

## Chapter 12

---

# Continuing Research Needs

In the introduction to this book, three possible results of a *Community Guide* systematic review were described: an intervention is found to be effective, it is found to be ineffective or harmful, or insufficient evidence is available to determine its effectiveness. This chapter addresses the ways in which the *Community Guide* might inform public health intervention research by identifying the areas where insufficient evidence is found or where there is conflicting evidence. We also discuss specific measures to improve the quality of intervention research. This chapter is intended to serve as a guide for organizations that fund public health intervention research and for researchers themselves. Because the information in this chapter is based entirely on our review process, it is not a comprehensive summary of the entire field of intervention research. We hope, however, that it will help a range of organizations set research agendas and contribute to improving research quality.

### **IMPROVING THE QUALITY OF PUBLIC HEALTH INTERVENTION RESEARCH**

In the course of developing the *Community Guide*, we learned a great deal about the quality of public health intervention research and how it could be improved. This section describes lessons learned that might contribute to the overall public health intervention research agenda. The numerous partners involved in the *Community Guide* provided a wide range of insights, ideas, and examples about how their organizations use the *Community Guide*. These examples serve as the basis for this section.

#### ***Evaluate High-Priority Interventions in High-Priority Topics***

The topics chosen and reported in this book and at [www.thecommunityguide.org](http://www.thecommunityguide.org) are high-priority public health issues. The process of identifying them emphasized a preventable public health burden. The list of review topics was finalized by the Task Force on Community Preventive Services only after a process that included extensive input from broad multidisciplinary teams drawn from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the U.S. Department of Health and Human

Services (HHS), state and local public health departments, the healthcare delivery sector, purchasers of health care, and others. Once topics were selected, we also used a process of broad stakeholder input to determine which interventions to review within those topics.

Thus, the *Community Guide* provides information on interventions that address problems widely held to be among the most important ones that public health must address. When the science base for these interventions is sparse or of low quality, the reviews can provide systematically collected and evaluated information on promising but understudied topics with important public health implications. For example, some topics have an extensive evidence base (e.g., reducing tobacco use), while other critical public health areas (e.g., the sociocultural environment, obesity prevention) are relatively understudied. The reviews can also reduce repetition of research beyond that needed for appropriate replication, making it easier to allocate limited research resources to the issues where additional information might make a greater difference. Researchers and research funding organizations can use the *Community Guide* to inform their priority setting among research questions.

### ***Develop or Adapt a Conceptual Model for the Intervention***

Each intervention to be implemented and tested should have a conceptual or theoretical model like those illustrated in this book. Such models can improve the quality of research by making the conceptual or theoretical basis of the intervention explicit, by specifying hypotheses to be tested, and by documenting outcomes to be measured. For these reasons, research funding organizations should require applicants to specify a conceptual model. The *Community Guide* methods (summarized in Chapter 10) and the individual chapters provide examples of such a conceptual modeling process.

### ***Measure Outcomes That Credibly Reflect Intervention Effectiveness***

Each of our reviews defines which outcomes are thought to represent the *success* of the intervention. For these reviews, intervention effectiveness is usually assessed according to health outcomes (e.g., injury rates), established proxies for health outcomes (e.g., vaccine coverage rates), or health behaviors with established links to health outcomes (e.g., seat belt use or tobacco use). Intermediate outcomes (e.g., knowledge, attitudes, process measures, or environmental characteristics) are important mediators, but they do not always correlate well with the ultimate goal of improving health behaviors and health outcomes. The individual chapters of this book can provide researchers and research funding organizations with key health, proxy, or behavioral out-

come measures for individual interventions identified by large multidisciplinary teams of experts on the methodology and subject matter.

### ***Conduct Research on Understudied Interventions***

We have found great variability in the number of evaluations performed on each intervention, from no evaluations to as many as several dozen. The smaller the number of high-quality evaluations of interventions, the greater the need for additional studies, unless the findings are remarkably persuasive. Therefore, by identifying understudied areas, the *Community Guide* can help to increase the impact of limited research resources.

For every intervention reviewed, a list of the major remaining research needs was developed by the review team. Topic-specific lists have been published as part of the scientific review articles<sup>1-12</sup> and are not repeated in this book, although we identify cross-cutting research needs later in this chapter. The process for summarizing research gaps has been described elsewhere<sup>13</sup> and is summarized in Chapter 10.

### ***Consider Harms as Well as Benefits***

When making recommendations, the Task Force attempts to balance the benefits of public health interventions with potential harms. Some interventions may not pose a credible risk of harms. Even when harms are possible, however, potential negative effects are studied much less frequently than potential benefits. Where harms are a concern and have not been studied, they should be studied to better assess the net benefit of the intervention.

