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Wolfenden, Luke, Williams, Christopher M., Wiggers, John, Nathan, Nicole, Yoong, Sze Lin. "Improving the translation of health promotion interventions using effectiveness-implementation hybrid designs in program evaluations", Published in Health Promotion Journal of Australia Vol. 27, Issue 3, p. 204-207 (2016)

Available from: <http://dx.doi.org/10.1071/HE16056>

Accessed from: <http://hdl.handle.net/1959.13/1346378>

Title: Improving the translation of health promotion interventions using effectiveness-implementation hybrid designs in program evaluations

Abstract: Bridging the gap between research evidence and public health policy and practice represents a considerable challenge for public health improvement this century, requiring a challenge to conventional approaches to health research production and use. Traditionally the process of research translation has been viewed as linear and uni-directional, from epidemiological research to identify health problems and determinants, to efficacy and effectiveness trials, and studies of strategies to maximise the implementation and dissemination of evidence based interventions in practice. A criticism of this approach is the considerable time, typically 17 years, it takes to achieve translation of health research into practice. Hybrid evaluation designs provide one means of accelerating the research translation process by simultaneously collecting information regarding intervention impacts and implementation and dissemination strategy. However, few health promotion research trials employ such designs and often fail to report information to enable assessment of the feasibility and potential impact of implementation and dissemination strategies. In addition to intervention effects, policy makers and practitioners also want to know the impact of implementation strategies. This commentary will define the three categories of effectiveness-implementation hybrid designs, describe their application in health promotion evaluation, and discuss the potential implications of more systematic use of such designs for the translation of health promotion evaluation.

So what: Greater use of effectiveness-implementation hybrid designs may accelerate research translation by providing more practice and policy relevant information to end-users, more quickly.

Manuscript

Despite substantial investments in health research there remains considerable discrepancy between what evidence indicates is effective in promoting health and what is adopted and implemented in practice. For example, in Australia, despite two decades of evidence demonstrating the benefits of brief interventions for lifestyle risk factors, between 23-54% of New South Wales primary care practitioners report that they never provide smoking cessation, nutrition, alcohol use, or physical activity advice to patients.¹ Similarly, a recent audit of Australian childcare services found that none met best practice nutritional guidelines for the sector,² despite evidence shows providing healthy foods to children, while in care, improves child dietary intake.³ Further, up to 10 years after release of guidelines and government policy to restrict unhealthy foods from sale at school canteens, less than 30% of schools in most Australian states have implemented a healthy canteen consistent with these recommendations and policies.^{4,5}

Insufficient evidence to guide policy and practice

A fundamental barrier to the translation of health research is the research process itself. Traditionally the process of research translation has been viewed as linear and uni-directional, from epidemiological research to identify health problems and determinants, to efficacy and effectiveness trials, and studies of strategies to maximise the implementation and dissemination of evidence based interventions in practice.⁶ A criticism of this approach is the considerable time, typically 17 years, it takes to achieve translation of health research into practice.^{7,8} A further criticism is that the research output that is generated is typically focused on the early stages of the process, and in particular descriptive and epidemiological research where health issues and determinants are described.⁹ In contrast, the information needs of policy makers and practitioners are primarily focused on identifying interventions that are effective in improving

health, and strategies to best implement and deliver them to the community.¹⁰ However, just 11% of public health research publications describe trials testing health interventions, while implementation studies represent less than 3% of all systematic reviews,¹¹ 2% of public health research output,¹² and 2% of funded National Health and Medical Research Council (NHMRC) trials.¹³

Effectiveness-implementation hybrid designs may improve the relevance of research

Bridging the gap between research evidence and health promotion policy and practice represents a considerable challenge, requiring a change to conventional approaches to health research production and use. Effectiveness-implementation hybrid evaluation designs have been promoted in the implementation science field as one means of accelerating the research translation process and providing important information to inform policy and practice.¹⁴

