

Behavior Change Intervention Research in Health Care Settings:
A Review of Recent Reports, with Emphasis on External Validity

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Abstract

Background: Information to judge both the internal and external validity of health behavior research conducted in health care settings is vital to translate research findings to practice. This paper reviews the extent to which this research has reported on elements of internal and external validity, with emphasis on the extent to which research has been conducted in representative settings with representative populations.

Methods: A comprehensive review was conducted of controlled interventions for dietary change, physical activity, or smoking cessation conducted in health care settings and published in 12 leading health behavior journals between 1996 and 2000. Using the RE-AIM framework, the characteristics and results of these studies were summarized to document the extent to which intervention reach, adoption, implementation, and maintenance were reported and what has been learned about each of these dimensions.

Results: A total of 36 studies qualified for review. Participation rates among eligible patients were reported in 69% of studies and were generally quite high; in contrast, only 30% of studies reported on participation rates among either health care settings or providers. Implementation data were reported in 77% of the studies and were generally high, with the caveat that intervention was often delivered by paid research staff. Long-term maintenance results were reported very consistently at the individual level, but program continuation was almost never reported at the setting level.

Discussion: We conclude that a much stronger emphasis needs to be placed on the representativeness of providers and settings that are studied. Examples of how this can be done and recommendations for future research are provided.

Keywords: literature review, health care, behavior change, generalization, evaluation

Introduction

There is increasing recognition of the gap between research findings and recommendations for preventive care, and the extent to which evidence-based interventions are implemented in practice.¹ Practitioners often raise questions about how relevant the literature is to the situations they face in everyday practice. Research, if conducted on representative samples and in representative settings, can inform better training and facilitate implementation of proven and broadly applicable interventions. However, if the external validity of our research knowledge base is either unknown or low, then changes in the way in which health behavior change research is conducted and reported, and possibly in the types of interventions that are evaluated, may be needed.

In this paper, we evaluate the extent to which external validity dimensions of health behavior change research conducted in health care settings have been reported in the recent literature. We conducted a review of health behavior change interventions on dietary change, smoking cessation, and physical activity published in 12 leading journals between 1996 and 2000. We also provide recommendations on ways to help close the gap between research and practice. We used the RE-AIM evaluation framework^{2,3} to structure our review. This framework organizes and integrates issues important for evaluating the impact of health promotion interventions identified by Green^{4,5} and others,⁶⁻⁹ and is designed to place balanced emphasis on internal and external validity by addressing five criteria important for translation of research findings. While recent reviews have begun to empirically describe some of these translation elements,^{9,10} we are not aware of other reviews that have evaluated all or most of the RE-AIM criteria simultaneously or that have reported across multiple target behaviors.

RE-AIM is an acronym standing for Reach, Efficacy or Effectiveness; Adoption; Implementation, and Maintenance.^{2,3} Reach refers to the percent of potential participants who will take part in an intervention, and to how representative they are of the population from which they are drawn. Reach and Efficacy/Effectiveness operate at the individual level. Efficacy/Effectiveness concerns both the intended results of an intervention; and also possible negative or unintended consequences on quality of life and related factors.

Adoption and Implementation operate at the setting, rather than individual level. Adoption refers to the participation rate and representativeness of both the settings (e.g., worksites, medical offices) in which an intervention is conducted and the intervention agents (e.g., physicians, health educators) who deliver a program. Implementation refers to the extent to which various components of an intervention are delivered as intended.

Maintenance has indices at both the individual and setting level. At the individual level, it refers to the long-term results of intervention (defined as a minimum of 6 months following the last contact). At the setting level, Maintenance refers to the institutionalization of a program.¹¹ This is the extent to which organizations will continue a program (and which components of the intervention) once a study or initial trial is completed.

Methods

Literature review methods

This project was carried out in association with the Behavior Change Consortium, a collaboration among 15 NIH funded projects addressing theory based health behavior change.¹²

Because the majority of these projects targeted dietary change (including weight loss or dietary fat reduction), smoking cessation, or physical activity enhancement, we focused on these three target behaviors.