### ***Perform Evaluations Appropriate to the Stage of Progress of the Field***

Different types of intervention studies are more or less appropriate, depending on the stage of development of a particular field, such as cancer prevention and control. As a field matures, the research focus may shift over time. In the early stages of public health research in a given area, researchers define the problem epidemiologically and identify risk factors that are possible targets for intervention. Later, they develop theory-based interventions and a taxonomy of those that are promising. This stage is followed by evaluating the effectiveness of the interventions and assessing the applicability, efficiency, and barriers to implementing effective interventions.

Each of our reviews presents background information and conceptual models that help to show the stage of progress of a given field. In addition, each review of an individual intervention provides information about what is

already known and what remains to be studied about the intervention's effectiveness, applicability, efficiency, and barriers to implementation.

### ***Assess Intervention Effectiveness Using the Most Suitable Study Design Possible***

*Suitability* is the appropriateness of the study design for measuring effectiveness. Designs that best limit biases and confounding are considered to be of greater suitability and generally result in greater confidence in the findings. However, such designs (including randomized controlled trials) are often not feasible or ethical in evaluating population-based interventions such as those reviewed here. In addition, designs of greater suitability can limit the external validity of a study (our confidence that the study results can be generalized to populations and contexts beyond the particular ones included in the studies themselves). For example, a study in which specially selected volunteers are assigned to an intervention under conditions in which they are closely monitored by study staff may not translate well to routine practice. It is often therefore reasonable to use a design of lesser suitability if it has advantages with respect to external validity that compensate for any disadvantages with respect to internal validity (our confidence that the intervention being evaluated really caused the effects or outcomes being measured). In addition, if designs with greater suitability are not feasible or appropriate, the use of the best possible design should not impede one's ability to draw conclusions. Non-comparative study designs (i.e., studies without a concurrent or other comparison group), although useful for some questions, are not appropriate for evaluating intervention effectiveness. The reviews in this volume include studies with a range of suitable study designs to ensure a comprehensive assessment of the effectiveness of population-based interventions.<sup>14</sup>

### ***Conduct and Describe Effectiveness Studies in Ways That Minimize Potential Threats to Internal Validity***

The Task Force and its methods work group<sup>14</sup> developed a standard taxonomy of important quality indicators that are applicable to diverse study designs and intended to help minimize threats to internal and external validity.<sup>15</sup> This taxonomy forms the basis for the following recommendations on study design, execution, and dissemination of intervention evaluation studies:

1. Describe the study population in terms of person, place, time, and other relevant characteristics.
2. Describe the intervention in enough detail so that it can be replicated. If journal space is a limiting factor, consider supplementary reports or supporting Internet publications.

3. Describe the selection of the study population. Choose this population in ways that minimize selection bias or threats to external validity (e.g., minimize unnecessary exclusions).
4. Measure exposure to the intervention and its relevant outcomes in reliable and valid ways. Document reliability and validity of both exposure and outcome measures.
5. Conduct statistical tests where appropriate. Choose appropriate statistical tests and perform them correctly.
6. Ensure high follow-up rates.
7. Minimize confounding through study design and analytic techniques.
8. Minimize and explain other potential biases.

Additional advice about assessing quality<sup>16,17</sup> and improving reporting for randomized<sup>18</sup> and non-randomized studies<sup>19</sup> is available elsewhere.

### ***Maximize the External Validity of Effectiveness Studies***

The advice above primarily addresses the internal validity of studies that evaluate intervention effectiveness. External validity is also important, especially for population-based research. In addition to steps 1 and 3 above, external validity may be enhanced by performing additional research in new populations or contexts, thus complementing rather than duplicating existing research.

### ***Maximize Credibility and Comparability of Economic Studies***

Our reviews involve a concerted effort to systematically include and review all information about the economic impact of each recommended intervention (see Chapter 11). Unfortunately, economic evaluations of population-based interventions are rare, and there is considerable variation in the quality and comparability of those that have been published. Enormous gaps in this research area provide ample opportunity for researchers and research funding organizations to explore new areas of public health intervention research. The *Community Guide* process includes innovative methods for systematic reviews and adjustments of economic research, building on the work of the Panel for Cost Effectiveness in Medicine.<sup>20</sup> In addition, our method of conducting economic reviews is unique in its use of quality-scoring criteria for assessing the appropriateness of methods, the validity of results, and the completeness of reporting.<sup>21,22</sup>

### ***Describe Implementation Processes for Effective Interventions***

In developing and communicating findings, we are often asked to provide information about how to implement interventions. Although this is beyond

the current scope of the *Community Guide* and information on this topic is available elsewhere,<sup>23</sup> this is nonetheless a critical aspect of public health that has been surprisingly underemphasized. Research on the steps needed to implement interventions, and on the identification of and methods for overcoming barriers to intervention implementation, is needed to provide public health programs with adequate information for implementing effective interventions. In addition, researchers, funders, government agencies, voluntary organizations, and others should work together to make their intervention materials and processes widely available (e.g., on the Internet). This would go a long way toward reducing the need to “reinvent the wheel” each time an intervention is implemented.

