

Transferring Behavioral Interventions for Global Health: Intellectual Property Barriers, Information Constraints, and Possible Solutions

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TRANSFERRING BEHAVIORAL INTERVENTIONS

INTRODUCTION

Diseases are “biosocial realities”¹: health problems arise not only from biological vulnerability to disease but also from complex systems of environmental risk factors. Such factors range from individual risks, such as behavior and exposure, to mid-level risks, such as neighborhood and culture, to large-scale structural risks, such as war and intellectual property regimes.² Each layer of risk presents an opportunity to intervene and to modify not only individual biological and behavioral processes but also the social and structural contexts that threaten health.

Practitioners and researchers in the global health field have for decades emphasized effective biomedical interventions for improving health,³ often focusing on technology that addresses physiological causes and cures: pharmaceuticals, medical devices, and clinical protocols designed to address the biomedical components of disease. More recently, health researchers have focused on international- and national-level determinants of health, such as international intellectual property interests,⁴ poverty and marginalization,⁵

1. PAUL FARMER, *INFECTIONS AND INEQUALITIES: THE MODERN PLAGUES* 5 (1999) (emphasis removed).

2. The multi-level description of risk factors originated in Urie Bronfenbrenner’s ecological theory. See URIE BRONFENBRENNER, *THE ECOLOGY OF HUMAN DEVELOPMENT: EXPERIMENTS BY NATURE AND DESIGN* (1979). Bronfenbrenner’s work has heavily informed more recent models of risk for disease, as in K.E. Poundstone, S.A. Strathdee & D.D. Celentano, *The Social Epidemiology of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome*, 26 *EPIDEMIOLOGIC REVIEWS* 22 (2004); Craig R. Waldo & Thomas J. Coates, *Multiple Levels of Analysis and Intervention in HIV Prevention Science: Exemplars and Directions for New Research*, 14 *AIDS* S18 (Supp. 2 2000).

3. See, e.g., Gareth Jones et al., *How Many Child Deaths Can We Prevent This Year?*, 362 *LANCET* 65 (2003) (quantifying the preventive effects of various technological interventions for averting child mortality); H. Varmus et al., *Grand Challenges in Global Health*, 302 *SCIENCE* 398, 399 (2003) (denoting fourteen research priorities in global health for the scientific community). The effectiveness of technological interventions is a key component of efforts to increase access to technological treatments.

4. See, e.g., Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 *JAMA* 1886 (2001); Michael Westerhaus & Arachu Castro, *How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?*, 3 *PUB. LIBR. SCI. MED.* e332 (Aug. 2006), available at <http://www.plosmedicine.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.0030332&representation=PDF>.

5. See, e.g., WORLD HEALTH ORG., THE WORLD BANK & VOICES OF THE POOR, *DYING FOR CHANGE: POOR PEOPLE’S EXPERIENCE OF HEALTH AND ILL-HEALTH* (2002), available at http://www.who.int/hdp/publications/dying_change.pdf (describing the health-related consequences of severe poverty in various countries); Thomas Pogge, *Severe Poverty as a Human Rights Violation*, in *FREEDOM FROM POVERTY AS A HUMAN RIGHT: WHO OWES WHAT TO THE VERY POOR?*

conflict,⁶ climate change,⁷ human rights abuses,⁸ market forces,⁹ brain drain,¹⁰ and other social factors.¹¹ Improving access to highly effective technological interventions is undoubtedly a critical priority in global health.

While there has been longstanding discussion regarding access to effective biomedical interventions, scientists have only recently begun to study facets of health shaped by the behaviors of individuals and communities. Scientists in this emerging field consistently point out that behavioral choices are shaped by larger-level social factors, such as poverty and discrimination.¹² However, individuals can often find opportunities to make healthier decisions even within these contexts.¹³ Health behaviors are particularly important in the context of the

12-13 (Thomas Pogge ed., 2007) (stating that “[r]oughly one third of all human deaths, 18 million annually or 50,000 each day, are due to poverty-related causes”).

6. See, e.g., Catherine A. Hankins et al., *Transmission and Prevention of HIV and Sexually Transmitted Infections in War Settings: Implications for Current and Future Armed Conflicts*, 16 AIDS 2245 (2002).

