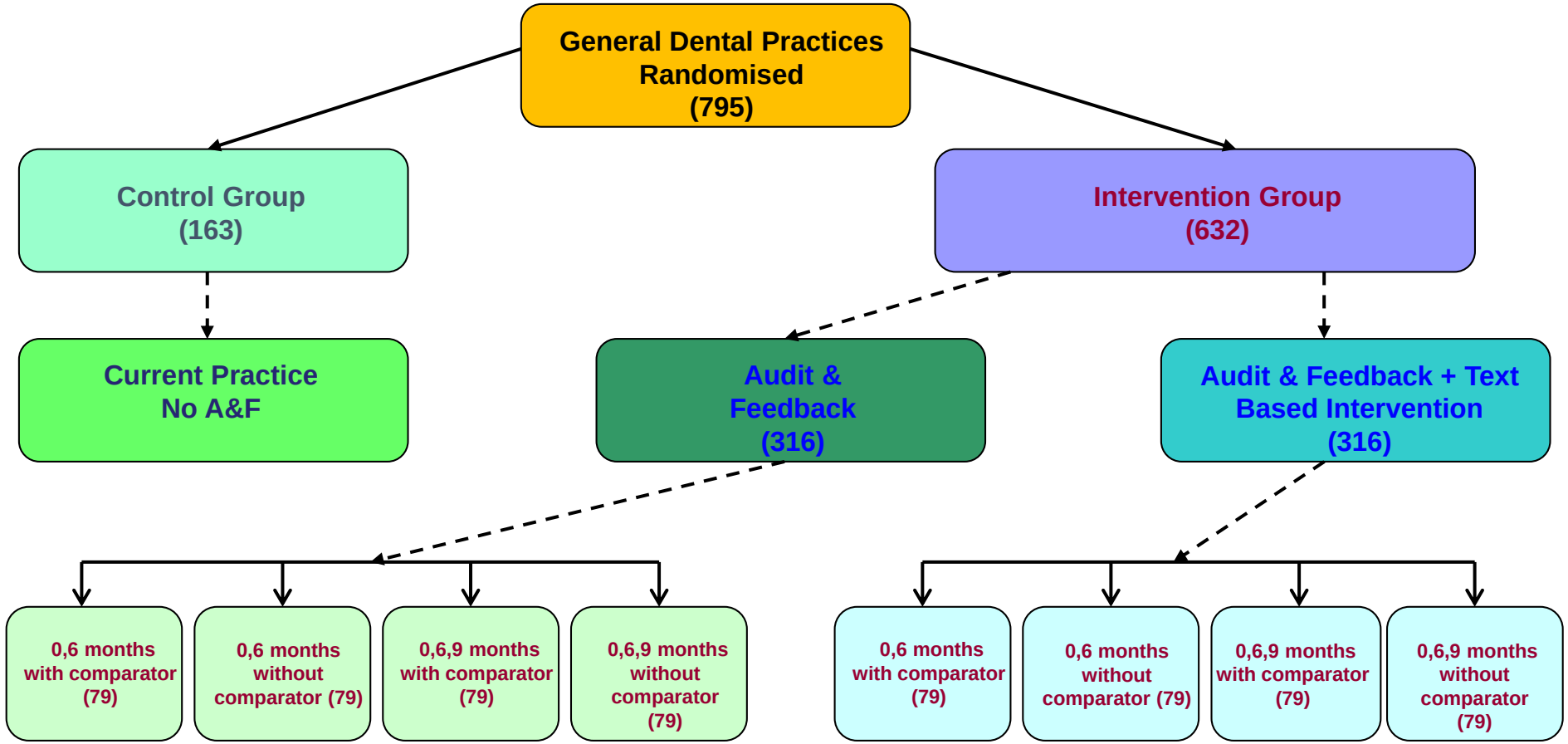
This should be the first step even if patients request antibiotics and even when time is short.

Antibiotics are appropriate for oral infections where there is evidence of spreading infection, systemic involvement or persistent swelling despite local treatment.

Use antibiotics in conjunction with, and not as an alternative to, local measures.

If you would like to discuss any part of this feedback please contact: Dr Paula Elouafkaoui, Tel: 01382 740913, e-mail: TRiaDS@nes.scot.nhs.uk.

