Reducing Racial/Ethnic Disparities in Reproductive and Perinatal Outcomes

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Editors

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The Evidence from Population-Based Interventions

Springer

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Preface

Why a Review of the Evidence Base for Interventions to Improve Reproductive and Perinatal Health Outcomes?

Over 2 decades ago, the Institute of Medicine (IOM) released its influential report *Preventing Low Birth Weight* (IOM, 1985), galvanizing and mobilizing community, state, and federal MCH practitioners and policy-makers to improve maternal and infant health status. Despite the development of numerous programs, initiatives, and approaches to address the delivery of care during the preconceptional, prenatal, and postpartum periods, the major indicators of maternal and infant morbidity and mortality in the US have not uniformly shown marked improvement during this time (Martin, Hamilton, Sutton, et al., 2009); most notably, racial/ethnic disparities in key maternal and infant health status measures have remained persistent, and in some cases, even increased.. However, to date there has been no systematic effort to examine these interventions in a comprehensive fashion, or to specifically look at the evidence vis a vis their potential for reducing racial/ethnic disparities in reproductive and perinatal outcomes. Thus, the focus of this book.

Given that one of the major initiatives to improve reproductive and perinatal outcomes in the last 20 years has been the expansion of financial access to care, particularly during the prenatal period, a large portion of this book reviews the evidence for the public health interventions (as opposed to clinical interventions such as blood pressure checks, urinalysis, the use of risk assessment, fundal height measurement, etc.) that are incorporated into, or delivered concomitantly with prenatal care, such as depression screening and treatment, nutritional supplementation, smoking cessation programs, and prenatal case management. This book focuses on the contribution of these interventions to the overall improvement of reproductive and perinatal outcomes and their potential to reduce disparities in such outcomes between racial/ethnic groups in the United States.

We believe this book is an important undertaking, particularly since there has been an ongoing discussion of the prenatal care investment (Huntington & Connell, 1994; Fiscella, 1995; Strong, 2000). This discussion has arisen in response to the Medicaid expansions which increased the number of women with financial access to prenatal care (Kaiser Family Foundation, 2009), resulting in improved utilization, but not in associated decreases in prematurity and LBW (Martin et al., 2009). In addition, with the publication of studies showing no difference in perinatal outcomes with a reduced schedule of prenatal visits compared to a standard schedule of prenatal visits (McDuffie, Beck, Bischoff, Cross, & Orleans, 1996), and a recognition that in many Western European countries, the schedule of visits is often fewer but outcomes are better (Papiernik, 2007), it has become increasingly clear that more prenatal care (at least as measured by number of visits) in and of itself is not necessarily better.

Some of the expectation for significant positive changes in birth outcomes as the result of the Medicaid expansions was not likely justified, as many women eligible for Medicaid only due to

pregnancy do not access Medicaid and/or prenatal care early enough to allow for any potential impact (Simon & Handler, 2008). More importantly, the Medicaid expansions were not expected to have any effect on the pregnancy outcomes of the lowest income women, who were already covered by Medicaid during pregnancy, many of whom have multiple risk factors placing them at high-risk for poor birth outcomes (Guyer, 1990). Finally, beyond the numerous issues related to adequately defining and measuring prenatal care (Bell & Zimmerman, 2003; Misra & Guyer, 1998), the assumption of an independent impact of prenatal care alone on maternal and infant outcomes, disregards the current and historical context of women's lives and the established contribution of this context to reproductive health and pregnancy outcomes.

Because there is both widespread disappointment at the "failure" of the Medicaid expansions to improve pregnancy outcomes over the last 2 decades as well as widespread acknowledgement of the conceptual and measurement issues related to establishing prenatal care's effectiveness, it has been easy for some researchers and policy-makers to dismiss the relevance of increasing access and enhancing the quality of prenatal care as strategies for improving pregnancy outcomes. These circumstances provide the opportunity for us to reframe the issues pertaining to prenatal care effectiveness and advance our understanding of the contribution made by the various interventions and programs developed for women prior to, during, or soon after pregnancy, in improving their reproductive health and perinatal outcomes. A critical review of the evidence emphasizing the breadth and timing of such interventions as provided by this book, highlights the potential of a lifespan approach and creates the opportunity to consider the evidence for each of these interventions vis a vis their potential for reducing racial/ethnic disparities in reproductive and perinatal outcomes.

What's Included in This Book?

This book focuses on a systematic review of the evidence for interventions that surround a woman's childbearing years (see chapter by Kennelly for a description of methodological approaches used). It begins with a brief discussion of evidence-based medicine (EBM) and evidence-based public health (EBPH) by Handler, with a focus on the specific challenges of implementing EBPH. The principles and underlying assumptions of the scientific process to generate 'evidence' are then presented and critiqued by Aviles and Filc. Hogan, Shanahan and Rowley's chapter outlines critical and methodological issues specific to evidence generation focused on reproductive and perinatal outcomes. Subsequent chapters focus on one or more interventions to improve reproductive and/or perinatal outcomes. The chapters span the childbearing years addressing family planning and abortion, access to and use of infertility services, specific aspects of preconception care, prenatal care overall, as well as public health interventions during the prenatal period (e.g., STD and HIV screening, smoking cessation, group prenatal care, use of doulas, prenatal case management, depression screening and treatment, nutrition supplementation, and screening and treatment for substance use) that extend, enhance, and complement prenatal care. Related topics, such as genetic disease screening, and domestic violence screening and counseling during pregnancy, were originally targeted for inclusion in the book but were ultimately not able to be included.

The book also includes a chapter on intrapartum interventions prompted by the spiraling rate of C-sections and the need to examine whether certain clinical interventions which may increase or decrease maternal and infant morbidity/mortality are differentially offered to and/or used by various racial/ethnic groups. Likewise, a chapter on perinatal regionalization examines whether this system, heralded as playing a major role in reducing infant mortality in the U.S., has additional potential for reducing racial/ethnic disparities in reproductive and perinatal outcomes by focusing beyond the prenatal and perinatal periods.

