HMC Research Translation: Speculations about Making It Real and Going to Scale

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Objectives: To discuss cross-cutting issues that emerge from this special issue on health behavior maintenance and to present recommendations from an "implementation and dissemination" perspective. Methods: Reviews collective implementation strengths and limitations of the HMC articles and provides recommendations for dissemination. Results: Strategies for dissemination include actions-related study planning, analysis, promotion, and distribution of research

results. Alternatives, which should be tailored to setting, intervention, and patient factors, include analyses of generalization, use of narratives, networks, and innovative partnerships. Conclusions: Dissemination strategies can be used to enhance the chances that results will be translated into policy and practice.

Key words: health behaviors, dissemination, implementation, RE-AIM, translation, maintenance, research design

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The series of articles in this special issue is impressive. The papers explore critically important and cutting-edge topics, including attention to the natural history of long-term behavior-change maintenance as well as the effectiveness of specifically targeted maintenance strategies. The NIH and especially the Office of Behavioral and Social Sciences Research made a major commitment to funding this content area and consortium, and it is rewarding and informative to read the results of this support.

My purposes in this article are to briefly comment on some cross-cutting issues that emerge from these reports and then to present ideas and recommendations

from a "dissemination and implementation" perspective1 (http://www.cancer.gov; http://research-practice.org). In particular, I offer thoughts about actions that can be taken to translate these findings for larger-scale application, to turn them into programs that can produce high reach especially to high-risk and medically vulnerable populations), be widely adopted, successfully implemented, sustainable, and produce robust results across clinically and societally important outcomes.^{2,3} Stated in the form of questions, what is needed to take the behavioral science lessons from this series to scale and to address the IOM4 priorities of care to produce results that are equitable, efficacious, efficient, safe, timely, and patient centered? Admittedly, this is an ambitious task that involves a fair amount of speculation about what the future will bring⁵ and how to get there.

I am struck by the diversity of behaviors, settings, target populations, and research designs included in this special issue. This diversity makes it challenging to draw generalizable conclusions

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about lessons learned concerning maintenance of behavior change. The target behaviors and issues addressed range from drug and alcohol use/abuse, suicidality, and cancer screening to major diabetes and heart disease risk factors. Of particular interest is that several studies^{6,7} address the complex issue of maintenance of multiple behaviors. ^{8,9} Ory et al have done a stellar job of drawing conclusions from these reports and indicating where gaps and uncertainty remain as directions for future research. ¹⁰

Cross-cutting Comments

Context. I see 3 cross-cutting issues of relevance to translation and dissemination that emerge from this series of papers. The first is that of *context*, by which I mean the social, interpersonal, environmental, and historical setting in which a study is conducted. One of the key lessons of dissemination and implementation (D&I) research^{2,11-13} is that all evidence is contextual. Reporting of context in a transparent manner is an evolving trend that has recently been addressed in both the TREND statement¹⁴ and CON-SORT guidelines for "pragmatic" trials (http://www.consort-statement.org/extensions/designs/pragmatic-trials). 15 These guidelines recommend including information on how typical the participants, providers, institutions, and setting in a report are; the number of participants or units approached for participation; and generalizability. Other researchers have advocated even more thorough reporting on contextual and external validity issues to enhance understanding of generalization. 11,12 Description of the setting conditions in which a study takes place helps readers to evaluate how similar these are to their own situation. A summary of a meeting of journal editors and funders on this topic is provided by Green et al16 (see also www.re-aim.org). In addition to the CONSORT recommendations above, these authors also recommend reporting on representativeness of participants, setting, and staff; intervention implementation and adaptation; qualitative data to help interpret contextual factors; and costs.

What specific contextual information is most relevant to judge external validity depends on evidence in the particular content area; but in general, setting, patient, and staff characteristics most strongly related to the outcomes of interest should be reported. In addition to standard structural and demographic characteristics, information reported should include factors related to costs, representativeness, and health disparities.

Several of the papers do a good job of describing the context of their research findings. Many should have considerable applicability to emerging contexts such as the primary care medical home, 17 the eHealth and social media movements, 18 adherence to new preventive care guidelines, and new health care delivery and health insurance settings. Further, the context of even an efficacy study is important because it describes the starting point of translation into practice. Studies that do not present clearly the context in which they were conducted handicap translation efforts. For example, whether the intervention was covered by insurance or was paid for by the grant, whether there were competing or alternative therapies offered for the same condition, and whether the intervention was offered after a run-in period in which only the most adherent patients were selected for the study, or if hours of medical contact time were provided to ensure safety, but these hours were not counted in the intervention, affect the probability of generalization and translation.

Disparities. There are many recalcitrant health and health behavior disparities in today's world and a great need for interventions that can reduce these disparities. ¹⁹ Recent data have indicated that even when available measures of quality of care are equal or accounted for, disparties in health outcomes still remain. ²⁰ These findings remind us there are likely both biological and social-environmental factors outside the medical and/or intervention setting that influence outcomes. Identifying and mitigating such factors should be a key priority for future research.