We did not employ electronic literature searches because of the multitude of studies within each of these behavioral areas and because the majority of RE-AIM issues are not indexed in such databases. Instead, we selected a more focused approach. Our basic research question concerned the extent to which recent behavior change intervention studies conducted in health care settings and reported in leading health promotion journals addressed the various RE-AIM dimensions. Therefore, we reviewed the years 1996-2000 of the 12 journals listed in Table 1 using an abstracting form to code the variables defined below. These journals were chosen based on feedback from a panel of leading health promotion researchers and based on the following criteria: circulation, frequency of reporting intervention studies, and coverage of general health promotion (specialty journals and those restricted to a single discipline or target behavior were excluded). We included all intervention studies reporting results on dietary intake, smoking, or physical activity endpoints that included some type of comparison or control condition. This included randomized studies and reports using quasi-experimental control conditions, but not studies reporting only pre-post results from a single condition. Studies had to be conducted in a health care setting (e.g., primary care office, hospital, community health center) or to recruit from such settings and be linked to care in a health setting, as health education is often provided on a referral basis.

Definitions used for coding the various RE-AIM criteria are summarized below. Under Reach, we coded whether a study reported on a) the percent of potential participants excluded by study investigators, b) the percent of eligible patients who chose to participate in the study, and c) whether analyses were conducted to compare characteristics of participants and non-participants. Because a host of other reviews have reported on the efficacy or effectiveness of health promotion interventions (see Cochrane collaboration and AHRQ evidence-based reviews),^{13,14} the variety of target behaviors addressed, and since the focus of this paper is on external validity, we did not code the Efficacy/Effectiveness dimension. The one exception is that we did code whether a quality of life or other measure that could potentially reveal negative consequences of intervention was included.

For Adoption, we recorded several results: whether a study a) reported the number or percent of potential study sites that investigators excluded; b) the percent of eligible sites (e.g., clinics or offices) that participated; and c) the characteristics of sites that participated vs. declined. Within participating sites, we also coded d) if the percent of potential intervention agents (e.g., doctors or nurses) who took part was reported, and e) if analyses were conducted of the characteristics of potential intervention agents who took part vs. those who did not.

For Implementation, we coded a) whether data were reported on the extent to which different intervention components were delivered to participants, and b) whether there were data on either the cost or the total time required to deliver the intervention. Finally, there were four elements of Maintenance coded: a) whether the study included at least a 6-month follow-up; b) attrition rates at the longest follow-up assessment (generally 6 or 12 months); c) if either imputation or intent

to treat analyses were used to evaluate the impact of attrition; and d) if there was any report of whether the intervention was continued after the research study was completed.

Coding Reliability. We randomly selected 9 papers (25% of those selected for review) on which to examine coding reliability. Inspection of coding revealed that agreement indices on whether or not a study reported a RE-AIM component made the most sense. This was because actual rates were reported seldom for several variables, and when they were reported, the raters virtually always coded identical rates. Percent agreement scores were uniformly high across the various RE-AIM components. Agreement for Reach components ranged from 89% for whether representativeness of participants was reported, to 100% for whether exclusion rate and participation rate were reported. Agreement on reports of Adoption components also ranged from 89% (for adoption rate) to 100% (for both site exclusion rate and if representativeness of sites participating were reported). Finally, agreement on Implementation was 89% and agreement on Maintenance measures were all 100%. In cases of disagreement, we retained the ratings of the primary reviewer.

Results

As summarized in Table 1, we identified a total of 36 articles meeting the criteria above in these 12 journals between 1996-2000. These articles were fairly evenly distributed across target behavior areas (from 9–16 articles per target behavior) with the exception of one article that reported on multiple behavior change targets. The Appendix provides citations for the articles included.

Table 1

The majority of studies reviewed (86%) were randomized trials, often utilizing a usual care or no treatment control condition. A sizable percentage--36% and especially the more recent reports, used cluster randomization procedures in which units such as clinics were randomized to conditions. Less encouraging from the perspective of comprehensively evaluating outcomes, only 17% of studies reported a quality of life measure or other index of possible adverse outcomes.

Reach

The studies were variable in the extent to which they reported different dimensions of Reach. A majority (69%) reported on the percentage of eligible patients who participated (Table 2). Of those reporting this element, the median participation rate was quite high (77%), indicating that the interventions studied reached a majority of their intended audience. However, few studies (28%) reported on the representativeness of those patients who participated on demographic or medical status variables. Without such information, it is not possible to evaluate whether interventions reach those who need them the most. Of those studies that did report on characteristics of participants vs. those who declined, the vast majority reported that these groups were very similar. Finally, only 33% of studies reported on the percentage of potential participants who were excluded by investigators. Studies which did report on the rate of

investigator exclusions reported widely varying rates, but the median exclusion rate of 38% raises questions about the breadth of applicability of the interventions studied.