What Have We Learned?

Considered together, the reviews of the evidence in this book suggest that with respect to the effectiveness of prenatal care itself, promise may lie in more integrated care models in which "enhancements" are standardized and delivered as part of comprehensive high quality care within systems that are accessible to all women, rather than as "siloed" interventions. The evidence also suggests that going beyond the prenatal period to include well-women care across the lifespan may hold significant promise and potential not only for improving reproductive and perinatal outcomes, but for reducing disparities in these outcomes as well.

More generally, the chapters in this book reveal that the depth and range of the evidence varies with respect to both the demonstrated and potential effect of each intervention to reduce racial/ethnic disparities in reproductive and perinatal outcomes. Importantly, for many interventions, information about effects on racial and ethnic disparities does not exist or can only be inferred; for the most part, the studies reviewed tend to focus on improving outcomes in one or more populations but not necessarily on approaches to reducing disparities between populations Likewise, in many cases, overall weak or modest effects might suggest potential for effectiveness but also point out difficulties related to the lack of theoretical models for how an intervention might produce an effect, inadequate or incomplete intervention implementation, lack of standardization of program models, as well as failure to move from targeted to universal implementation, thus leading to differential uptake of interventions. Additionally, several chapters caution that it is important to ensure that differential implementation of interventions (whether in quality or quantity) does not inadvertently lead to an increase in disparities, or possibly a decrease in disparities due to a worsening of outcomes for the majority population.

Despite the caveats and challenges raised by each chapter, when reviewed as an entire body of evidence for interventions to improve the reproductive health of women as well as perinatal outcomes, this book enables us to determine the "stuck points" for the field, and to identify the necessary steps for generating future evidence and improving practice to effectively address racial/ethnic disparities in reproductive and perinatal health. Importantly, this book makes clear that such an evidence-informed practice will need to recognize context and nuance, consider factors related to program/policy implementation, and appreciate the often distal relationship between public health interventions and health status outcomes. With these common understandings as the basis for action, it is our hope that this book will be a useful tool and reference for students, researchers, and practitioners alike as they pursue a wide variety of approaches to improve reproductive and perinatal health outcomes.

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References

Bell, J., & Zimmerman, F. (2003). Selection bias in prenatal care use by Medicaid recipients. *Maternal and Child Health Journal, 7*(4), 239–251.

Fiscella, K. (1995). Does prenatal care improve birth outcomes? A critical review. *Journal of Obstetrics and Gynecology, 85*, 468–479.

Guyer, B. (1990). Medicaid and prenatal care: Necessary but not sufficient. *JAMA: The Journal of the American Medical Association, 264*, 2264–2265.

Huntington, J., & Connell, F. (1994). For every dollar spent – The cost-savings argument for prenatal care. *New England Journal of Medicine, 331*, 1303–1307.

Institute of Medicine, Committee to Study the Protection of Low Birthweight, Division of Health Promotion and Disease Prevention. (1985). *Preventing low birth weight*. Washington, DC: National Academy Press.

Kaiser Family Foundation. (2009). Statehealthfacts. Income eligibility levels for pregnant women by annual income and as a percent of Federal Poverty Level (FPL). Retrieved November 6, 2009, from, http://www.statehealthfacts.kff.org/comparetable.jsp?ind=206&cat=4

Martin, J., Hamilton, B., Sutton, P., Ventura, S., Menacher, F., Kirmeyer, S. et al. (2009). Births: Final Data for 2006. *National Vital Statistics Reports, 57*(7), 1–101.

McDuffie, R., Beck, A., Bischoff, K., Cross, J., & Orleans, M. (1996). Effect of frequency of prenatal care visits on perinatal outcome among low-risk women. A randomized controlled trial. *JAMA: The Journal of the American Medical Association, 275*(11), 847–851.

Misra D.P., & Guyer B. (1998) Benefits and limitations of prenatal care: From counting visits to measuring content. *JAMA: The Journal of the American Medical Association, 279*, 1661–1662

Papiernik, E. (2007). Preventing preterm birth – is it really impossible? A comment on the IOM report on preterm birth. *Maternal and Child Health Journal, 11*, 407–10.

Simon, K., & Handler, A. (2008). Welfare reform and insurance coverage during the pregnancy period: Implications for preconception and interconception care. *Women's Health Issues, 18S*, S97–S106.

Strong, T. (2000). *Expecting trouble. The myth of prenatal care in America*. New York: New York University Press.

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Chapter 1
Introduction: Challenges in Reducing Disparities in Reproductive and Perinatal Outcomes Through Evidence-Based Public Health

Arden Handler

Introduction

Over the past decade, there has been an increased focus on the use of "evidence" to enhance practice in the delivery of health and human services. This is partially due to the ease with which data can now be accessed and turned into information (Dobrow, Goel, & Upshur, 2004). Also influential have been increases in budget deficits at all levels of government, challenging the role of the public sector as a provider of services and requiring increased justification of the use of public resources. Public health programs and interventions have come under increasing pressure to demonstrate their impact and cost-effectiveness in improving population health as reflected in major health status indicators such as the Healthy People objectives (USDHHS, 2000).

Along with increasing attention to public health performance, there is a growing awareness that to make progress in improving the health of the population, particularly to reduce intransient disparities between racial and ethnic groups, new approaches may be needed. Potential strategies may include among others, universal application of an intervention that is currently available but under-resourced, widespread endorsement and implementation of an intervention that is typically not thought of as a health intervention (e.g., social welfare, income, nutrition, or environmental strategies), and/or the development of new models for an ordinary/common intervention.

