

When Do We Know Enough to Recommend Action on the Social Determinants of Health?

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Abstract: The Robert Wood Johnson Foundation Commission to Build a Healthier America was charged to identify strategies beyond medical care to address health disparities in the U.S. related to social and economic disadvantage. Based on insights gained while providing scientific support for the commission's efforts, this paper presents an overview of major issues that arise when assessing evidence to inform policies and programs to address the social determinants of health. While many of the insights are not new, they have not been widely assimilated within medicine and public health. They have particular relevance now, given growing awareness of the important health influences of social factors. The discussion presented here is intended to highlight key considerations for researchers who study social determinants of health and policymakers whose decisions are shaped by research findings. Policies should be based on the best available knowledge, derived from diverse sources and methods.

An array of tools and guidelines is now available to guide the assessment of evidence on the social determinants of health, building on—and going beyond—principles first articulated in the “Evidence-Based Medicine” movement. The central thesis of the current paper is that the standards for evidence to guide social policies must be equally rigorous but also more comprehensive than those traditionally used to inform clinical interventions, because social policies must deal with upstream factors that affect health through complex causal pathways over potentially long time periods.

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Introduction

This paper critically examines several challenging methodologic issues that arose in the context of providing scientific support to the Robert Wood Johnson Foundation's Commission to Build a Healthier America (the commission). Other papers in this supplement to the *American Journal of Preventive Medicine* describe the commission and its charge,¹ the rationale and conceptual framework for its efforts,² and its findings and recommendations.^{3–5} Stated briefly, the commission's primary focus was on the social factors that fundamentally shape health; its charge was to identify and recommend policies beyond the realm of clinical medicine that would improve health for all Americans while narrowing health disparities among socioeconomic and racial or ethnic groups. A multidisciplinary research

group (based at the University of California, San Francisco with collaborators at George Washington, Harvard, and Virginia Commonwealth Universities, and at the University of Texas, University of Michigan, and two independent research consulting organizations) provided scientific support to the commission. (The reports and issue briefs produced to inform the commission effort are available at www.commissiononhealth.org/Publications.aspx.)

In its work to synthesize existing knowledge about both the social factors influencing health and health disparities, and potential interventions, the research group faced a variety of analytic challenges. For example, the criteria for evidence to be used in this effort clearly needed to extend beyond the prevailing hierarchy of evidence, with its “gold standard” of RCTs for studies to inform medical practices. In this paper, a summary is presented of the development of our thinking about appropriate criteria for evaluating evidence on health effects of social policies. The goal is to affirm the scientific principles of the “evidence-based medicine” (EBM) movement, while at the same time recognizing the limitations of its hierarchy of evidence, particularly when applied outside selected categories of clinical interventions. Many of the insights included here have been noted in the literature, but have not been adequately promulgated

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among public health and medical researcher, practitioner, and policymaker audiences, particularly in the context of understanding and addressing the social determinants of health.

Historical Background: Recognizing the Need for Evidence-Based Practices in Medicine and Public Health

During the 1970s and 1980s, growing evidence of wide geographic variations in medical care and health outcomes and the proliferation of guidelines based on expert opinion raised questions about the appropriateness of many medical interventions, which heightened interest in more rigorous documentation of effectiveness. Based on principles originally outlined by Cochrane in the 1970s⁶ and elaborated by Eddy,⁷ Sackett,⁸ and others in the 1980s, an interest in empirical demonstrations of outcomes and careful quantitative comparison of benefits and harms laid the foundation for EBM. In the late 1970s, the Canadian Task Force on the Periodic Health Examination introduced a hierarchy of evidence for inferring effectiveness from published studies, in which findings from RCTs held preeminent standing over findings from observational studies, and expert opinion ranked lowest.⁹ This approach was adopted during the 1980s and 1990s by the U.S. Preventive Services Task Force,¹⁰ the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality),¹¹ the American College of Chest Physicians,^{12,13} and others in the U.S.¹⁴ and elsewhere.^{15,16}

