

TABLE 2—Ways to Address RE-AIM<sup>26,27</sup> Issues in Efficacy and Effectiveness Studies

	Reach	Efficacy or Effectiveness	Adoption	Implementation	Maintenance
Efficacy trials (Phase III research)	Have specified inclusion criteria or purposeful selection, but participants will be volunteers in a specific research setting. Report exclusions, participation rates, dropouts, and representativeness on key characteristics.	Measure outcomes using intent to treat assumptions or imputation of missing values and a high level of rigor. Assess both positive (anticipated) and negative (unintended) outcomes. Report effects of moderator variables.	Have potential adoptees assess fit of prototype intervention to their setting. Include "proxy measures" of adoption, such as participation among those staff members of a system who will participate in the study.	Collect data on likely treatment demands. Evaluate delivery of intervention protocol by different intervention agents (usually research staff).	Assess recidivism among participants. Engage potential community settings in strategic planning efforts from the outset. Document extent to which research protocol is retained by setting/agency once the formal study is completed.
Effectiveness trials in defined populations (Phase IV research)	Include all relevant members of a defined population. Report exclusions, participation rates, dropouts, and representativeness.	Address as above, though measures are usually more limited. Include economic outcomes.	Assess willingness of stakeholders from multiple settings to adopt and adapt the program. Report on representativeness of settings, participation rate, and reasons for declining.	Assess staff ability to implement key components of the intervention in routine practice. Evaluate consistency of intervention delivery by agency staff who are not part of research team.	Assess continuation of program over time, and especially after research phase concludes. Systematically program for and evaluate the level of institutionalization of the program elements after formal study assistance is terminated.

tion must also have high reach. To the  $\text{Impact} = R \times E$  formula, we would add a third component: implementation (I). As discussed by Basch et al.,<sup>19</sup> a program cannot be effective if it is not implemented. Thus, we propose that *individual-level*  $\text{Impact} = R \times E \times I$ . b. An individual-level focus is, however, not sufficient. An intervention also has to be acceptable to and adopted by a variety of intervention settings, and to be implemented relatively consistently by different intervention agents. In other words, the parallel setting or *organizational-level* impact formula should be  $\text{Organizational Impact (OI)} = \text{Adoption (A)} \times \text{Implementation (I)}$ . Several authors have discussed issues of nesting and setting factors<sup>37,48</sup> and how to adjust individual-level effects for issues of nonindependence. However, to our knowledge, the  $A \times I = \text{OI}$  formula for estimating the impact of an intervention across settings has not been discussed, with the exception of an early related proposal by Kolbe<sup>49</sup> that  $\text{Impact} = \text{Effectiveness} \times \text{Dissemination} \times \text{Maintenance}$ . It is important

to emphasize that in terms of overall public health effect, adoption and implementation are as important as reach and efficacy, and that we need more emphasis on studies of organizational- and system-level factors.

3. *Include external validity reporting criteria in author guidelines.* Within medicine, a widely agreed upon set of criteria for reporting the results of randomized clinical trials has been developed. Known as the CONSORT criteria,<sup>50</sup> these reporting standards have been widely adopted by leading medical journals and have helped to increase the quality of published research. As helpful as the CONSORT criteria are, they are almost exclusively concerned with issues of internal validity. Only 1 out of 22 recommendations directly addresses external validity issues<sup>51</sup>; in contrast to the other very specific and concrete criteria, it simply states "Generalizability (external validity) of the trial findings" and provides no guidance as to *how* this issue should be reported.

We propose the following 7 additions to the existing CONSORT criteria, which would help greatly to increase awareness of and reporting on external validity. If such criteria were widely adopted, it would greatly enhance the quality and information value not only of individual studies but also of evidence-based reviews and meta-analyses. The current state of health promotion research is so biased toward reporting on internal validity issues that it is difficult to draw any conclusions about generalization. In particular, there has been a serious lack of attention to issues of representativeness, especially at the level of settings and intervention agents.<sup>21,28,52</sup> This becomes even more problematic when the evidence upon which meta-analyses and practice recommendations are based consists largely or solely of efficacy studies of unknown generalizability.