Because reporting on RE-AIM dimensions and external validity measures are new to many readers, in this and the following results sections, we provide a brief example of a study that has addressed that particular RE-AIM factor well. In their study of smoking cessation during pregnancy, Wakefield, et al.,¹⁵ illustrate how Reach issues can be incorporated. They begin by explicitly reporting their exclusion criteria (e.g., non-English speaking, presenting for first visit later than 20th week of pregnancy) and the percent of potential participants excluded for each reason. They tracked recruitment efforts and reported that 62% of remaining eligible patients agreed to participate. Finally, they compared characteristics of eligible patients who agreed to participate vs. those who declined and found no systematic differences.

Table 2

Adoption

Very few studies reported any measure related to the percent or representativeness of the organizations or intervention agents participating in the study (Table 2). Only 4 studies (11%) reported on the percent of sites (e.g., clinics or practices) approached who agreed to participate, and only 8 (22%) reported on the percent of potential intervention agents (usually physicians or nurses) who participated. In these 8 studies, the median percentage of intervention agents taking part was 81-87%. No studies compared the characteristics of sites or intervention agents who

participated with those who declined. Finally, only one study reported on the percent of possible settings that were excluded by the investigative team.

An exemplar study for reporting on Adoption was by Lazovich, et al.¹⁶ In their evaluation of a dietary intervention conducted in primary care practices, they reported on participation at both the site level (6 of 22 clinics) and at the intervention agent level (39 of 193 family practice physicians). This information could have been even more informative if data had also been reported on the representativeness of the clinics and physicians who participated.

Implementation

Measures of intervention delivery were frequently reported (77%) and the vast majority of reports indicated consistent delivery of the protocol, with the median implementation rate being 85%. Fewer studies (31%) reported on the resources (i.e., specific cost or time) required to deliver the intervention, with the majority of these studies reporting on intervention time rather than other economic issues.

The Albright, et al.,¹⁷ study reported on both implementation and resource utilization. Their physician advice based physical activity trial used a computerized tracking system. A health educator inquired if patients had received physician advice to increase exercise (99% reported hearing this message), and entered this information into a laptop computer. A separate physician survey found that the majority of physicians were able to implement the intervention protocol in less than 4 minutes.

Maintenance

Almost all studies (86%) reported on individual level outcomes at least six months following the final intervention contact. A majority (87%) of studies reported attrition rates at follow-up, and although there was considerable variability, the median attrition rate was only 16%. Just over half (56%) of the studies reported on some analytic procedure to evaluate the potential impact of attrition on outcomes.

At the setting level, only two studies (6%) reported on the extent to which the intervention was continued after the study period had concluded. In addition to reporting patient level long-term follow-up results and attrition rates, Richmond, et al.,¹⁸ followed up on family physicians who had participated in their smoking cessation training program. They found that 6 months after the 2-hour training, 93% of intervention condition physicians reported still using the program.

Discussion

In general, recent studies in the health care area have done a much better job of reporting data related to internal validity as compared to external validity. The low proportion of studies reporting on external validity dimensions reflects a disparity between current research and an emphasis on increasing the number of effectiveness interventions. Although translation of research to practice and dissemination of research programs is being heavily promoted in the behavior change field,^{2,4,5,19} the recent empirical literature does not reflect this emphasis.

We are not suggesting that all intervention studies must be generalizable or address maintenance; there is still an important place for basic mechanistic and efficacy research. We are suggesting though, that there is a huge cumulative imbalance in the attention to internal vs. external validity, and that researchers who are concerned with translation of their results should report more consistently on RE-AIM dimensions. Since external validity issues are essentially questions about potential interactions between treatment and contextual variables (i.e., subject selection, research setting), reporting such information provides important data on moderators that may qualify the cause-effect relationship in both efficacy and effectiveness studies.^{20,21}

Only a minority of studies reported on elements critical to the understanding of external validity. Specifically, the representativeness of individual participants was described in only 28% of studies. While availability of existing data, such as census and health systems data, have made it increasingly possible to compare study participants with population characteristics, investigators may be unaware of or lack access to these data. More problematic than simple omission of participation rates would be differential bias in reporting. Since no journals presently require reporting of participation rates, it may be that those who have high rates tend to report their success, and those having low rates omit this information.

Description of the number and characteristics of participants who were excluded by investigators was absent in two-thirds of studies. Although studies reporting exclusionary criteria appear to have used reasonable conventions to improve internal validity (e.g., not having disease complications or comorbid conditions, planning to be in the area for at least a year; able to attend

multiple sessions), these decisions can substantially limit the applicability of an intervention, and may implicitly exclude those most in need.