By the 1990s the EBM approach had gained wide acceptance in the United States, UK, and elsewhere,¹⁵ and the term “evidence-based” entered everyday usage in public health as well as medicine. The application of EBM standards for public health decision-making is exemplified by the work of the U.S. Task Force on Community Preventive Services^{17,18} and of the international Cochrane Collaboration’s Public Health Group,¹⁹ initially established as the Cochrane Health Promotion Field in 1996.¹⁵ While the Campbell Collaboration, launched in 2000 to systematically review the effectiveness of social interventions, has not primarily focused on health impacts, it has recently worked with the Cochrane Collaboration’s Public Health Group to produce joint reviews relevant to public health, as well as to education, justice, and social welfare.²⁰

The Need for More-Comprehensive Criteria When Assessing Evidence on a Broader Range of Interventions

Applying an evidence-based approach to medicine and public health practice was long overdue, given the wasted resources and potential harm to patients resulting from

practice norms shaped by opinion rather than science. As reflected in the hierarchy of evidence espoused by this approach, results of well-designed and properly conducted RCTs provide the most internally valid basis for causal inference about an intervention’s efficacy. If done properly, random assignment of study participants into intervention and control groups greatly increases the likelihood that observed effects on health are due to the intervention, and not to unmeasured differences between the two groups; nonrandomized studies are inherently more susceptible to bias related to noncomparability of intervention and control groups.

While the application of EBM principles in medicine has contributed to the safety and efficacy of clinical practices, widespread endorsement of the standard EBM hierarchy of evidence has often led to an implicit devaluing of information from sources other than RCTs.²¹ The limitations of relying solely on RCT evidence have been noted in clinical medicine, health promotion, and public health.^{22–29} For example, randomly assigning some study participants to a control group poses ethical issues if current scientific thinking strongly suggests that an intervention is likely to be beneficial. This can be a problem in clinical medicine and in public health (e.g., for testing drugs and population interventions thought to be beneficial, such as automobile airbags or smoking prevention curricula for school children). Even when adequate evidence of benefit is lacking, enrolling participants may be difficult if public opinion regards the intervention as beneficial.

An RCT can be especially problematic for evaluating community-level health interventions, such as media campaigns to promote healthy eating or clean indoor air laws, where exposure in the control group may be unavoidable. Given the logistic challenges and expense of conducting a sufficiently long trial, an RCT may also be inappropriate for studying health effects that manifest over the course of years or decades. Many sources have noted the potentially limited generalizability of results from RCTs, which typically involve relatively small samples drawn from specific populations and settings.^{22,29–32} Victora²⁹ and others^{31,33} have noted that most RCTs provide inadequate information on context, which is crucial for assessing whether a tested intervention can be effectively implemented within other populations and settings.

Although applications of the classic EBM hierarchy of evidence approach have at times emphasized research design, Rychetnik et al.³⁴ have noted that other criteria also are important for judging scientific evidence. Evidence from a rigorously designed and interpreted quasi-experimental or observational study may have far more value for informing practice and policy than results of a

poorly designed or poorly implemented RCT^{35,36} or an RCT that cannot answer crucial questions to guide practice. The work of the Task Force on Community Preventive Services, which in 1999 recognized the need to consider approaches and information sources beyond those traditional to EBM,¹⁷ reflects a major effort to apply systematic standards in assessing evidence on population-based health interventions, including those addressing social determinants of health.^{37,38}

Another paper² in this supplement issue provides an overview of the knowledge base supporting the health effects of many social factors, such as education, income, and the living and working conditions they shape. Although public health has always reached beyond medical care in its concern for water quality, food safety, and environmental and occupational hazards, the growing concern about social determinants of health reflects a broader focus, encompassing health impacts of factors that are the responsibility of—and shaped primarily by decisions in—social sectors such as education, child welfare, transportation, housing, and employment.