As we seek further understanding and develop new frameworks to guide our approach to reach Healthy People 2020 and beyond, it is important to take stock of our current repertoire of interventions, understand their value, carefully examine the results of relevant evaluations, and recognize that within our current body of evidence, hidden nuggets which suggest future directions for intervention may be revealed when the body of evidence is examined as a whole. This book, focused on the evidence base for public health interventions to improve reproductive and perinatal health, is written in this spirit.

Given that this is a book about the potential of *public health* approaches to reduce racial/ethnic disparities in reproductive and perinatal health outcomes, the reviews of the variety of interventions discussed within are subject to some of the unique challenges of evidence-based public health (EBPH) in contrast to those presented by evidence-based medicine (EBM). While the chapter by Aviles and Filc critically assesses the basic assumptions of scientific inquiry in generating evidence,

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the focus of this chapter, is to briefly discuss the difference between EBPH and EBM and to delineate some of the global and specific challenges that researchers and practitioners face when engaging in EBPH.

The Challenges of Evidence-Based Public Health

While there are multiple reasons for the advent of EBPH, some of which are mentioned above, the pressure for increased accountability in public health has arisen in part because of the increasing focus on the generation and use of evidence in the field of clinical medicine (Evidence-Based Medicine), public health's major partner in improving health status. Much has been written on the difference between Evidence-Based Public Heath (EBPH) and Evidence-based Medicine (EBM) (Brownson, Baker, Leet, & Gillespie, 2003; Brownson, Gurney, & Land, 1999; Dobrow et al., 2004; Heller & Page, 2002; Jenicek & Stachenko, 2003; Kohatsu, Robinson, & Torner, 2004) In short, although EBM uses a key public health science (clinical epidemiology) to produce evidence, the focus of EBM is on enhancing the ability of practitioners to engage in informed clinical decision-making at the *individual* (patient) level. EBPH, on the other hand, uses scientific principles for decision-making to improve the health of *populations*. Specifically, EBPH generates and uses evidence to evaluate existing interventions, to determine the efficiency and effectiveness of different intervention strategies, and to develop new programs and policies that have the greatest promise to improve population health.

A key distinction between EBM and EBPH centers on how evidence is created and what constitutes evidence. The randomized controlled trial (RCT), the hallmark of the evidence base for EBM, also has value in EBPH as a tool to determine the potential effectiveness of particular public health interventions and policies. However, most public health interventions address complex problems within multi-level systems and require context specific adaptations to ensure effectiveness. The conduct of an RCT to evaluate an intervention does not guarantee that there has been adequate problem identification or effective program implementation. In addition, as currently conceptualized, an RCT does not necessarily account for community and population context, essential components of EBPH practice. As such, EBPH incorporates evidence from a variety of sources and study types including RCTs. Methods for establishing and evaluating the suitability (hierarchy of evidence) of intervention and evaluation designs other than randomized controlled trials have been promulgated by the public health enterprise [e.g., the U.S. Task Force on Community Preventive Services, Guide to Community Preventive Services; (Briss et al., 2000; Zaza et al., 2000)].

Another key difference between EBM and EBPH is related to the range and types of interventions considered. If we accept the definition of public health as "what we as a society do collectively to assure the conditions in which people can be healthy" (Institute of Medicine, 2002), ensuring that the practice of public health is based on evidence is clearly an enormous undertaking, with a potentially vast range of interventions as well as outcomes to be considered.

While EBM and EBPH may focus on the same health status outcomes (e.g., injury, cancer, low birthweight), EBM typically considers the most proximal causes, and evaluates individual level interventions and treatments. On the other hand, EBPH recognizes and indeed emphasizes the multi-factorial etiology of almost all health status outcomes, and examines the effects of population level practices, programs, and policies on such. Likewise, public health interventions are usually designed to modify or ameliorate risk factors and their associated complex pathways often significantly upstream from a health status outcome. Examples of more upstream risk factors include knowledge and attitudes about a health behavior, the availability of substances such as tobacco and alcohol, whether or not one lives in a low or high income family or community, the presence of supermarkets or parks in a neighborhood, and the extent of residential segregation or

racism. Addressing such risk factors, in other words, the more distal or upstream "causes", makes establishing a causal link between a particular public health intervention and one or more health status outcomes a particularly difficult endeavor.

In addition to the challenge of the distal nature of the relationship between public health interventions and health status outcomes, the selection of outcome measures for public health interventions is often not guided by explicit theoretical frameworks or a complete understanding of the chain of "events" that lead to the anticipated effects in intended populations. Notably, even when there is an understanding of the underlying causal chain, public health professionals are often forced to measure effectiveness according to outcome measures selected by funders (e.g., reduce infant mortality by 50% in 5 years) or other external parties, rather than being able to select the most potentially sensitive structure, process and outcome measures.

Another challenge in EBPH relates to public health's emphasis on primary prevention. Proving that an intervention has prevented an outcome from occurring (e.g., rates of unplanned pregnancy) in a community is much more difficult than showing that a new medication or treatment led to a cure in an individual (e.g., a child's cancer). Further complicating EBPH, the path to "health" (health status) can be affected by a variety of characteristics of the population, health system, or the broader physical, social, economic or political environment (Victora, Habicht, & Byrce, 2004). Thus, given that the implementation of a successful population-based intervention likely varies from community to community as noted above, testing and evaluating public health interventions in any one community rarely provides a definitive answer or solution to a prevalent public health problem.

Even when there is sufficient evidence in support of an intervention in one or more populations or settings, there is not always the political will to fully implement the intervention or to commit to implementation in ways that allows tailoring to the needs of unique and diverse populations. A consequence of the latter phenomenon is that widespread or universal introduction of an intervention may inadvertently lead to continued racial/ethnic disparities in outcomes. This may occur if there is differential implementation, uptake and/or effectiveness of the intervention in various communities or populations. Because the intervention may be understood by the public health community to be effective (e.g., Back to Sleep Campaign for SIDS; education on signs and symptoms of preterm labor for prematurity), there may be insistence that the intervention be implemented as originally delivered in research studies, without the tailoring and nuance needed for adaptation within specific and varied cultural contexts, thus precluding full (or even minimal) effectiveness.