The 7 items that we propose below should apply to both efficacy and effectiveness studies. They would not require a great deal of additional journal space and are de-

scribed below in the same format as existing CONSORT items. These criteria were recently added by the Evidence-Based Behavioral Medicine Committee of the Society of Behavioral Medicine<sup>53</sup> to their recommendations for reporting on behavioral intervention studies.

- a. State the target population to which the study intends to generalize.
- b. Report the rate of exclusions, the participation rate among those eligible, and the representativeness of *participants*.
- c. Report on methods of recruiting study settings, including exclusion rate, participation rate among those approached, and representativeness of settings studied.
- d. Describe the participation rate and characteristics of those delivering the intervention. State the population of *intervention agents* that one would see eventually implementing the program and how the study interventionists compare with those who will eventually deliver the intervention.
- e. Report the extent to which different components of the intervention are delivered (by different intervention agents) as intended in the protocol.
- f. Report the specific time, and costs required to deliver the intervention.
- g. Report on organizational level of continuance, discontinuance or adaptation in modified form of the intervention once the trial is completed, and individual-level maintenance of results.

We think that such information should be of relevance not only to researchers but also to clinicians, health directors, and decision-makers responsible for selecting prevention and health promotion programs. In fact, we think that these parties already make implicit use of these dimensions. Making them explicit should aid reading of the literature and guide more informed program selections.

4. *Increase funding for research focused on moderating variables, external validity, and robustness.* The large imbalance between the extent to which health promotion investigations focus on internal validity and the extent to which they focus on external validity will not be remedied without substantial changes in funding priorities. Table 3 lists several recom-

**TABLE 3—Recommendations for Funding Organizations to Accelerate Transfer of Research to Practice**

- Solicit proposals that investigate interventions in multiple settings and especially settings that are representative of those to which the program is intended to generalize.
- Fund innovative investigations of ways to enhance reach, adoption, implementation, and maintenance (which have all been de-emphasized relative to efficacy).
- Require standard and comprehensive reporting of exclusions, participation rates, and representativeness of both participants and settings.
- Fund cross-over designs, sequential program changes, replications, multiple baseline, and other designs in addition to randomized controlled trials that can efficiently and practically address key issues in translation.
- Invite programs that investigate and can demonstrate quality implementation and outcomes across a wide range of intervention agents similar to those present in applied settings.
- Require a maintenance/sustainability phase in research projects and implementation of plans to enhance institutionalization once the original research has been completed.
- Fund competitive proposals to investigate long-term effects and sustainability of initially successful interventions.
- Encourage innovation in intervention design and standardization in reporting on process and outcome measures at both individual and setting/intervention agent levels.
- Request more cost-effectiveness studies and other economic evaluations that are of interest to program administrators and policymakers.

mendations for funding organizations that would help correct this imbalance.

These recommendations would have 2 effects. The first would be to increase the small number of well-conducted effectiveness studies now available. The second would be to increase the relevance of efficacy studies for practice by focusing attention on moderating variables and the range of conditions, settings, intervention agents, and participants to which the results apply. Such refocused fund-

ing priorities should also increase understanding of health disparities and help reduce them, since more research would be conducted involving minorities and low-income settings. Finally, funding organizations might explicitly have reviewers rate proposals on their likely robustness or potential for widespread application and impact. This could be done by methods described in the Guide to Community Preventive Services.<sup>54</sup>

## CONCLUSIONS

In summary, at least part of the reason for the slow and uneven translation of research findings into practice in the health promotion sciences is lack of attention to issues of generalization and external validity (moderating factors that potentially limit the robustness of interventions). There also needs to be a greater understanding of, and research on, setting-level social contextual factors.<sup>16,55,56</sup> If these issues were addressed in the design and reporting of efficacy as well as effectiveness studies, it would greatly advance the current quality of research and our knowledge base. These issues are to a large extent under the control of researchers, reviewers, and funding organizations, and we have listed actions that each of these parties can take to facilitate better transfer from efficacy to effectiveness research. ■

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All authors produced original drafts of sections of the manuscript, extensively edited each other's contributions, and made substantive contributions to the ideas expressed in the manuscript.