As documented by knowledge accumulated over centuries in the U.S. and globally, nonmedical factors play a fundamental role in determining both the occurrence of illness and injury among individuals and disparities in health across populations and communities. It is now known, for example, that family social and economic circumstances can have crucial influences on children's development, through many different and often complex pathways.^{39–44} Beginning at conception, a child's development interacts with conditions influenced by family wealth and education to shape his or her health throughout life.

Many of the above limitations of RCTs apply widely to clinical medicine as well as public health, but several challenges are accentuated for research on social policies and reinforce the need for evidence from a broader array of approaches. For example, studies of social determinants of health and social policy are more likely to introduce ethical or logistic challenges to randomization that do not occur in the clinical setting. Even when the health consequences of a particular social intervention are unknown, it may have recognized nonhealth benefits, such as increased employment or earnings, that introduce ethical concerns about randomization. While some notable randomized experiments have been conducted in the social policy arena, such as the RAND Health Insurance Experiment,⁴⁵ the methodologic challenges can be formidable.

In the clinical sector, the quality of an RCT is judged largely by the standardization, consistency, and fidelity of the intervention. In community-based research on social factors, variation is often inevitable, if not desirable. Suc-

cessful implementation of a social policy intervention at the community level (e.g., bringing full-service grocery stores into disadvantaged neighborhoods) often involves mobilizing political will and community-specific actions across diverse constituencies; random assignment of communities to receive or not receive the intervention can be impractical or even impossible. Variation is often the right way to deliver interventions in the field, especially when they must be tailored to community needs, capabilities, and priorities to achieve maximal effectiveness.

Only by documenting how outcomes vary across different approaches do we begin to understand barriers and facilitators. This concept should not be unfamiliar to clinical researchers. For example, in a randomized trial of a new diabetes medication, the dose and timing will be adjusted to the clinical responses of individual patients, and to the circumstances affecting the level of glycemic control. This variation is considered helpful and, in fact, crucial to determining the actual effect of the medication when used properly. The same principles should apply to testing an intervention in community settings, where variations in populations and contexts will require adjustments in the intervention.

But perhaps the most daunting challenges to relying on RCT evidence to inform social policies relate to difficulties in documenting the health effects of most social factors and interventions, particularly those that are “upstream” health determinants. Compared with the relatively straightforward health effects of more “downstream” or proximal factors (e.g., poor nutrition and physical inactivity, which occur closer in time to the health outcomes of interest), the causal links between upstream social factors (e.g., wealth, neighborhood characteristics, and educational attainment) and health involve multiple complex and lengthy pathways, making it much more difficult to study the effectiveness of social interventions under controlled conditions.

The relationships between upstream social determinants and health are subject to amelioration or exacerbation by a multiplicity of downstream factors and typically involve influences at multiple levels—individual, household or family, neighborhood or community, and state—that may interact with each other and potentially with biological factors. This potential for interaction along the causal pathway represents a potential source of “noise” in measuring the health impacts of upstream interventions that address social conditions. Furthermore, these complex relationships can play out over long periods of time, with implications for the feasibility and costs of intervention research. Because the health effects of social determinants can take decades to manifest, observing the health impacts of many social interventions may take years (al-

though nonhealth impacts might become apparent within a shorter time); for example, social policies focused on children may yield benefits into adulthood and in subsequent generations. Even if a sufficiently lengthy study could be conducted, the Congressional Budget Office's standard time frame for scoring the likely economic impact of a policy is 5–10 years⁴⁶—an inadequate window of time to fully capture the longer-term beneficial effects of many social policies.

A More-Comprehensive Approach: Using the Best Available Knowledge from a Range of Sources and Methods

These challenges serve as reminders that, although the commitment to maximizing internal validity should indeed be an expectation of all studies, the RCT cannot be regarded as the “gold standard” source of evidence for all research questions. Even early proponents of EBM, as well as leaders of the Community Guide effort, reasoned that policies should be based on the “best available” evidence^{9,25} derived from a range of sources and methods. The call for methodologic pluralism and greater conceptual clarity about causal links was emphasized by the WHO's Commission on the Social Determinants of Health's Knowledge Network on Measurement and Evidence,⁴⁷ which laid out important theoretic and operational issues to be considered in developing and assessing knowledge about the associations between health and social factors.