### **CROSS-CUTTING RESEARCH NEEDS IDENTIFIED THROUGH THE *COMMUNITY GUIDE* REVIEW PROCESS**

Each *Community Guide* review leads to the identification of specific questions related to intervention research, which we publish in the scientific review articles.<sup>1-12</sup> In this chapter we identify a number of cross-cutting research needs that have emerged in two or more reviews. These questions will not apply to all interventions, but are issues that come up frequently and are generally worth considering systematically. Intervention studies designed and reported with these questions in mind should provide useful answers. In each section, a specific representative question from a review is presented as an example.

#### ***Questions Pertaining to Methods***

As the reviews were carried out, we uncovered a number of questions about the process of synthesizing intervention research consistently. In this section, we identify general questions that can be answered using rigorous scientific techniques. We do not include questions that resulted from poor execution or reporting of intervention evaluations.

Several issues related to study outcomes emerged during these reviews. In some cases, further research is necessary to determine “What is the public health importance of the outcomes under study?” Questions about the process by which interventions are presumed to affect final outcomes also frequently arose, such as:

- What theoretical or conceptual basis links the outcome measures with the intervention under study?
- To what extent are proximal outcomes predictive of or related to health outcomes? For example, in some interventions provided for children, desired outcomes are far in the future.

Other methodological challenges are related to the improvement of measurement in evaluation research:

- When interventions are implemented, to what extent is the target population exposed?
- How do we improve the measurement (reliability, validity, sensitivity, specificity) of outcome and exposure measures?

Finally, several questions were raised about potential ways of improving future research syntheses:

- How much can a specific intervention vary (e.g., content, materials, setting) and still be assumed to belong to the same class of interventions? For example:

Even though disease and case management [for diabetes] were found effective in the managed care setting for improving glycemic control and provider monitoring of certain important outcomes, several important research gaps were identified in this review. One of the most pressing needs is to better define effective interventions. Disease management has multiple component interventions. To make optimal use of resources, however, only the interventions that contribute most to positive outcomes should be implemented, and these interventions need to be defined.<sup>8</sup>

- How can meta-analytic and information synthesis techniques be improved for summarizing studies, explaining variability across studies, or both?
- How can reporting of studies be improved to facilitate the inclusion of studies involving research synthesis and meta-analysis?

## ***Questions Pertaining to the Interventions***

### ***Effectiveness***

Several key questions about an intervention's effectiveness could be better answered if researchers considered them in the design and reporting of intervention studies.

- How do various intervention characteristics (e.g., content, specificity, method of delivery, frequency of delivery) contribute to effectiveness? For example:

Which neighborhood features (e.g., sidewalks, parks, traffic flow, proximity to shopping) are the most crucial in influencing [physical] activity patterns?<sup>7</sup>

- Do multiple prevention messages act synergistically or do they contradict one another?
- What is the relationship between the level of program intensity and the level of program effectiveness?
- What are the minimum requirements for duration and intensity of interventions to achieve effectiveness?
- What are the optimal requirements for duration and intensity of interventions to achieve maximum effectiveness?
- Are interventions with a strong theoretical basis more likely to be effective than others?
- How is effectiveness of the intervention affected by the baseline rate of the risk factor or disease under study?
- What are the most and least effective combinations of services in multi-component interventions?
- What is the minimal combination of core components required for intervention effectiveness?
- Can components of multicomponent interventions that don't contribute to overall intervention effectiveness be identified and eliminated to maintain effectiveness and increase efficiency?

### *Applicability*

Several issues in data collection and reporting might strengthen conclusions about applicability. For example:

- Do the effects of these interventions vary by key social or demographic variables (e.g., gender, age, race, ethnicity, or socioeconomic status)?
- What is the effectiveness of the intervention in reducing racial and ethnic disparities?
- How do cultural characteristics of the target population contribute to increased or decreased effectiveness?
- Do the effects of these interventions vary by different implementation settings? For example:

How do different practice settings (e.g., independent private practice settings versus [health] management organization settings) contribute to increased or lessened effectiveness of various interventions?<sup>4</sup>

- Does intervention effectiveness vary by urban or rural setting?
- Does intervention effectiveness vary depending on who delivers the intervention (e.g., physicians vs. others; lay health workers vs. others; people of particular demographics or backgrounds vs. others)?
- What theoretical or conceptual basis suggests that effectiveness might vary by different population or setting characteristics?

