

Value in Development of Complex Interventions

Anne E. Sales, PhD, RN; and Christian D. Helfrich, MPH, PhD

The article by Byrne et al¹ in this issue of the *Journal* offers a more systematic approach to planning complex interventions than has generally been used in the past. It is an important addition to the literature on planned and organized diffusion of innovation and implementation of evidence-based care. The authors provide an excellent counterpoint to prescriptive approaches for designing interventions to speed the adoption of evidence-based practice. Implementation studies too often focus on specific tools, such as reminders, provider education, and performance feedback; treating contextual factors, such as organizational structure and culture; and the health policy environment, as factors to be controlled through random assignment.²⁻⁴ Such studies tell us neither why interventions achieve the results they do, nor why we might expect different results from one setting to another. If there is consensus in implementation research, it is that there is tremendous unexplained variation in effectiveness of diffusion, adoption, and implementation.⁵⁻¹⁰

Understanding these differences is a goal of many healthcare organizations and funders of health services research. Indeed, the Institute for Healthcare Improvement's acclaimed "Break-through Collaboratives" adopted the plan-do-study-act approach in part to address differences in context: to try out multifaceted change interventions on a small scale in order to understand how they work in a given context and to provide an opportunity for refinement before rolling them out on a larger scale. The Medical Research Council (MRC) framework serves a similar purpose, but provides more structure, particularly in beginning with a systematic review of the existing literature, focus groups, and pilot testing.

In secondary prevention of coronary disease, the authors find an excellent example for applying and studying the MRC framework. These therapies are relatively simple to deliver. While not appropriate for all patients, prescribing the "cardiac cocktail" is not as complex as applying evidence-based therapies in other disease states. In addition, there have been multiple efforts to implement adherence to evidence-based therapies for coronary disease prevention across settings, in

many healthcare systems, and in several countries. Yet, despite the relative ease of adherence (compared to therapies in other healthcare problems) and the amount of attention that has been focused on the area, we have not yet found consistent, transferable approaches to increasing adherence to these practices across settings, systems, and countries. This makes it an excellent clinical area in which to launch complex interventions: The evidence base is strong, and the therapies are relatively simple to administer.

Why This Study Is Relevant to US Managed Care

US readers may look at this study's Irish setting and presume the study has little bearing on their own work. This would be incorrect for 2 reasons.

First and foremost, the MRC framework is not about the Irish healthcare system so much as it is about accounting for the dynamics of a given healthcare setting whenever designing a trial. As a result, the framework is highly applicable to the American healthcare system, which has enormous variation in environments from locality to locality. Differences arise from state regulations, levels of managed care penetration, and extent of employer-sponsored coverage, not to mention differences in demographic factors such as age and ethnicity, and behavioral factors such as regional differences in diet and lifestyle. All of these factors profoundly affect how a complex intervention might work in a given setting. A major purpose of the MRC framework is to capture contextual variables like these in a systematic way.

Second, the findings of this study may have more relevance to the US healthcare system than one might assume initially because the healthcare system in Ireland is quite similar to that in the United States in some important regards. First, general practice physicians are not employees of a public health service, but independent practitioners who provide services under contract to public agencies called Health Service

From the VA Puget Sound Health Care System, Seattle, Wash.

Address correspondence to: Anne E. Sales, PhD, RN, Health Service Research and Development, VA Puget Sound Health Care System, 1880 S. Columbia Way, Seattle, WA 98108. E-mail: ann.sales@med.va.gov.

Executive Areas. As a result, the discussion related to physician willingness to participate and barriers to complying with evidence-based practice is likely to be similar to responses and attitudes of US primary care physicians. Second, Ireland does not have universal health insurance coverage for all services, particularly outpatient primary care; the majority of Irish citizens are covered for these services under private arrangements with either employment-based insurance coverage or out-of-pocket payment.

There are differences. In Ireland lower income residents, older persons, and other groups are guaranteed care and all citizens are guaranteed certain services, such as public healthcare and maternity care. This has resulted in the creation of public bodies that plan and oversee healthcare services in ways quite unlike in the United States. As a result, the perception that providing preventive services, including secondary prevention, as a public good may be stronger in Ireland than in the United States, and public sector bodies, in particular, may have a greater willingness to fund interventions to improve preventive care. While different from much of the US healthcare system, this support for preventive care is very similar to the few public systems of care in the United States, notably the Veterans Health Administration of the Department of Veterans Affairs. It is also relevant to health management organizations (HMOs) that include both delivery and payment systems under the same organization, such as staff model HMOs. In these organizations, similar economic and policy incentives exist that align healthcare and public health interest in longer term outcomes.

Overall Lessons

The complex intervention development described in the article by Byrne et al functions as an important

“ideal case” of following a highly structured, intensive process of preparing interventions for systematic study. Implicit in the MRC framework is an investment of time and resources at the initiation of an implementation effort, in order to understand the contexts in which the intervention will be implemented and to maximize the probability of success. This is relevant to the market-based US healthcare system, as researchers and healthcare providers in the United States have myriad contextual factors unique to the local environment with which to contend. The MRC framework provides a structured method of assessing those factors. To be of greatest utility, this article should be read in conjunction with the articles describing the outcomes of the randomized trial for which Byrne et al applied the MRC framework.

REFERENCES

1. Byrne M, Cupples ME, Smith SM, et al. Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council framework. *Am J Manag Care*. 2006;12:261-266.
2. Solberg LI, Brekke ML, Fazio CJ, et al. Lessons from experienced guideline implementers: attend to many factors and use multiple strategies. *Jt Comm J Qual Improv*. 2000;26:171-188.
3. Solberg LI, Kottke TE, Brekke ML, et al. Failure of a continuous quality improvement intervention to increase the delivery of preventive services. A randomized trial. *Eff Clin Pract*. 2000;3:105-115.
4. Solberg LI, Kottke TE, Brekke ML, Magnan S. Improving prevention is difficult. *Eff Clin Pract*. 2000;3:153-155.
5. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82:581-629.
6. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. *Health Aff (Millwood)*. 2005;24:138-150.
7. Shojania KG, Grimshaw JM. Still no magic bullets: pursuing more rigorous research in quality improvement. *Am J Med*. 2004;116:778-780.
8. Grimshaw JM, Eccles MP. Is evidence-based implementation of evidence-based care possible? *Med J Aust*. 2004;180(suppl 6):S50-S51.
9. Sanson-Fisher RW, Grimshaw JM, Eccles MP. The science of changing providers' behaviour: the missing link in evidence-based practice. *Med J Aust*. 2004;180:205-206.
10. Grimshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. 2004;8:iii-iv, 1-72.