There are now compelling data on health disparities related to race, ethnicity, and SES²¹ and on the costs of disparities to society. ^{22,23} Additional studies are emerging on disparities in areas such as patient-provider communication behaviors, mental health outcomes, and use of various services related to age, acculturation, rural/urban location, and gender. What are needed now are not more documentations of disparities, but

interventions capable of mitigating or eliminating these disparities.²⁴ Of particular relevance to disparities research are impressive data on the potential role of health literacy and numeracy^{25,26} in health disparities.²⁷⁻²⁹ Future health maintenance research should evaluate the generalizability (or robustness) of intervention effects across subgroups differing in such disparity-related characteristics.

Replication. One of the reasons that I emphasize reporting outcomes across settings, staff, and patient characteristics is that generalizability across these contextual factors provides important information about the robustness of an intervention. Replication is one of the cornerstones of scientific causality^{30,31} but is frequently ignored in our societal obsession with finding new cures.¹⁹ Identifying the conditions under which an intervention effect holds—and when it does not leads to better understanding of the program; often suggests new directions for research; and may save time, money, and effort.

What Else Could Addressed by HMC Studies?

Realizing the limitations on how much can be studied with limited resources in any given study, it is still telling that, considering the HMC studies as a whole, several types of information that would aid understanding potential for dissemination are generally lacking.

Cost and cost-effectiveness. Although the HMC Consortium held a special meeting on practical ways to collect cost and cost-effectiveness data for behavioral interventions, few of the studies were able to include such measures. It is recognized that this meeting occurred after the grants had been funded and that inclusion of such data would likely have required some modest supplemental funding for many projects. However, it has been demonstrated that important intervention cost data can be collected relatively efficiently and inexpensively. 32,33 This is important because the first question almost always asked by decision and policy makers when considering adoption of a behavioral intervention is "How much does it cost?" It is beyond the scope of this commentary to go into detail (or to discuss why this question is often not asked with equal intensity about medical-surgicalpharmacological interventions), but there

are available, helpful guides and models for collecting and presenting cost and cost-effectiveness data.³⁴ Sensitivity analyses and simulation exercises can be valuable in helping to estimate and understand the scalability of interventions.

Reach, adoption, and participant **perceptions.** Although these reports of the HMC studies give some attention to participation rates and representativeness of participants, there is less attention to participant reactions to the intervention experience or the settings of intervention delivery. Notable exceptions are the studies in workplaces, which reveal how different aspects of the work environment could help sustain long-term behavior change. Of special note, the manuscript on intervention taxonomy³⁵ suggests the importance of describing the essential features of interventions, including settings of care and interventionist characteristics. This lack of reporting on context is not unique to HMC studies^{2,36} and is likely equally or more true of medical intervention studies. Such information, and especially mixedmethod and qualitative information on why those invited declined to participate (or dropped out), how participants interpreted intervention components, and how they did (or did not) incorporate treatment recommendations into their lives would be extremely helpful in planning largerscale applications.

Policy and social-environmental context. Because it is not typically required for journal articles and grant applications, investigators seldom report information on the health policy and social-environmental context—and whether these contexts change over time.³⁷

There has been a much-needed increased attention to policy and social context in behavioral medicine,38 but with the exception of projects whose primary purpose is to assess or intervene on social environmental or built environment factors, few studies report on such issues. An encouraging footnote is that many of the HMC projects have incorporated geographical information system (GIS) coding, and it is increasingly possible to extract policy and social-environmental data such as income, crime rates, population density, and even proximity of various types of stores and parks from various GIS databases.

Table 1 Recommendations to Get Your Research Used

- 1. Get your program or measure listed in evidence-based resources.
- 2. Develop users' guide or intervention manual with directions on appropriate adaptations.
- 3. Develop representative stories
- 4. Use professional and social networks and media
- 5. Develop new partnerships you would not have thought of 5 years ago—e.g., business, pharmaceutical, military, regulatory agencies.
- 6. Use self-test of your product against checklist of Roger's diffusion and RE-AIM characteristics.

Mediation and moderation analyses.

Few of the papers, with notable exceptions include either mediation or moderation analyses. Acknowledging that these may be planned for other papers, the absence of such data limits readers' ability to judge dissemination potential. Moderation analyses and important potential moderating variables were discussed above. The science of mediation analyses is rapidly evolving and has been advanced by several recent publications.^{39,40} At least 3 HMC projects have made mediation analyses a priority. 41-43 Such analyses aid conceptual understanding of mechanisms of effective programs and inform adaptation for dissemination.

Research design and practical tri**als.** The HMC studies employed a variety of experimental designs, including longitudinal observation (out to 7-15 years in some studies) and randomized designs including both individually and cluster randomized trials. These designs are appropriate and informative and likely the types of designs that were able to be approved by conservative grant-review study sections. From a dissemination perspective, however, it is disappointing that more studies did not employ innovative designs, such as multiple baseline across settings, ⁴⁴ preference, fractional factorial designs, ⁴⁵ or more "practical behavioral trials." ^{41,42} The latter type of research trials can be either randomized or other types of designs and employ multiple, diverse, and ideally, purposefully selected intervention settings; study heterogeneous and, ideally, representative populations; compare realistic alternative interventions, answer questions of interest to policy and decision makers; and include multiple outcomes, including the types of results discussed above. Such alternatives or creative adaptations of traditional RCTs provide safeguards against threats to both internal and external validity and are often helpful when traditional RCTs are not possible, ethical, or agreed to by community partners.