***Other Benefits or Harms***

Potential harms of interventions are frequently not studied or not reported. The same applies to unanticipated beneficial effects. Without better information about the full range of intervention consequences, it is difficult to assess the net benefit of the intervention. It may be helpful to ask questions like:

- Does the intervention result in unintended harms? For example:
  - If mixed-income housing developments are effective in beginning a process of revitalization that attracts higher-income households to a neighborhood, to what extent does this revitalization and the related increases in housing costs ultimately push poor families out of the area?<sup>2</sup>
- Does the intervention result in unanticipated positive (beneficial) side effects?

***Questions Pertaining to Diffusion, Dissemination, Implementation, and Sustainability of Interventions***

To promote and implement effective interventions that can ensure a sustained positive impact on communities, research questions such as the following should be addressed:

- What are the most effective ways of disseminating research findings?
- What are the most effective ways of communicating findings so that they will be useful and used?
- How can we help communities with priority setting and planning?
- How can a more strategic approach be applied to the selection of interventions so that they are more likely to reach important goals?
- What information and actions are most important in gaining community or political support for interventions?
- How do community coalitions affect or influence the delivery and effectiveness of interventions?
- To ease implementation of interventions, what strategies are effective in reducing barriers?
- What is the nature and role of *opinion leaders* or *champions* in implementing and sustaining an intervention?
- What kinds of community involvement in intervention design contribute to sustainability of community-based interventions?
- What is the pattern of effectiveness of the intervention over time (e.g., continuing improvement, deterioration)? For example:

What effects do these interventions [to reduce alcohol-impaired driving] have on long-term changes in social norms about drinking and driving?<sup>10</sup>

- How long does the effect of the intervention endure after the intervention itself is completed?
- What are the most effective ways to maintain the effects of the intervention?
- What effects do these interventions have on long-term changes in social norms?
- How can community-wide efforts become embedded in the regular activities of local organizations, government, and institutions?

### ***Questions Pertaining to Economic Methods, Measurement, and Studies***

Our systematic reviews of the economic literature on population-based interventions identified a consistent lack of information across all of the topics reviewed. Thus, the research questions in this section are basic economic efficiency questions that need to be answered for nearly all population-based interventions. For a set of examples of economic research questions, see Table 12–1.

- What are the costs (e.g., economic, productivity, or opportunity costs) of these interventions?
- What is the cost benefit, cost utility, or cost effectiveness of these interventions?
- Which specific characteristics of these interventions contribute to economic efficiency?
- How do the opportunity costs of multicomponent interventions compare with those of single-component interventions?
- What combinations of components in multicomponent interventions are most cost-effective?
- How does cost or cost effectiveness vary by context?
- What are the most cost-effective combinations of intervention components?

**Table 12–1.** Example of Economic Research Questions

---

Available economic information was limited to a single study of mass media campaigns (to prevent youth tobacco use initiation). Therefore, considerable research is warranted regarding the following questions:

- Are the costs and cost-effectiveness, net cost, or net benefit of mass media campaigns similar to or substantially different from those that have been previously reported?
  - How do the costs per tobacco user averted by this intervention compare with other tobacco prevention interventions?
  - How do specific characteristics of mass media campaigns contribute to economic efficiency?
  - What combinations of components in multicomponent interventions are most cost-effective?
-

## CONCLUSION

The basic premise of the *Community Guide* is that decisions about intervention selection should be informed, at least in part, by existing scientific understanding of the effectiveness and applicability of those interventions. Our process of conducting systematic reviews also identifies gaps in the evaluation of high-priority interventions and policies, either lack of available research or ways in which the available research can be improved. The fact that these gaps exist is not an indictment of public health research: scientific research is always built piece by piece, and new opportunities will always exist to build on the work that has already been done. Recognition of these gaps confirms that a data-based decision-making process can be applied to how our research resources—most importantly time and funding—are spent to fill those gaps and improve quality efficiently. Researchers, research organizations, and funders of public health intervention research who need to take a strategic approach to answering those needs should find this chapter helpful.

### *Acknowledgments*

This chapter was written by Peter A. Briss, MD, MPH, Community Guide Branch, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia; Barry Portnoy, PhD, Office of Disease Prevention, Office of the Director, National Institutes of Health (NIH), Rockville, Maryland; Martina Vogel-Taylor, MT, Office of Disease Prevention, Office of the Director, NIH, Rockville; and Stephanie Zaza, MD, MPH, Steps Program Office, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta.