7. See, e.g., WORLD HEALTH ORG., CLIMATE CHANGE AND HUMAN HEALTH: RISKS AND RESPONSES (2003), available at <http://www.who.int/globalchange/publications/climchange.pdf>.

8. For illustrations of the intersection between human rights and HIV, see, e.g., STEPHEN LEWIS, RACE AGAINST TIME (2005); STEPHANIE NOLEN, 28 STORIES OF AIDS IN AFRICA (2007); UNAIDS, COURTING RIGHTS: CASE STUDIES IN LITIGATING THE HUMAN RIGHTS OF PEOPLE LIVING WITH HIV (2006), available at http://data.unaids.org/Publications/IRC-pub07/JC1189-CourtingRights_en.pdf; UNAIDS, Human Rights and HIV, <http://www.unaids.org/en/PolicyAndPractice/HumanRights/default.asp> (last visited Mar. 31, 2010).

9. See, e.g., Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184 (2009) (describing market forces at work in the patenting of pharmaceutical interventions).

10. See Barry R. Bloom, *Public Health in Transition*, SCI. AM., Sept. 2005, at 92, 98.

11. For an explanation of some of these factors, see SOCIAL DETERMINANTS OF HEALTH: THE SOLID FACTS (Richard Wilkinson & Michael Marmot eds., 2d ed. 2003), available at <http://www.euro.who.int/DOCUMENT/E81384.pdf>. The WHO recently established the Commission on Social Determinants of Health to identify social causes of disease and possible remedies. See Michael Marmot, *Social Determinants of Health Inequalities*, 365 LANCET 1099 (2005); WHO, Social Determinants of Health, http://www.who.int/social_determinants/en/ (last visited Mar. 31, 2010).

12. Paul Farmer has referred to institutionalized discrimination and marginalization as “structural violence.” FARMER, *supra* note 1, at 79 (“[S]ickness is a result of structural violence: neither culture nor pure individual will is at fault; rather, historically given (and often economically driven) processes and forces conspire to constrain individual agency.”). Specific social and biological risk factors may vary by illness. This interplay of risk has been elegantly summarized for HIV by Poundstone, Strathdee & Celentano, *supra* note 2.

13. It is important to be realistic and sensitive to real constraints when addressing health behaviors. For example, it would be unrealistic and unfair to expect people who live in unsafe areas to exercise outside their homes or to fault individuals who live in areas of famine or “food deserts” for not eating an optimum balance of vegetables, fruits, and whole grains. However, sensitively

“double burden” of disease, where developing countries now experience not only the “unfinished agenda” of infectious disease but also the growing prevalence of chronic health conditions, such as diabetes and various types of cancer.¹⁴ Health behaviors contribute to both sides of this double burden: some behaviors can make individuals more vulnerable to infections (for example, unprotected sex and HIV), while other behaviors can make individuals more susceptible to chronic conditions (for example, diet and obesity, lack of exercise and heart disease, smoking and lung cancer, and alcohol use and cirrhosis). Efforts to improve individual health behaviors have gained recognition as necessary components of global and national health strategies.¹⁵

Just as pharmaceuticals and medical devices are designed to address the biological elements of disease, a growing number of behavioral interventions are specifically designed to address the *behavioral* risks that make individuals more vulnerable to certain types of illness. Some of these interventions are already well-known globally; for example, Alcoholics Anonymous, Weight Watchers, Drug Abuse Resistance Education (“DARE”), and a variety of smoking cessation programs are household names. The terminology used to refer to such programs varies,¹⁶ but for consistency this Note will refer to them as “behavioral interventions.” Health researchers have noted that, although some programs have no effect on behavior,¹⁷ many others are not only *effective* (in other words, they have protective effects on different health behaviors) but also *transferable* (in other words, they work in multiple settings or for multiple populations).¹⁸

designed behavioral interventions recognize these real constraints and attempt to help people maximize health-promoting behaviors among the options available.

14. See Julio Frenk, *Bridging the Divide: Global Lessons from Evidence-Based Health Policy in Mexico*, 368 LANCET 954, 954 (2006).