How to Enhance Adoption, Implementation, and Sustainability

The discussion this far addresses the results of the HMC papers and some directions for future research. This section presents concrete steps that these investigators—and developers of other evidence-based programs—can take to increase the chances that their products are disseminated successfully. These recommendations are summarized in Table 1.

List programs and create users' guides. The first step to enhance use of one's program is to submit it to one or more of the evolving databases for evidence-based programs. Probably most directly relevant for the HMC interventions is http://cancercontrolplanet.cancer.gov. This Web site is for programs shown in controlled research to be effective at improving one or more health behaviors (or other cancer risk factors). Other relevant listings depend on the content area but include University of North Carolina TRT (for obesity www.center-trt.org), SAMHSA (http://www.nrepp.samhsa.gov, for mental health and substance abuse), and an increasing number of state health departments. The HMC Resource Center (http://hmcrc.srph.tamhsc.edu) will apparently also house intervention manuals. The process of answering the application questions for these various registries can also provide ideas about the types of additional evidence needed to

Table 2 RE-AIM Criteria for Identifying Programs with Potential for Dissemination

High REACH Broad EFFECTIVENESS Good ADOPTION Strong IMPLEMENTATION Stress MAINTENANCE Representative participants, smart recruitment Across subgroups, outcomes, and settings Key settings and staff will participate Consistent delivery across settings, staff, and time

From outset at patient and settings levels

enhance likelihood of dissemination.

Many behavioral researchers, especially those in mental health areas, have developed users' guides or treatment manuals that specify the intervention components, how they are to be delivered, and often include useful checklists, patient materials, and answers to commonly asked questions. Such documents, especially if they are on-line, are crucial aids to effective implementation and replication. Especially recommended are clear discussions of what are considered essential components of the intervention that cannot be modified and aspects of the program that can and should be adapted to one's setting, 48,49 along with examples of successful adaptation, if available. Similarly, it is important to distinguish the intervention components that are likely to be sensitive to changes in context from those that need to be delivered with fidelity regardless of setting.

Networking and stories. Two informal, but highly effective methods of promoting one's program are using networks and narrative stories. Having one's program featured or mentioned in newsletters, on-line discussions, or other media outlets of professional organizations such as SBM, APA divisions, and the International Society of Behavioral Nutrition and Physical Activity are helpful, as are notices in media from health organizations such as AHA, ACS, ADA, etc.

The use of narratives to convey research results can be highly effective^{50,51} and is a rapidly expanding area of research. It is increasingly recognized that policy makers, legislators, and other decision makers are often more influenced by a compelling personal story (which can come from either staff who have implemented a program or participants who have benefited). What distinguishes the

evolving science of evidence-based narrative from traditional testimonials is their representativeness.⁵¹

New partners. In today's interconnected and transdisciplinary world,52 researchers are advised to consider partnerships with organizations that have large reach, resources, power, or influence. For many academics, partnerships with groups such as social marketers, food or pharmacological (and increasingly pharmcogenetic) companies, business organizations, the military, police and public safety departments, or planning and regulatory agencies may seem foreign or distasteful. However, such groups have enormous influence and success at selling their products or policies and influencing large segments of the population. Possibly most important, many of these organizations have established, robust marketing and distribution networks53 unlike behavioral science. These types of partnerships, like many of the things we were taught implicitly or explicitly in graduate school, need to be re-thought. Use of such partnerships or distribution channels is not inherently "selling out" or limiting to one's scientific integrity. One obviously needs to enter into such relationships carefully and with clear specification of issues related to ethical and conflict-of-interest issues, but such partnerships are much more likely to produce impact (examples are partnerships of tobacco researchers with quit lines and manufacturers of stopsmoking medications).

Remember what works and what is needed. In closing, those who hope to broadly disseminate research results are well served by periodically returning to Everett Roger's pioneering work on characteristics of innovations that are adopted broadly⁴⁷ (and more recent applications by his colleagues and students).^{54,55} In par-

ticular, the diffusion principles of change orientation, homophily, relative advantage, complexity, compatibility, observability, trialability, and relative advantage (including cost) are well worth considering. ⁵⁴ The RE-AIM criteria^{2,11,36} are also worth reviewing, as interventions that have the characteristics summarized in Table 2 are more likely to be successfully disseminated (www.re-aim.org). ²

In summary, there are numerous opportunities for researchers to increase broader use of their work, both in terms of the types of studies and analyses conducted and approaches to dissemination. If we expect to change the off-cited time lag between research findings and their application, we cannot, however, keep doing the same things and expect different results.⁵⁷

Rather, we need to think through the issues above and consider how various decisions increase or decrease the probability that an intervention—or maintenance program—will reach those in need, be effective across broad and diverse populations, be adopted by typical organizations, and be successfully implemented and maintained.

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