### *References*

1. Anderson LM, Shinn CM, Fullilove MT, et al. The effectiveness of early childhood development programs: a systematic review. *Am J Prev Med* 2003;24(3S):32–46.
2. Anderson LM, St Charles J, Fullilove MT, et al. Providing affordable family housing and reducing residential segregation by income: a systematic review. *Am J Prev Med* 2003;24(3S):47–67.
3. Anderson LM, Scrimshaw SC, Fullilove MT, Fielding JE, Normand J, Task Force on Community Preventive Services. Culturally competent healthcare systems: a systematic review. *Am J Prev Med* 2003;24(3S):68–79.
4. Briss PA, Rodewald LE, Hinman AR, et al. Reviews of evidence regarding interventions to improve vaccination coverage in children, adolescents, and adults. *Am J Prev Med* 2000;18(1S):97–140.
5. Dinh-Zarr TB, Sleet DA, Shults RA, et al. Reviews of evidence regarding interventions to increase use of safety belts. *Am J Prev Med* 2001;21(4S):48–65.
6. Hopkins DP, Briss PA, Ricard CJ, et al. Reviews of evidence regarding interventions

to reduce tobacco use and exposure to environmental tobacco smoke. *Am J Prev Med* 2001;20(2S):16–66.

7. Kahn EB, Ramsey LT, Brownson R, et al. The effectiveness of interventions to increase physical activity: a systematic review. *Am J Prev Med* 2002;22(4S):73–107.

8. Norris SL, Nichols PJ, Caspersen CJ, et al. The effectiveness of disease and case management for people with diabetes: a systematic review. *Am J Prev Med* 2002;22(4S):15–38.

9. Norris SL, Nichols PJ, Caspersen CJ, et al. Increasing diabetes self-management education in community settings: a systematic review. *Am J Prev Med* 2002;22(4S):39–66.

10. Shults RA, Elder RW, Sleet DA, et al. Reviews of evidence regarding interventions to reduce alcohol-impaired driving. *Am J Prev Med* 2001;21(4S):66–88.

11. Truman BI, Gooch BF, Sulemana I, et al. Reviews of evidence on interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries. *Am J Prev Med* 2002;23(1S):21–54.

12. Zaza S, Sleet DA, Thompson RS, Sosin DM, Bolen JC, Task Force on Community Preventive Services. Reviews of evidence regarding interventions to increase use of child safety seats. *Am J Prev Med* 2001;21(4S):31–47.

13. Zaza S, Carande-Kulis VG, Sleet DA, et al. Methods for conducting systematic reviews of the evidence of effectiveness and economic efficiency of interventions to reduce injuries to motor vehicle occupants. *Am J Prev Med* 2001;21(4S):23–30.

14. Briss PA, Zaza S, Pappaioanou M, et al. Developing an evidence-based Guide to Community Preventive Services— methods. *Am J Prev Med* 2000;18(1S):35–43.

15. Zaza S, Wright-de Aguero L, Briss PA, et al. Data collection instrument and procedure for systematic reviews in the Guide to Community Preventive Services. *Am J Prev Med* 2000;18(1S):44–74.

16. Agency for Healthcare Research and Quality. Systems to rate the strength of scientific evidence. Available at: [www.ahrq.gov/clinic/epcsums/strengthsum.pdf](http://www.ahrq.gov/clinic/epcsums/strengthsum.pdf). Accessed May 12, 2003.

17. Deeks JJ, Dinnes J, D'Amico R, et al. Evaluating non-randomised intervention studies. *Health Technol Assess* 2003;7(27):1–186.

18. Moher D, Schulz KF, Altman D, CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001;285(15):1987–91.

19. Des Jarlais DC, Lyles C, Crepaz N, the TREND Group. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. *Am J Public Health* 2004;94(3):361–6.

20. Gold MR, Siegel JE, Russell LB, Weinstein MC. Cost-effectiveness in health and medicine. New York: Oxford University Press, 1996.

21. Carande-Kulis VG, Maciosek MV, Briss PA, et al. Methods for systematic reviews of economic evaluations for the Guide to Community Preventive Services. *Am J Prev Med* 2000;18(1S):75–91.

22. Economic evaluation abstraction form, version 3.0. Available at: <http://www.thecommunityguide.org/methods/econ-abs-form.pdf>. Accessed September 9, 2003.

23. Work Group on Health Promotion and Community Development at the University of Kansas in Lawrence. Community Tool Box. Available at: <http://ctb.ku.edu>. Accessed April 7, 2004.