Unlike traditional uni-directional approaches to research translation, where efficacy and effectiveness trials are conducted to establish intervention effects before trials are undertaken to assess models of intervention dissemination and implementation, hybrid designs seek to accelerate the translation process through the collection of such information simultaneously. Specifically, the research designs simultaneously collect information regarding intervention impacts on health outcomes as well as the effects of an implementation strategy in improving intervention (such as a health policy or program) implementation¹⁵ Hybrid designs therefore enable policy makers and practitioners to harvest both information regarding intervention effects and implementation approaches - key for decisions regarding investments in interventions for large-scale roll-out,¹⁶ and as such represent an efficient use of research resources. While consideration and collection of effectiveness and implementation data in health promotion trials is not new, and previous hybrid evaluation frame-works such as RE-AIM have existed for some time,¹⁷ the explicit typology of the hybrid design is novel.

Further, as the specific intent of hybrid designs is improved translation, its broad application has considerable potential to strengthen the evidence base and facilitate the translation of effective health promotion interventions into practice.

Three types of hybrid research designs have recently been proposed in the literature. In health promotion, Type 1 hybrid designs primarily aim to test the effectiveness of interventions in improving health outcomes, while collecting information about its implementation during the effectiveness trial.¹⁴ This can often be achieved in trials without compromising assessments of effectiveness. For example, collecting process data to describe the extent of intervention implementation, or assessing the acceptability of the initiative, would represent an example of a type 1 hybrid design. If such trials find the intervention to be effective, they provide preliminary data about the potential suitability of delivery strategies if implemented in the real world. A case study of a type 1 implementation trial is provided in Box A.

Box A: Case study of a Type 1 Hybrid design- Improving child fruit and vegetable intake¹⁸

Aim	The primary aim of the trial was to assess the effectiveness of a scripted telephone-based parent intervention, delivered by non-health profession call centre staff, in improving the fruit and vegetable intake of preschool aged children.
Design	Randomized controlled trial of 394 parents.
Intervention	The intervention consisted of printed resources plus four 30-min telephone calls targeting aspects of the home food environment associated with

	children's fruit and vegetable consumption. Calls were scripted, and delivered using computer assisted telephone interviewing software by call centre staff with no formal health qualifications.
Comparison	Generic print resources
Evaluation	<p><i>Effectiveness:</i> The impact of the intervention on child fruit and vegetable intake was assessed using a subscale of a validated food frequency questionnaire reported by parents during a telephone survey.</p> <p><i>Implementation:</i> Project records were used to record the number of calls received, interviewer deviations from script and parent completion of the intervention.</p>

Type 2 hybrid¹⁴ designs test concurrently the effectiveness of an intervention and an implementation strategy. They will therefore typically use comparative designs assessing both the effects of a health promotion intervention in improving health behavior, and of an implementation strategy in improving the implementation of the intervention components relative to a control. This could include assessments of cost, acceptability and feasibility of both the intervention and implementation approach. Such trials may be particularly useful when there is evidence of efficacy of an intervention but where approaches to achieving implementation in a way which preserves intervention effects are being sought.

Box B: Case study of a Type 2 hybrid design - Smoking cessation in a preoperative surgical clinic^{19, 20}

Aim	<p>The trial aims were to assess:</p> <ul style="list-style-type: none"> i) the effectiveness of providing smoking cessation intervention, consistent with clinical practice guidelines on the cessation rates of pre-operative surgical patients ii) the impact of a clinical practice change strategy to support the implementation of smoking cessation care consistent with guidelines by staff of a surgical preoperative clinic.
Design:	Randomized controlled trial in a single preoperative clinic.
Intervention	<p>The smoking cessation intervention consisted of the computerized assessment for tobacco use, a computer delivered behavioural intervention and the provision of brief advice, nicotine replacement therapy (NRT), and referral to the Quitline by preoperative clinic medical staff.</p> <p>The strategies to improve implementation of advice, NRT provision and referral by staff included the use of local opinion leaders and implementation consensus processes, computer-generated prompts for care provision by staff, training, and performance feedback.</p>
Comparison	Usual care