EBPH is also hindered by the lack of adequate surveillance and quality data systems to provide suitable performance measurement and ongoing population-based outcome information. "Evidence" for EBPH practice requires timely, relevant, and appropriately analyzed data generated from population interventions (Brownson et al., 1999). However, in the US, there is no commitment to the generation and maintenance of high quality data systems, evidenced by our currently underfunded and struggling vital statistics system, insufficient resources committed to our national health surveys, and inadequate support for institutions like the U.S. Census Bureau.

All of these issues and caveats plaguing public health science and thus EBPH, create a situation in which an evaluation of a population or community intervention frequently yields a finding of "no or minimal effect" with respect to improving or reducing disparities in a health status outcome. However, interpretation of such a result in EBPH is a delicate undertaking. While a review of the evidence demonstrating "no or minimal effect" might provide support for a disinvestment in a particular intervention or policy, those closely involved and familiar with the intervention delivery may be reluctant to endorse this action, emphasizing that the intervention makes sense "on the face of it" (e.g., nutrition support, depression screening, smoking cessation services). Likewise, the intervention may be supported because it is consistent with the social justice roots/philosophy of public health which recognizes that there are many basic services to which all populations should have access (e.g., STI screening and treatment, family planning, nutrition services, prenatal care). On the

other hand, if the populations who are the recipients of the program/policy might be better served by new models or strategies, complacency or commitment to a particular intervention regardless of the evidence, gives preference to the status quo and may further compromise the health of some populations.

Also contributing to the delicate balance of weighing the evidence in public health, is the fact that many public health interventions are aimed at low-income communities. Such interventions may provide a substantial portion of the infrastructure and other resources available to address a particular health problem or related health and social issues in any one community. In such instances, making an EBPH decision must be contextualized to consider not just individual program recipients but the community as an entire unit. Finding "no effect" in the reduction of infant mortality of a case-management program, for example, might lead one to argue for the termination of this program. However, the program might improve overall maternal well-being or bring as yet unmeasured benefits to the community such as the provision of jobs for lay health workers, or the development of a community advisory council that has become involved in health issues as a result of the intervention. As this example demonstrates, explicit, multilevel theoretical frameworks are necessary to guide the development and implementation of evidence-based interventions as well as the delineation of structure, process and outcome measures to assess their effectiveness.

Clearly, tension exists in EBPH practice between the ongoing funding of programs which while not "proven" to be effective, bring additional needed resources and secondary benefits to high-risk communities and the potential termination of such programs due to inability to demonstrate a discernible impact of a particular intervention approach. Importantly, as public health practice increasingly relies on 'evidence and best practice' in the development and implementation of the best program models available to communities, ensuring that resources continue to flow to at-risk communities (if an intervention is terminated) is imperative.

Similarly, balancing fidelity to the social justice roots of public health and being responsive to the evidence base has implications for the focal points and process of generating evidence. While it is important for scientific inquiry on the effectiveness and efficacy of certain interventions to continue, particularly those which have become widespread without the development of a solid evidence base for a particular outcome of concern (e.g., prenatal care and preterm birth), it is equally, if not more important to also ensure the generation of evidence related to the accessibility, quality, and acceptability of such interventions (e.g., ensuring access to and utilization of high quality prenatal care).

Conclusion

Given the challenges and dilemmas that are part and parcel of EBPH as described above, it is essential that researchers and practitioners evaluate and make the most of the evidence for particular public health interventions recognizing the following caveats:

1. "No effect" is usually not a clear-cut outcome and may have multiple interpretations and implications.
2. Interventions may be effective, but not for the measures that have been selected as the focus of evaluation; therefore, continued implementation may be justified when considered vis a vis an alternative set of measures (structure, process or outcome) that are more sensitive to the intervention.
3. Even when there is strong evidence for the effectiveness of an intervention, there is not always sufficient will or resources to support its implementation/expansion/dissemination.
4. Strong evidence against the effectiveness of the intervention may not always lead to revision or termination; this may have both positive and negative effects for the affected populations.

5. When an intervention appears to be effective, widespread dissemination may not uniformly improve health or decrease racial/ethnic disparities, if access to or uptake of the intervention is differential across population groups.
6. When access to an intervention is a matter of ensuring equity between populations, the generation of evidence may need to increase its focus on quality improvement or implementation strategies, rather than continue to focus only on the effectiveness of the intervention as currently delivered.

Acknowledging these caveats does not preclude making the best possible decisions given the current state of knowledge about any particular public health intervention. However, to maximize the ability of public health practice to improve health outcomes, future efforts to develop and implement public health interventions based on the evidence must synergistically consider the evidence as well as the context of both evidence generation and implementation.

References

Briss, P. A., Zaza, S., Pappaioanou, M., Fielding, J., Wright-De Agüero, L., Truman, B. I., et al. (2000). The Task Force on Community Preventative Services. Developing an evidence-based Guide to Community Preventive Service-Methods. *American Journal of Preventative Medicine*, *18*(1 Suppl.), 35–43.

Brownson, R., Baker, E., Leet, T., & Gillespie, K. (Eds.). (2003). *Evidence-based public health*. Oxford, New York: Oxford University Press.

Brownson, R., Gurney, J., & Land, G. (1999). Evidence-based decision-making in public health. *Journal of Public Health Management Practice*, *5*(5), 86–97.

Dobrow, M., Goel, V., & Upshur, R. E. G. (2004). Evidence-based health policy: Context and utilization. *Social Science and Medicine*, *58*, 207–217.

Heller, R., & Page, J. (2002). A population perspective to evidence based medicine: Evidence for population health. *Journal of Epidemiology and Community Health*, *56*(1), 45–47.