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## References

1. Clark GN. Improving the transition from basic efficacy research to effectiveness studies: methodological issues and procedures. *J Consult Clin Psychol.* 1995;63:718–725.
2. Weisz JR, Weisz B, Donenberg GR. The lab versus the clinic: effects of child and adolescent psychotherapy. *Am Psychol.* 1992;47:1578–1585.
3. Briss PA, Zaza S, Papaioanou M, et al. Developing an evidence-based Guide to Community Preventive Services—methods. *Prev Med.* 2000;18(suppl 1):35–43.
4. Centers for Disease Control and Prevention. The Guide to Community Preventive Services. 2002. Available at: <http://www.thecommunityguide.org>. Accessed March 11, 2003.
5. Whitlock EP, Orleans CT, Prender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence-based approach. *Am J Prev Med.* 2002;22:267–284.
6. Department of Health and Human Services. Healthy People 2000. 2002. Available at: <http://www.health.gov/healthypeople/data/PROGRVW/default.htm>. Accessed March 11, 2003.
7. Smedley BD, Syme SL. Promoting health: intervention strategies from social and behavioral research. *Am J Health Promot.* 2001;15:149–166.
8. *Integration of Health Behavior Counseling Into Routine Medical Care.* Washington, DC: Center for the Advancement of Health; 2001.
9. Committee on Quality Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academy Press; 2001.
10. Joyner L, McNeeley S, Kahn R. ADA's provider recognition program. *HMO Pract.* 1997;11:168–170.
11. Glasgow RE, Strycker LA. Level of preventive practices for diabetes management: patient, physician, and office correlates in two primary care samples. *Am J Prev Med.* 2000;19:9–14.
12. *Health Behavior Change in Managed Care: A Status Report.* Washington, DC: Center for the Advancement of Health; 2000.
13. Kottke TE, Edwards BS, Hagen PT. Counseling: implementing our knowledge in a hurried and complex world. *Am J Prev Med.* 1999;17:295–298.
14. Woolf SH, Atkins D. The evolving role of prevention in health care contributions of the US Preventive Services Task Force. *Am J Prev Med.* 2001;20:13–20.
15. Orlandi MA. Promoting health and preventing disease in health care settings: an analysis of barriers. *Prev Med.* 1987;16:119–130.
16. Green LW. From research to “best practices” in other settings and populations. *Am J Health Behav.* 2001;25:165–178.
17. Greenwald P, Cullen JW. The new emphasis in cancer control. *J Natl Cancer Inst.* 1985;74:543–551.
18. Flay BR. Efficacy and effectiveness trials (and other phases of research) in the development of health promotion programs. *Prev Med.* 1986;15:451–474.
19. Basch CE, Sliepcevich EM, Gold RS. Avoiding type III errors in health education program evaluations. *Health Educ Q.* 1985;12:315–331.
20. King AC. The coming of age of behavioral research in physical activity. *Ann Behav Med.* 2001;23:227–228.
21. Glasgow RE, Bull SS, Gillette C, Klesges LM, Dziewaltowski DA. Behavior change intervention research in health care settings: a review of recent reports with emphasis on external validity. *Am J Prev Med.* 2002;23:62–69.
22. Oldenburg B, Ffrench BF, Sallis JF. Health behavior research: the quality of the evidence base. *Am J Health Promot.* 2000;14:253–257.
23. Hiatt RA, Rimer BK. A new strategy for cancer control research. *Cancer Epidemiol Biomarkers Prev.* 1999;8:957–964.
24. Kerner JF. *Closing the Gap Between Discovery and Delivery.* Washington, DC: National Cancer Institute; 2002.
25. Teutsch SM. A framework for assessing the effectiveness of disease and injury prevention. *MMWR Recomm Rep.* 1992;41(RR-3):1–12.
26. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health.* 1999;89:1322–1327.
27. Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? *Patient Educ Couns.* 2001;44:119–127.
28. Glasgow RE, Klesges LM, Dziewaltowski DA, Bull SS, Estabrooks P. The future of health behavior change research: what is needed to improve translation of research into health promotion practice? *Ann Behav Med.* In press.
29. Estabrooks PA, Dziewaltowski DA, Glasgow RE, Klesges LM. How well has recent literature reported on important issues related to translating school-based health promotion research into practice? *J School Health.* 2003;73:21–28.