One bit of good news is that over two-thirds of the studies reported participation rates among those persons eligible, and these rates were generally high, with a median of over 75%.

Apparently, the research community has “gotten the word” about participation at the level of recruiting individual participants. This message seems not to have transferred to the organizational or setting level.

Health care organizations are increasingly encouraged to adopt effective health promotion programs.^{14,22-24} Understanding organizational characteristics related to the adoption and maintenance of programs will be a key element in targeting interventions and marketing of such programs. Methods and incentives to improve reporting of these characteristics are needed, given that this review found that only 11% of studies reported participation rates of organizations, none included description of the representativeness of organizations, and only two reported maintenance at the organizational level.

Several methodological dimensions relevant to both internal and external validity, namely intervention implementation, individual level maintenance of behavior change, and attrition at follow-up, were reported in over three-quarters of the studies. In contrast, only about half of the studies reporting attrition used techniques to address this appropriately, such as imputation or intent-to-treat analyses.

It is also of concern that only 17% of studies reported on quality-of-life or other assessments that could reveal negative outcomes. Such assessments would improve our understanding of potential iatrogenic effects and our ability to assess risk-to-benefit ratio when disseminating interventions. Additionally, estimates of intervention costs in terms of dollars and other resources such as time were not often described. This information would be very useful to organizations selecting programs, by comparing the costs and cost-benefit of various options.

Recommendations

Although the task of reporting internal and external validity dimensions in a single report may seem daunting, examples of how this can be done were cited throughout the results section. More standard methods for reporting on external validity issues would be of benefit to both the research community, and to organizations interested in selecting programs. One efficient method of including such information might be a reporting template such as that in Figure 1. This template adds information on external validity issues to the information currently required by many health journals²⁵ concerning recruitment and retention. By making explicit participation and implementation results at the organizational (as well as individual) level, public health impact becomes more clear. Such a template could be helpful not only for reporting purposes, but also for designing interventions that have high potential for being adopted widely. Also needed are similar reviews of research conducted in other settings to determine the extent to which our findings are specific to health care settings and to other areas of preventive medicine.

Figure 1

Caveats

Our literature review was not exhaustive because our purpose was to characterize reporting practices in recent, state of the art journals. The extent to which the selected articles reflect the larger body of behavior change literature is not documented, but we speculate that the percentages reported are overestimates of how often external validity dimensions have been reported in earlier issues and less demanding journals. Additionally, although several dimensions were infrequently reported, this does not prove that investigators did not collect such information. Lack of information on representativeness might reflect editorial requirements to preserve journal space or a perceived lack of interest in such issues.

Conclusions

The purpose of this review and one of the goals of the RE-AIM framework is to help researchers, funders, editors, and training programs to judge the external validity of behavior change research. As translation of health care-based strategies becomes a priority, increased reporting of information along all RE-AIM (or similar) dimensions is needed. Of special concern are methods to address current shortcomings in reporting representativeness of results and providing cost data. Limitations in our ability to compare and describe programs in terms of external validity characteristics are important to recognize and address if we hope to achieve the goal of reducing disease through translation of behavior change programs into practice.

Acknowledgements

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Table 1. Number of Studies Included by Journal and Target Behavior

Journal	Physical			Multiple	Total
	Nutrition	Activity	Smoking	Behaviors	
American Journal of Health Promotion	1				1
American Journal of Preventive Medicine	3	3	2		8
American Journal of Public Health	2		4		6
Annals of Behavioral Medicine		1	1	1	3
Australia and New Zealand Journal of Public Health			2		2
Health Education and Behavior			1		1
Health Education Research		1			1
Medical Care	1				1
Patient Education and Counseling	1	2			3
Preventive Medicine	1	3	6		10
Total	9	10	16	1	36