Institute of Medicine, Committee on the Assuring the Health of the Public in the 21st Century. (2002). *The future of the public's health in the 21st century. Board on Health Promotion and Disease Prevention*. Washington, DC: National Academics Press.

Jenicek, M., & Stachenko, S. (2003). Evidence-based public health, community medicine, preventive care. *Medical Science Monitor*, *9*(2), SR1–SR7.

Kohatsu, N., Robinson, J., & Torner, J. (2004). Evidence-based public health: An evolving concept. *American Journal of Preventive Medicine*, *27*(5), 417–421.

U.S. Department of Health and Human Services. (2000). *Healthy people 2010: Understanding and improving health* (2nd ed.). Washington, DC: U.S. Government Printing Office.

Victora, C., Habicht, J. P., & Byrce, J. (2004). Evidence-based public health: Moving beyond randomized trials. *American Journal of Public Health*, *94*(3), 400–405.

Zaza, S., Wright-de Agüero, L., Briss, P. A., Truman, B. I., Hopkins, D. P., Hennessy, M. H., et al. (2000). Data collection instrument and procedure for systematic reviews in the Guide to community Preventative Services. *American Journal of Preventative Medicine*, *18*(1 Suppl.), 44–74.

Chapter 2
Methodological Approach to Assessing the Evidence

Joan Kennelly

The approach taken in this book to guide authors in assessing the evidence for their respective topic areas was generated by the editors. It represents a combination of current recommendations for describing the state of public health evidence, assessing the quality of that evidence, including the suitability of the various studies reviewed to assess the effectiveness of their respective interventions, along with a good dose of practicality.

It was beyond the scope of this book to conduct meta-analyses or full systematic reviews of the literature on the various topics. On the other hand, it was the intent of the editors and authors to provide a thorough and comprehensive review of the literature on select interventions designed to promote reproductive and perinatal health and to identify the role of the interventions with respect to reducing racial and ethnic disparities in related outcomes. Through this review, we expected to further our collective understanding of the strength of the evidence base for the common interventions examined and their associated outcomes, as well as the underlying assumptions of such interventions and their potential for decreasing relevant population health disparities.

Although the complexity of public health interventions is well recognized, the difficulty in assessing and evaluating the impact of population based interventions is often underappreciated and misunderstood. Public health's focus on diverse populations in real life settings presents a significant set of challenges for evaluating and assessing impact. Understanding the effect of context on the design of interventions, their implementation and potential impacts, is central for an adequate and meaningful consideration of evidence for effectiveness. Unfortunately, fundamental information on the quality of interventions as well as critical details on the value and potential replication of such, are not usually included in most systematic reviews or evaluations of public health activities and programs.

Therefore, the guidance to authors and tools for reviewing the evidence that were developed by the editors for this book attempted to address some of these limitations (Appendix A). Specifically, authors were asked to focus on a particular intervention that has been assumed to have a positive influence on reproductive and perinatal outcomes, and to provide an overview of the theoretical and scientific basis of the intervention.

Authors were directed to include a spectrum of study designs including randomized control trials, observational studies, quasi-experimental designs, and expert reports, including both quantitative and qualitative methodologies and to summarize the reviewed studies in both tabular and narrative form. For each study, authors were asked not only to delineate the study

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type and provide a description of the intervention and key findings, but to also specify the characteristics of the population studied and to list major caveats or biases that may influence the outcomes or interpretation of the study's findings, including identifiable contexts within which the intervention was designed and implemented. This information was to be included in a table which focused on the evidence for the effectiveness of the intervention with respect to major reproductive or perinatal outcomes selected by the chapter authors (see Table 2.1 template below).

Note that column eight asks for information about caveats and biases. In addition to the common use of the term caveat, some authors also used this column to provide explanations and modifying details to prevent misinterpretation and promote a more accurate understanding of the study being reviewed.

Furthermore, in an attempt to standardize the review of study quality across the variety of interventions and study designs, authors were initially asked to complete a quality checklist covering the following domains: reporting, external validity, internal validity (bias and confounding), and power. The checklist was an adaptation of the Methodological Quality Checklist developed by Downs and Black in 1998, to accommodate approaches used in most population based evaluations as opposed to clinical research. (Downs & Black, 1998) It became obvious that this checklist was not adequate for the qualitative studies that a number of authors were including in their reviews. Thus, an additional checklist was developed by the editors to provide consistency in the evaluation of study quality and evidence for qualitative studies. This checklist included specific questions related to the study's research design, sampling, data collection, data analysis, results, as well as research value, and was adapted from existing work (Beck 1993; CASP 2002; Rychetnik & Frommer 2002; Miles & Huberman, 2002). The checklists are included in Appendix B.

Importantly, while each study reviewed by authors was given a "total quality score," categorized as good, fair and poor, each study was also rated in terms of its respective "suitability." For quantitative studies, suitability related to the study's capacity to assess the effectiveness of the particular intervention, and was classified as greatest, moderate or least. This rating (Appendix A) was adopted from the Guide to Community Preventive Services (Briss et al. 1999.) Suitability of qualitative studies (Appendix B2) referred to the study's capacity to generate knowledge, facilitate interpretation of quantitative studies, as well as illuminate factors relevant to intervention's effectiveness. Studies were designated as having high, fair, or low value. This rating was adopted from previous work (Beck, 1993; Critical Appraisal Skills Program (CASP), 2002; Miles & Huberman, 2002; Rychetnik & Frommer, 2002). Authors were asked to tabulate the information from the quality checklists and suitability assessments (see Table 2.2 template below).

Table 2.1 Major outcomes associated with studies of x intervention

Health status outcome No.1								
Author, Year	Study design	Study type	Description of intervention what, how and where	Populations studied (ages included, race and ethnicity) and Sample size	Address disparities (Yes/No)	Key findings related to intervention effectiveness (OR with CI or p values reflecting the intervention-outcome relationship	Caveats/ Biases	Findings support the intervention? Yes/No For which populations?