Glasgow and Emmons⁴⁸ list an array of different types of evidence—along with strengths and weaknesses of each type—with potential relevance for guiding public policies with health implications. The recommendations of the Task Force on Community Preventive Services^{38,49} and others^{18,29,34,50–66} provide valuable guidance for assessing the strength of evidence regarding the health impacts of social interventions. The following section echoes some of those widely applicable recommendations and introduces some additional considerations.

Assess the Quality of Evidence Based on Multiple Considerations, Including—but Not Limited to—Study Design

Research design is only one of several criteria that should be used to assess the quality of evidence;³⁴ no study design has an inherent claim on methodologic quality, which depends on both the appropriateness of the design and the quality of its implementation. If, as stated by Banta, “the research method should be fitted to the question,”⁶⁷ then findings from a range of study designs—including but not limited to RCTs—should be considered and judged not only for internal and external validity, but also

for relevance to translation into practice.^{30,68} Much can be learned from natural experiments—for example, comparing health outcomes before and after a social policy, such as an increase in state tobacco taxes, is enacted—⁶⁹ and from the variation that standardized RCT interventions seek to avoid.

The quality of a study should also be distinguished from other considerations that reflect the strength of the evidence. As noted by the U.S. Preventive Services Task Force (USPSTF), the concept of “strength of evidence” has often conflated the methodologic quality with the magnitude of the detected effect.¹⁰ Glasgow and Emmons,⁴⁸ Anderson et al.,⁴⁹ and others⁵⁰ discuss the range of potentially relevant questions (and corresponding analytic methods) that should be considered when the goal is to inform policies intended to improve health. Examples include questions about the problem being addressed (e.g., its public health importance and preventability) and about the intervention (e.g., its effectiveness and associated benefits, harms and costs, and whether it is feasible, acceptable, equitable, and sustainable in the contexts where it is likely to be applied).

A decade ago, the Task Force on Community Preventive Services developed an approach for systematically reviewing the evidence from research on population-based and public health interventions. For each study included in a review, this approach assesses whether the intervention of interest was found to be effective, and whether information was provided about the potential generalizability of results, intervention side effects, economic impact, and barriers to implementation.¹⁸ The Task Force's *Guide to Community Preventive Services* also laid out a series of steps for translating findings from research into policy or practice recommendations, acknowledging that less experience was available to guide the linkage of evidence to practical recommendations.^{18,25,70} These approaches are helpful for assessing the quality of evidence on population-based and public health interventions in general, and particularly on interventions addressing the social determinants of health (Tables 1 and 2).

Connect the Dots: Use Logic Models and Knowledge Linkage

One widely prevalent (but generally implicit) assumption that may underestimate the knowledge base for intervening with a given social factor to improve health is that high-quality evidence linking an intervention (A) with a health outcome (C) can be obtained only from studies that have directly tested the effects of A on C. While these kinds of studies may be desirable, for the many reasons noted above they are particularly challenging and rarely