30. Rogers EM. *Diffusion of Innovations.* 4th ed. New York, NY: Free Press; 1995.
31. Mook DG. In defense of external invalidity. *Am Psychol.* 1983;38:379–387.
32. Axelrod R, Cohen MD. *Harnessing Complexity: Organizational Implications of a Scientific Frontier.* New York, NY: Simon & Schuster; 2000.
33. Biglan A, Glasgow RE, Singer G. The need for a science of larger social units: a contextual approach. *Behav Ther.* 1990;21:195–215.
34. Gleser GC, Cronbach LJ, Rajaratnam N. Generalizability of scores influenced by multiple sources of variance. *Psychometrika.* 1965;30:1373–1385.
35. Shadish WR, Cook TD, Campbell PT. *Experimental and Quasi-Experimental Design for Generalized Causal Inference.* Boston, Mass: Houghton Mifflin; 2002.
36. Brunswik E. Representative design and probabilistic theory in functional psychology. *Psychol Rev.* 1955;62:217.
37. Murray DM. Statistical models appropriate for designs often used in group-randomized trials. *Stat Med.* 2001;20:1373–1385.
38. Cook TD, Campbell DT. *Quasi-Experimentation: Design and Analysis Issues for Field Settings.* Chicago, Ill: Rand McNally; 1979.
39. Brewer MB. Research design and issues of validity. In: Reis HT, Judd CM, eds. *Handbook of Research Methods in Social and Personality Psychology.* New York, NY: Cambridge University Press; 2000:3–39.
40. Oldenburg BF, Sallis JF, Ffrench ML, Owen N. Health promotion research and the diffusion and institutionalization of interventions. *Health Educ Res.* 1999;14:121–130.
41. Skinner CS, Campbell MK, Rimer BK, Curry S, Prochaska JO. How effective is tailored print communication? *Ann Behav Med.* 1999;21:290–298.
42. Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. *Ann Behav Med.* 1999;21:276–283.
43. Glasgow RE, Toobert DJ, Hampson SE, Strycker LA. Implementation, generalization, and long-term results of the “Choosing Well” diabetes self-management intervention. *Patient Educ Couns.* 2002;48:115–122.
44. Abrams DB, Emmons KM, Linnan L, Biener L. Smoking cessation at the workplace: conceptual and practical considerations. In: Richmond R, ed. *Interventions for Smokers: An International Perspective.* New York, NY: Williams & Wilkins; 1994:137–169.
45. Prochaska JO, Velicer WF, Fava JL, Rossi JS, Tsoh JY. Evaluating a population-based recruitment approach and a stage-based expert system intervention for smoking cessation. *Addict Behav.* 2001;26:583–602.
46. Jeffery RW. Risk behaviors and health: contrasting individual and population perspectives. *Am Psychol.* 1989;44:1194–1202.
47. Lichtenstein E, Glasgow RE. A pragmatic framework for smoking cessation: implications for clinical and public health programs. *Psychol Addict Behav.* 1997;11:142–151.
48. Elbourne DR, Campbell MK. Extending the CONSORT statement to cluster randomized trials: for discussion. *Stat Med.* 2001;20:489–496.
49. Kolbe LJ. Increasing the impact of school health promotion programs: emerging research perspectives. *Health Educ.* 1986;17:49–52.
50. Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports. *JAMA.* 2001;285:1987–1991.
51. Zaza S, Lawrence RS, Mahan CS, Fullilove M, et al. Scope and organization of the Guide to Community Preventive Services. Task Force on Community Preventive Services. *Am J Prev Med.* 2000;18(suppl 1):27–34.
52. Bull SS, Gillette C, Glasgow RE, Estabrooks P. Worksite health promotion research: to what extent can we generalize the results and what is needed to translate research to practice? *Health Educ Behav.* In press.
53. Davidson K, Goldstein M, Kaplan R, et al. Evidence-based behavioral medicine: what is it and how do we get there? *Ann Behav Med.* In press.
54. Green LW, Kreuter MW. Commentary on the emerging Guide to Community Preventive Services from a health promotion perspective. *Am J Prev Med.* 2000;18:7–9.
55. Institute of Medicine. *Promoting Health. Intervention Strategies From Social and Behavioral Research.* Washington, DC: National Academy Press; 2000.
56. Green LM, Kreuter MW. *Health Promotion Planning: An Educational and Ecological Approach.* 3rd ed. Mountain View, Calif: Mayfield Publishing Co; 1999.