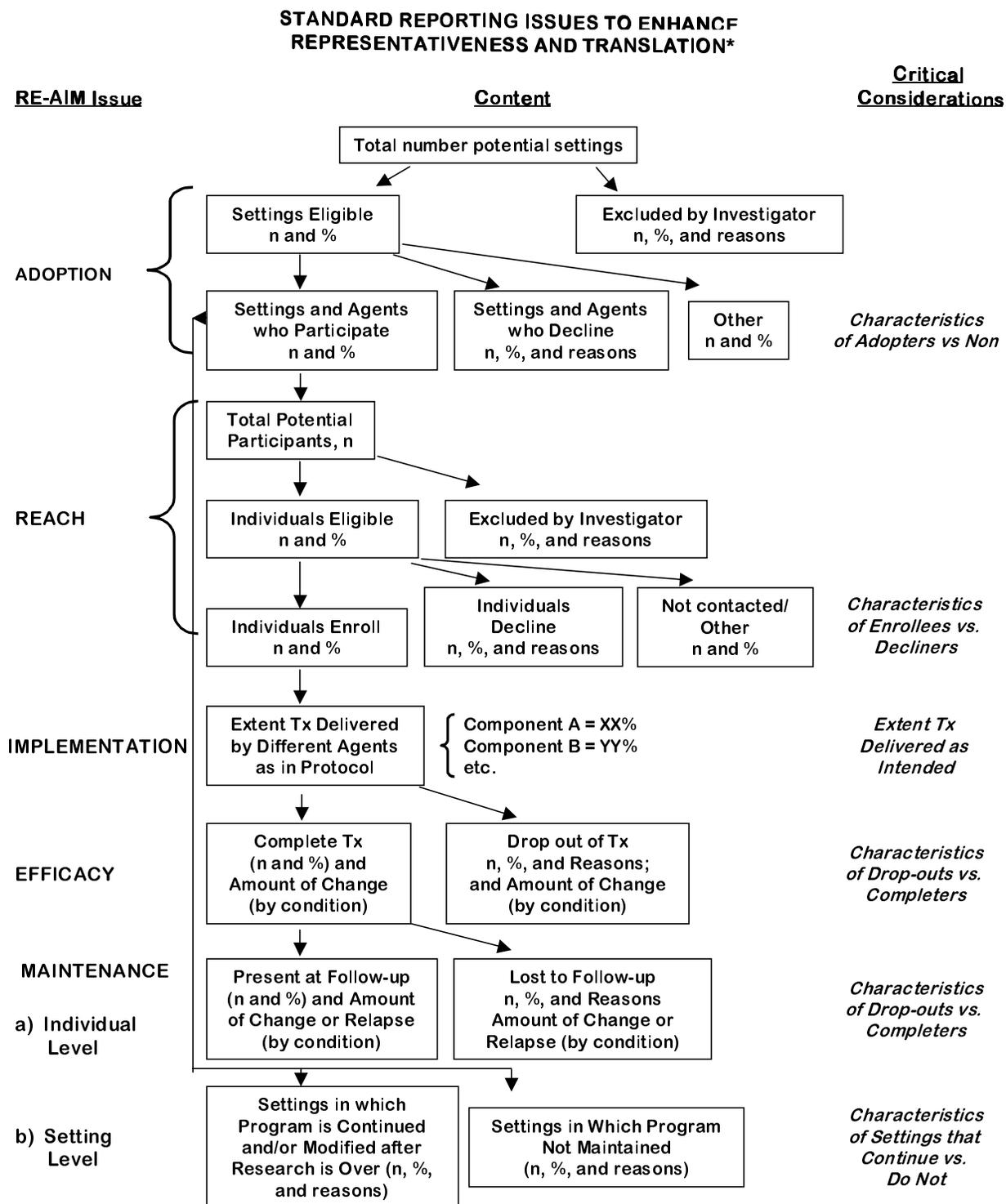
*Also reviewed were the Canadian Journal of Public Health and the Journal of Behavioral Medicine, but they did not have any articles meeting our review criteria during 1996-2000.

Table 2. Percent of Studies Reporting on RE-AIM Components

Component	Percent of Studies Reporting
REACH	
Participation rate	69%
Representativeness	28%
Investigator exclusion rate	33%
EFFECTIVENESS	
QOL or negative outcomes	17%
ADOPTION	
Participation rate:	
Site level	11%
Agent level	22%
Representativeness:	
Site level	0%
Intervention/Agent level	0%
Investigator exclusion rate	3%
IMPLEMENTATION	
Percent of treatment delivered	77%
Specific time or cost measure	31%
MAINTENANCE	
Individual level – \exists 6-month post-contact	86%
Attrition at follow-up	87%
Use of imputation or intent to treat	56%
Setting level – continuation after study	6%

QOL = Quality of life

Figure 1. Standard Reporting Issues To Enhance Representativeness and Translation



*At each step, record qualitative and quantitative information on factors affecting each RE-AIM dimension and step in the flow chart

Appendix: Articles Included in Review

1. Albright CL, Cohen S, Gibbons L, et al. Incorporating physical activity advice into primary care: Physician-delivered advice within the Activity Counseling Trial. *Am J Prev Med* 2000;18:225-234.
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