Case study: The RAPID study



Case study: The RAPID study

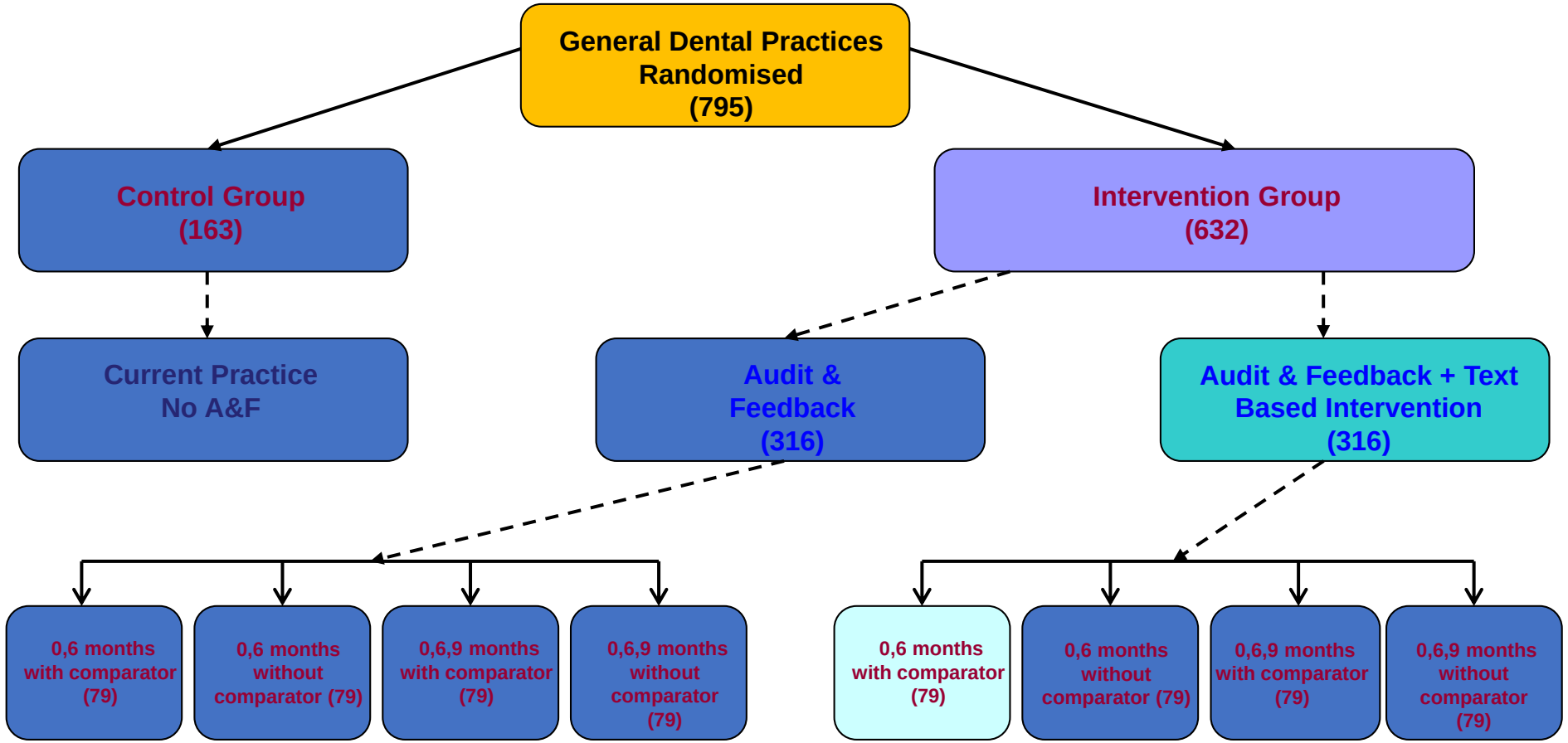
Primary Analysis

- Prescribing rate in the A&F group 6% lower than control
  - extrapolated decrease: 20,000 antibiotic items across Scotland

Comparing Intervention Components

- Prescribing rate lower for dentists:
  - receiving BC message (-6%)
  - provided with a HB comparator (-4%)
- Frequency of feedback did not make a difference

Case study: The RAPID study



Wrap up

1) to describe how implementation science laboratories may help achieve goals of scientists and healthcare systems
2) to consider barriers and facilitators to development of implementation science laboratories
3) to examine interesting methodological opportunities with implementation science laboratories
4) to discuss the skill sets needed to have productive implementation science laboratories

THANKS FOR PARTICIPATING

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