Table 2.2 Quality rating of studies associated with x intervention

Health status outcome No. 1							
Author, Year	Reporting	External validity	Internal validity-bias	Internal validity-confounding	Power	Total quality score <14 = poor 15–19 = fair >20 = good	Suitability of study to assess effectiveness

Table 2.3 Meta-analysis table: topic area

Source	Number of studies/*N*/(% receiving xx intervention)	Findings	Contextual factors	Disparities/Comments

In addition to individual studies, a number of the chapters also include reviews of meta-analyses and other systematic literature reviews. The importance of contextual factors that might influence the quality, strength, and external validity of the meta-analyses was noted by one of our book's chapter authors, Mary Barger. Thus, a third table template developed by Dr. Barger was included for authors' use in tabulating the findings of such inquiry and to facilitate discussion in the chapter narratives. However, not every meta-analysis discussed in the chapter narratives was included in such tables.

While there is no summary score for the totality of studies reviewed in relation to a particular intervention, authors were asked to provide a narrative summary of the evidence and the potential role of the intervention to reduce racial and ethnic disparities in reproductive and perinatal outcomes. In discussing the evidence summary, authors were specifically asked to address demonstrated effects as well as context and any variability in implementation of the intervention, along with the relevance of the evidence for public health practitioners. Finally, in the absence of any quantified effects or impact, authors were encouraged to speculate on reasons why the interventions continue to hold favor in public health practice.

Although efforts to standardize a quality review and discussion of the literature across the book chapters were agreed upon and embraced by authors, the actual process of reviewing the literature across the various topics did not always lend itself to such standardization. The range of intervention topics had their own set of exceptions in terms of the types of interventions and practice that were being considered, as well as the relevant studies and evaluations that had been carried out. There was also considerable variation in the availability of the desired information from the primary studies. This affected the extent to which some authors were able to address the issue of reducing racial and ethnic disparities for a particular intervention, as well as speculate on the relevance of the study findings for specific population groups or the feasibility of their replication. In addition to author preferences and prerogative, this variability is reflected in the type and number of tables included and their placement in the chapter, as well as in each chapter's narrative discussion.

Even though each chapter is distinctive, the uniqueness of several chapters is worth noting in terms of their departure from the proposed chapter structure. Specifically, the chapters on

childbirth practices, clinical interventions for preterm delivery, and screening and treatment of sexually transmitted infections and HIV, because of their focus on clinical guidelines and medical practice based on individual risk, posed challenges in terms of assessing and summarizing their relevance to population-based approaches to reducing disparities in reproductive outcomes. The chapter on family planning reviewed the evidence base for intervention strategies designed to increase access to family planning and safe abortion services (rather than reviewing the effectiveness of family planning services themselves, which is already well-established). Given the unique character of the evidence evaluated, results of this review were summarized in tables but not subjected to quality ratings. Another unique feature of some of the chapters in this book relates to those interventions (e.g., infertility treatments) which if made more available and accessible to women might potentially increase disparities in reproductive outcomes. Although the book editors were involved in extensive editing, each chapter ultimately reflects the perspective of the chapter author(s).

Overall, the chapters in this book highlight the dynamic relationship between politics and science and how social values are embedded in the scientific process of inquiry as well as in the application of "scientific" findings. Each chapter forces us to ask how and why it is that public health and medicine sometimes persist in pursuing practices and approaches that are in contradiction to solid evidence, or fail to universally adopt practices for which there is good evidence. The following chapters by Handler, and Aviles and Filc, highlight potential causes of these sometimes disconcerting approaches and the particular challenges of evidence-based public health.

Appendix A: Detailed Instructions to Substantive Chapter Authors

1) *Each chapter is expected to be no more than 25–30 pages double-spaced including the tables.* Authors will focus on a specific intervention that has been assumed to make a positive contribution to enhancing reproductive and perinatal health outcomes and examine the underlying theories and scientific basis of these assumptions. Chapters should address the following:

   - *Definition of the intervention*: Describe the selected intervention and provide a brief overview of its *theoretical or scientific* basis. Include a brief history and describe the current role of the intervention with respect to reducing racial/ethnic disparities in key reproductive/perinatal outcomes. If the studies to date have not focused on racial/ethnic disparities, state this.
   - *Outcomes affected by the intervention*: Provide a brief overview of the outcomes assumed to be affected by the intervention. Select no more than *two outcomes* which will be the focus of your review of the evidence. Typically, *these outcomes should be those considered to be the "main" outcomes related to the intervention.* However, if there has been a major review of the evidence of the intervention vis a vis a particular outcome, you might want to briefly summarize the findings of that review and provide readers with information about how to access that review. Then choose one of the "lesser" *outcomes* as one of your two outcomes for your review. *For each outcome chosen, very briefly describe the overall prevalence and trends over time for the major ethnic/racial disparities. Keep this brief as this information is likely to appear in more than one chapter.*

2) *Review of the evidence*

A. *Overall instructions*

Authors are requested to select research studies completed since *1985 or the last major review, if this is later*. To ensure consistency between chapters, we ask that authors use the following search engines: *MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Popline, WHO Reproductive Health Library, Web of Science, Cochrane Library, OCLC First Search and Academic Search Elite.* It is assumed that all authors will have access to the proposed search engines through their institutional affiliations. Some engines might require access through a university's library portal. If problems arise in freely accessing any of the engines, please consult with your university librarian and advise the editors.

1. *Study designs for consideration include*: randomized controlled trials, observational studies (cohort and case-control, ecologic epidemiology studies, quasi-experimental designs including time series analyses), studies that have integrated qualitative and quantitative methods (if not already included in above), and expert reports. If a meta-analysis has been done, authors should include the results of the meta-analysis in the list of studies. Authors are requested to follow the paradigm for classifying study designs and *determining the suitability of a study design for assessing effectiveness* as presented in "Developing an Evidence-Based *Guide to Community Preventive Services* – Methods," by Briss et al. The paradigm figure and suitability table are included below.