Table 1. Criteria and methods to increase internal validity

Several sources have reviewed methods that can be used to minimize bias and maximize internal validity when randomization is inappropriate, impossible, or unethical.^{18,34,52–57,62–65} For example, researchers designing nonrandomized studies should strive to include a comparison group that is as similar as possible in important ways to the group receiving the intervention. Victora argues that information from RCTs should be supplemented by “plausibility evaluations,” which “attempt to document impact and to rule out alternative explanations by including a [nonrandomized] comparison group—historical, geographic, or internal—and by addressing confounding variables.”²⁹ When analyzing and interpreting results, researchers can at least partially adjust for differences between intervention and comparison groups through stratification, regression, or other statistical techniques.⁵⁸ Instrumental variables are one such tool,^{59,60} as are propensity scores.⁶⁶ “Complex systems approaches” and “systems dynamic models” reflect efforts to address the multiplicity and complexity of causal pathways that may be involved in understanding the effects of social factors on health; currently used in many disciplines including political science and organizational science, these methods have been used in infectious disease epidemiology and are beginning to attract attention in population health.⁶¹ *Bridging the Evidence Gap in Obesity Prevention* provides a detailed discussion of potential designs to maximize internal validity when RCTs are unsuitable.⁷¹ Perhaps most important, those who interpret research findings with the goal of informing programs and policy should energetically, systematically, and critically seek both to identify and document potential unmeasured differences between intervention and comparison groups and to explore and explicitly acknowledge how such differences might affect results.

available in social policy research. There may be opportunities, however, to build a relevant knowledge base by acknowledging the upstream nature of most social determinants of health and linking evidence from research on specific steps in the likely causal pathways. Often, for example, there are existing bodies of knowledge (perhaps from entirely different disciplines) that respectively document: (1) effects of the social intervention (A) on an intermediate outcome (B); and (2) the association between that intermediate outcome (B) with the health outcome of primary interest (C).

For example, while findings from well-designed RCTs provide some evidence that directly links early childhood developmental interventions (such as high-quality Early Head Start programs or the Nurse–Family Partnership) with improved health outcomes in childhood,^{72–74} the links with adult health impacts have not been as extensively documented, although some evidence exists of effects on adult mental health.^{75,76} Those well-designed RCTs have, however, provided evidence that these interventions are associated with important social outcomes including higher educational attainment,⁷³ which, in turn, based on a solid body of research, is linked causally with an array of health outcomes in adulthood.^{77–83}

This principle of linked knowledge is a useful but often underused tool for inferring the benefits of public health and social interventions that demonstrate an effect on endpoints with solid evidentiary connections to health. Such inferences must be supported by logic models that carefully trace the series of causal inferences from intervention to effect; at each step, relevant evidence should be documented and distinctions between associations and likely causal links should be carefully considered. Caution must be applied when making such inferential leaps, however, particularly when the evidence supporting each association on the proposed causal pathway is derived from studies of different populations, settings, or time periods; furthermore, the strength of evidence supporting each inference must be critically assessed (Table 3).

Acting Responsibly in the Face of Uncertainty

Ogilvie et al.¹⁰¹ advanced the notion of the “inverse evidence law” whereby the least is known about the effects of interventions most likely to influence whole populations.” A primary tenet of EBM has been to withhold recommendations on issues for which the evidence is uncertain. When this is done, however, policy decisions may be made without the benefit of the best available scientific knowledge, making them unduly subject to vested interests and/or implicitly more likely to support the *status quo*. Research findings from *any* type of study rarely provide certainty on policy matters, if only because their generalizability to other populations and settings remains unclear. In addition, because the health conse-

Table 2. Resources to guide assessment of evidence on the social determinants of health

- Criteria for evaluating evidence on public health interventions.³⁴
- *Bridging the Evidence Gap in Obesity Prevention: a Framework to Inform Decision-making* (particularly Chapter 6 and Appendix E).⁵⁵
- *Introduction to Evidence-Informed Public Health and a Compendium of Critical Appraisal Tools for Public Health Practice*.⁶²
- Constructing the evidence base on the social determinants of health.⁶³
- Multiple tools and guidelines from the Campbell Collaboration, available at www.campbellcollaboration.org/resources/resource_center.php. (The Campbell Collaboration is devoted to conducting systematic reviews of interventions in education, crime and justice, and social welfare. While not focused on health outcomes per se, some reviews address health effects, and the methods are relevant for research on the health effects of social interventions.)
- *Handbook and Guidelines of Systematic Reviews of Health Promotion and Public Health Intervention* (Cochrane Collaboration)^{64,65} and other tools and guidelines available at www.cochrane.org. (The Cochrane Collaboration focuses heavily on reviews of evidence from randomized experiments, but has expanded its criteria to some extent in recent years; the basic principles regarding avoiding bias are relevant to all studies.)