Evaluation	<p><i>Effectiveness:</i> The impact of the intervention on patient smoking cessation rates was assessed via patient self- report during a telephone interview.</p> <p><i>Implementation:</i> The impact of the implementation strategy on staff provision of brief advice, NRT and referral was assessed by medical record audit and patient report during a telephone survey. The cost and acceptability of implementation was also assessed.</p>
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Type 3 hybrid¹⁴ designs are primarily concerned with testing the impact of a strategy in achieving implementation of a nominated policy recommendation or practice. As a secondary study objective such designs may also collect information about the impact of the intervention on health related outcomes. These evaluations of health outcomes may be less rigorous and conducted only in a nested sample of sites. Such trials are particularly appropriate where there is robust evidence of beneficial effects of an intervention, but where different (for example less costly) implementation approaches are being tested. Such trials are often large, and powered to detect meaningful changes in organisational or professional practice.

Box C: Case study of a Type 3 hybrid design - Healthy school canteens²¹

Aim	<p>The primary aim of the study was to assess the effectiveness of strategies to implement a healthy canteen policy in primary school canteens.</p> <p>A secondary aim of the trial was to assess if improvements in policy implementation improved healthy food purchases of students as school canteens.</p>
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Design	Randomized controlled trial with 70 NSW primary schools.
Intervention	A comprehensive strategy consisting of canteen manager training, resource provision, recognition and incentives, consensus and leadership strategies, follow-up support and implementation feedback was provided to schools to support implementation of a mandatory, state-wide healthy canteen policy. The policy sought to restrict the availability of unhealthy foods for sale at canteens and increase the availability of healthy foods.
Comparison	Usual care
Evaluation	<p><i>Effectiveness:</i> In a nested sample of schools, observations of student canteen purchases were conducted at to assess changes in the nutritional quality of foods sold between groups.</p> <p><i>Implementation:</i> The impact of the implementation strategy on canteen compliance with the healthy canteen policy was assessed via a comprehensive audit of canteen menus performed by a dietitian. The impact on school canteen revenue was also assessed.</p>

Few health promotion studies employ hybrid designs

Despite the potential of hybrid designs to provide more practice and policy relevant information and to hasten the speed of effective research translation, their specific use in health promotion is uncommon. For example, we reviewed all 50 manuscripts published in 2015 in the Health Promotion Journal of Australia, and Health Promotion International and were able to identify

just three trials employing a hybrid design (two Type 1 Hybrid trials and one Type 2 hybrid trial). The Cochrane review of interventions for preventing obesity in children noted the absence of implementation data reported in trials included in the review, providing limited contextual data to support the implementation of effective strategies.²² Similarly the Agency for Health Care Research and Quality²³ in the United States identified only 25 trials describing strategies to facilitate the implementation of cancer prevention interventions in community settings, including schools, childcare services, workplaces and sport or recreation centers.

Conclusion

The simultaneous collection of effectiveness and implementation data through the greater use of hybrid designs represents one means of improving the policy and practice relevance of health promotion evaluations. Greater engagement of health promotion policy makers and practitioners in the research process may improve the use of hybrid designs as such end-users seek to include measures of health outcomes and implementation processes to inform decision making. While a number of research funding opportunities have been established internationally to encourage research co-production between researchers and practitioners and may improve the collection of policy and practice relevant data from research trials, meaningful research partnerships remain elusive.²⁴ Evaluation of programs undertaken by health services may also provide fertile ground to establish partnerships between researchers and practitioners particularly when interventions can be delivered and evaluation data can be collected with usual health service resources and infrastructure. Such a partnership provides opportunities for researchers to undertake intervention trials without the need for significant external research funds, and provides practitioners with academic expertise for service evaluation and improvement. Modification to author guidelines for journal submission to encourage the reporting of implementation and effectiveness data, and investment in initiatives to improve

the capacity of health services and their staff to engage in research are also worthy of consideration and to improve the availability of effectiveness and implementation information to facilitate research translation.

Without shifts in research practice and reporting toward greater use of hybrid models of evaluation, health promotion evaluation will fail to fully capitalize on the opportunity to inform health policy and practice decisions. Addressing this impediment to translation should therefore be a priority for the health promotion field.

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