   Given the hierarchy of study designs determining suitability for assessing intervention effectiveness, and to reduce author burden, it might be best to select studies hierarchically, with a focus on the methodologically strongest studies. However, if you find a series of weaker studies that tend to support the same conclusion, you will want to include these as well. In general, where there is an overwhelming amount of evidence, focus on the strongest evidence and comment on the amount of evidence available.

   Because the focus of the book is on reducing racial/ethnic disparities, authors should if possible select studies conducted within racial/ethnic minority groups or those that directly compare the outcomes of an intervention for one or more racial/ethnic minority groups with the outcomes for European-Americans/majority culture. If a study directly addresses disparities, to the extent possible, please describe how "disparity" was defined and what determinants of disparity were included in the study. If none of the studies for this intervention are focused on racial/ethnic disparities per se, you should review the evidence at hand, and provide your own insights with respect to the potential effectiveness of the intervention for reducing racial/ethnic disparities.

   Studies need not be limited to the U.S; however, for the most part studies are expected to be derived from the developed world. We are still considering devoting a separate chapter to the effectiveness of developing world interventions introduced in multiple locales in improving reproductive/perinatal outcomes.

B. *Specific Approach for Identified Studies: Reviewed studies are to be summarized in both tabular (see mock Tables 2.1 and 2.2 below) and narrative format.*

1. **Table 2.1**

   For each study related to each selected health status outcome, delineate the study design according to the algorithm and identify the study type. Study type refers to where the

findings and evidence were found, such as in a published article, technical report, abstract presentation, book or book chapter, unpublished manuscript, dissertation or thesis. Provide a description of the intervention (what was done, how, and where), denote the populations studied (ages, racial and ethnic categories included) and the sample size. Summarize key findings related to intervention effectiveness, list major caveats/biases, and note whether the study supports the effectiveness of the intervention and for which populations, if known.

2. **Table 2.2**

   For each study, complete a set of questions (approximately 25–30) based on the Quality Checklist for RCTs and Observational Studies of Treatment Studies (used in the AHRQ study of perinatal depression and in turn, based on the Methodological Quality checklist developed by Downs & Black, 1998). This checklist (included in Appendix B) has several domains: reporting, external validity, internal validity (bias), internal validity (confounding), and power. Each domain generates a score; the scores are then summed for a total quality score. In the proposed checklist (slightly revised by the editors to accommodate approaches used in most population based evaluations as opposed to clinical research studies) scores greater than or equal to 20 are considered good studies, scores between 15 and 19 are considered fair, and scores of 14 and below are considered poor. Report the scores for each study in Table 2.2. *For meta-analyses, leave columns 3–9 blank*.

   In Column 9, indicate the suitability of each study's design for assessing intervention effectiveness. As noted above, this classification is taken from the *Guide to Community Preventive Services*. Table 2.2 will help authors in preparing a narrative summary of the evidence.

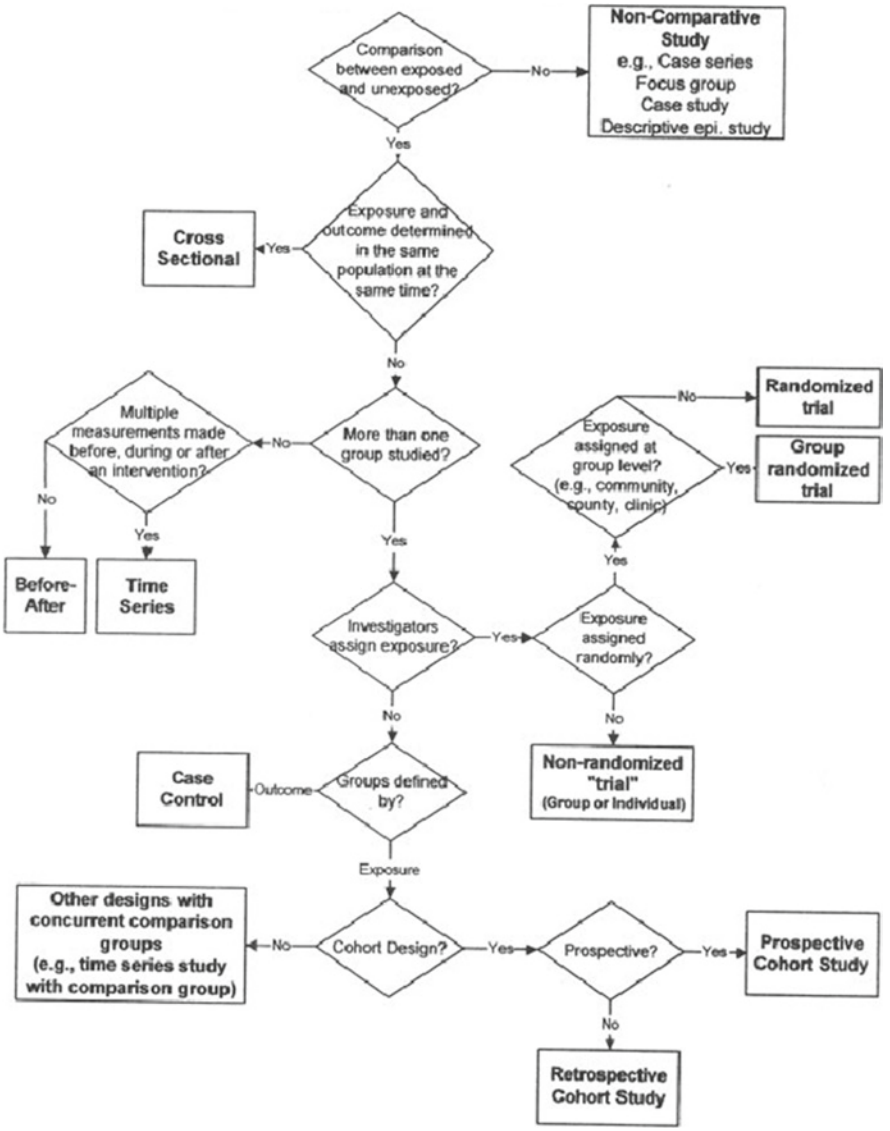
3) *Summary of the evidence and role or potential role of the intervention in reducing racial/ethnic disparities in repro/perinatal outcomes.*