Table 3. A case study

An early challenge for the Commission's research team was to assess the quality of evidence for early childhood developmental interventions (such as Early Head Start and similar center-based programs) in improving overall health and narrowing health disparities. Several well-executed RCTs and quasi-experimental studies suggest that high-quality early-childhood development programs have led to improved child development among disadvantaged children as measured, for example, by achievement scores, social/emotional behaviors, and/or IQ scores.^{84–93} While several of those studies have followed participants long enough to document higher educational attainment among those receiving the intervention programs,^{94–96} and a few have followed participants long enough to observe improved employment status and earnings, lower use of social services, or lower arrest rates,^{94,97,98} very few^{88,91,93,99,100} of the relevant RCTs have directly examined health outcomes. At the same time, however, two separate and mostly non-experimental bodies of literature demonstrate strong links of (1) children's cognitive, social, and emotional development with their educational and employment outcomes, and (2) educational attainment/employment with health and well-being among both adults and the children in their households. This linked knowledge was sufficient for the Commission to infer that certain early childhood interventions would indeed be effective approaches for improving health and reducing health disparities, despite limited information from RCTs directly documenting health effects; Miller et al.⁴ in this issue discuss the Commission's recommendation on this topic.

quences of interventions in childhood may not manifest for decades, children in particular may be shortchanged by prevailing approaches to assessing the effectiveness of proposed policies. Rather than pursuing certainty, the preferred goal is to identify and apply the best available knowledge, with full awareness and acknowledgment of its limitations.

There is increasing recognition of the need for a diverse range of sources and methods of acquiring knowledge to guide policies and practice.^{22,24,102–104} Medicine may be unique in the primacy it generally gives to evidence from randomized experiments; other fields such as law, commerce and economic policy—in which decisions are also made with respect to urgent societal issues—use very different standards for evidence. In criminal law, for example, the criterion for making a judgment is evidence beyond a reasonable doubt; in civil law, it is the preponderance of the evidence. Similarly, Air Force paratroopers have not been deprived of parachutes for lack of evidence of their effectiveness in free fall.¹⁰⁵

The rigorous standards developed by the EBM movement to ensure the quality of evidence should not be discarded. However, those standards must be broadened by the experience that has accrued since they were first explicitly articulated in the 1970s, recognizing their limitations and building on their strengths by adopting more comprehensive perspectives. The standard epidemiologic considerations codified in the classic EBM hierarchy of evidence remain useful guideposts when considering

the health effects of social interventions; those considerations still can guide systematic efforts to increase internal validity. Randomization is not always ethical, feasible, or desirable in medical or public health research, however, and the challenges are even greater when examining the health effects of social interventions designed to address factors that influence health through multiple, complex pathways over long periods of time. In assessing the quality of evidence, therefore, more emphasis needs to be placed on critical appraisal of a range of strengths and weaknesses, rather than mechanistic scoring based on narrow criteria.

In an ideal world, all policies—current and future—would be supported by a sound base of scientific evidence. In reality, in most situations, including ones in which experimental results are available, decisions affecting health must be made based on less-than-certain knowledge. While the standards for evidence to guide social policies may need to be more complex and diverse than those developed to ensure the effectiveness of medical devices and drugs in clinical practice, they should be no less rigorous. Decision makers face greater pressure than ever to ensure that funds are allocated in ways most likely to be effective, and social interventions will be at a disadvantage in policy discussions unless both appropriate criteria and rigorous methods are used to assess evidence of their effects on health. Applying more comprehensive standards for evidence can help us to maximize not only the scientific rigor of research on the social determinants of health, but also our understanding of when we do indeed know enough to recommend action.

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