Informed by the study designs, their suitability and quality, as well as the underlying theory and appropriateness of the intervention for the desired outcome, authors should use their judgment to describe and evaluate the overall state of the evidence reported. To the extent possible, authors should address: What are the demonstrated effects of the interventions with respect to reducing racial/ethnic disparities in reproductive/perinatal outcomes? Was there a great deal of variability in the implementation of the intervention? In the absence of any demonstrated effects, what might be reasons why these interventions continue to demand support and favor in public health practice? If positive effects of the intervention have been demonstrated but these effects have not been specific to reducing racial/ethnic disparities, consider the potential of this intervention for reducing racial/ethnic disparities. In doing so, be sure to consider whether (in your judgment), just simply "applying the evidence" to more populations will result in a reduction of racial or ethnic disparities, or whether other actions might need to be taken.

4) *Relevance of evidence for practitioners:*

Each chapter should provide commentary on whether the evidence to date has been well-translated into public health practice (e.g., how widespread is the intervention? where has it been implemented?). To the extent possible, discuss barriers, challenges, and solutions to translating the evidence into MCH public health practice. What can practitioners do to implement the evidence? What system/policy changes might be necessary to disseminate the evidence and to encourage its implementation?

Study Design Algorithm and Suitability Guidelines



Suitability of Study Design for Assessing Effectiveness in the Guide to Community Preventive Services

Suitability	Attributes
Greatest	Includes designs with concurrent comparison groups *and* prospective measurement of exposure and outcome
Moderate	Includes all retrospective designs *or* multiple pre or post measurement designs with no concurrent comparison group
Least	Includes single pre and post measurement designs and no concurrent comparison group designs *or* exposure and outcome measured in a single group at the same point in time

Appendix B: Quality Checklists

B1. Quality Checklist for RCTs and Observational Studies

(used in the AHRQ study of perinatal depression and based on a Methodological Quality checklist developed by Downs & Black, 1998).

Reviewer's initials _____
First Author _____ Journal: _____
Year published_____

	Reporting		Yes	No	U/D
1.	Is the hypothesis/aim/objective of the study clearly described?		1	0	0
2.	Is the underlying theory described?		1	0	0
3.	Are the main outcomes to be measured clearly described in the Introduction or Methods section?		1	0	0
4.	Are the characteristics of the study population included in the study clearly described?		1	0	0
5.	Are the interventions under study clearly described?		1	0	0
6.	Was exposure to the intervention measured?		1	0	0
		Yes	P*	No	U/D
7.	Are the distributions of principal confounders in each group of study participants to be compared clearly described?	2	1	0	0
			Yes	No	U/D
8.	Are the main findings of the study clearly described?		1	0	0
9.	Does the study provide estimates of the random variability (e.g., standard error, standard deviation, confidence intervals, inter-quartile range) in the data for the main outcomes?		1	0	0
10.	Have all important adverse events/negative outcomes that may be a consequence of the intervention been reported?		1	0	0
11.	Have the characteristics of study participants lost to follow up been described?		1	0	0
12.	Have actual probability values been reported (e.g., 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?		1	0	0
	Total reporting score:_____				

**P* partially; *U/D* unable to determine

	External validity	Yes	No	U/D
13.	Were the study participants asked to participate representative of the entire population from which they were recruited?	1	0	0
14.	Were study participants who agreed to participate representative of the entire population from which they were recruited?	1	0	0
15.	Were the staff, places, and facilities where the study participants received the intervention representative of the intervention the majority of subjects receive?	1	0	0

External validity	Yes	No	U/D
16. Were the screening criteria for study eligibility specified?	1	0	0
Total external validity score:_____			
Internal validity – bias	**Yes**	**No**	**U/D**
Answer this 17 and 18 only if this was a randomized controlled trial:			
17. Was an attempt made to blind study participants to the intervention they received?	1	0	0
18. Was an attempt made to blind those measuring the main outcomes of the intervention?	1	0	0
Answer alternative 17 and 18 if this was not a randomized controlled trial:			
19. Were appropriate methods used to adjust for the differences between groups with and without the intervention (to control for selection bias)?	1	0	0
20. Were appropriate methods used to account for any biases related to differential ascertainment of the outcome in groups with or without the intervention?	1	0	0
21. If any of the results of the study were based on "data dredging," was this made clear?	1	0	0
22. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of study participants, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	1	0	0
23. Were the statistical tests used to assess the main outcomes appropriate?	1	0	0
24. Was compliance with the intervention reliable?	1	0	0
25. Were the main outcome measures used accurate (valid and reliable)?	1	0	0
Total bias score:_____			

**P* partially; *U/D* unable to determine

Internal validity – confounding	Yes	No	U/D
26. Were the study participants in the different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	1	0	0
27. Were study participants in the different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	1	0	0
28. Were study participants randomized to intervention groups?	1	0	0
29. *Answer this Q.27, if randomization occurred:* was the randomized intervention assignment concealed from both study participants and intervention staff until recruitment was complete and irrecoverable?	1	0	0
30. *Answer this Q.27, if randomization did not occur:* were study participants in the research or evaluation, unaware of the study hypotheses?	1	0	0
31. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	1	0	0
32. Were losses of study participants to follow-up taken into account?	1	0	0
Total confounding score:_____			

Power

33. Did the study mention having conducted a power analysis to determine the sample size needed to detect a significant difference in effect size for one or more outcome measures?