15. As one example, the behavioral prevention movement has been particularly galvanized by the AIDS epidemic, as non-governmental organizations throughout high-prevalence countries have received funding to deliver preventive interventions. The U.S. President’s Emergency Plan for AIDS Relief is one example of funding for such prevention. See United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria, 22 U.S.C.A. § 7601 (West 2008).

16. These programs are variously referred to as behavior change programs, health promotion interventions, psychosocial interventions, social interventions, social marketing programs, multimodal or multi-component interventions, and complex social interventions. These programs vary widely in their approaches.

17. For instance, D.A.R.E., although popular in U.S. communities, is among programs that have been identified as ineffective. See CHRISTOPHER L. RINGWALT ET AL., PAST AND FUTURE DIRECTIONS OF THE D.A.R.E. PROGRAM: AN EVALUATION REVIEW (1994). There may also be little empirical evidence to support the use of Alcoholics Anonymous and other twelve-step programs; however, current studies have many limitations, and more research may be required. See M.M.F. Ferri, L. Amato & M. Davoli, *Alcoholics Anonymous and Other 12-Step Programmes for Alcohol Dependence*, 3 COCHRANE DATABASE SYSTEMATIC REVIEWS Art. No.: CD005032, 13 (2006).

18. For example, the Diffusion of Effective Behavioral Interventions (“DEBI”) project was

Adaptation is often necessary to transport effective behavioral interventions to new settings, such as language translation and modification of cultural references.¹⁹ Not every program will work in every setting. Many programs, however, have beneficial effects in a variety of settings when they are implemented with their essential components intact.

The promising, generalizable effects of many behavioral interventions prompt new questions about how to broaden access to such programs, particularly among people living in low-income countries. Patents are the most salient intellectual property barriers discussed in global health because of the lifesaving effect of many pharmaceuticals and the fact that monopoly pricing often makes drugs inaccessible to those who need them.²⁰ Very little literature, however, seeks to identify the legal barriers, if any, to the broad dissemination of behavioral interventions. This Note will examine the particular problem of information barriers and intellectual property interests in behavioral interventions—the programs that attempt to modify the way people behave with regard to their health. This Note is exploratory in nature, in part because this area is undertheorized and in part because it would be impossible to both characterize and solve these problems at once.

The exploration proceeds in five Parts. Part I briefly sketches the role that health behaviors play in global health, focusing particularly on the double burden of infectious and chronic disease. Part II describes behavioral interventions and notes that in practice, effective interventions are often not transferred to new settings. To investigate some reasons for these failings, Part III questions the formal and informal barriers to information-sharing that limit the transfer of effective behavioral interventions. In an attempt to diminish these barriers, Part IV contemplates solutions that might foster information-sharing, implicating the roles of researchers, funders, governments, institutional review boards, and the World Health Organization. Finally, Part V responds to potential arguments against broader information-sharing and the project of transferring effective behavioral intervention. The central argument of this Note is that expanding

founded in 1999 to promote the dissemination of empirically supported behavioral interventions, and the DEBI project provides training and materials free of charge to applicant organizations. Diffusion of Effective Behavioral Interventions Project, Fact Sheet, http://effectiveinterventions.org/files/09-0817_DEBI_overview_factsheet.pdf (last visited Mar. 31, 2010). See also CDC, 2009 Compendium of Evidence-Based HIV Prevention Interventions, <http://www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm> (last visited Mar. 31, 2010) (listing sixty-nine evidence-based behavioral interventions for HIV prevention that may be used in a variety of populations).

19. See Vel S. McKleroy et al., *Adapting Evidence-Based Behavioral Interventions for New Settings and Target Populations*, 18 AIDS EDUC. & PREVENTION 59 (Supp. 2006).

20. See, e.g., Richard D. Smith, Carlos Correa & Cecilia Oh, *Trade, TRIPS and Pharmaceuticals*, 373 LANCET 684, 685-86 (2009).

global access to effective behavioral interventions can reduce both infectious and chronic disease, and that reducing the barriers to disseminating these interventions can play a key role in improving global health.

I. HEALTH BEHAVIORS AND THE DOUBLE BURDEN OF DISEASE

Disease in developing countries is characterized by a double burden, both halves of which are affected by health behaviors.²¹ Julio Frenk has characterized this pattern of disease as a convergence of “the unfinished agenda of infections, malnutrition, and reproductive health problems” and “the emerging challenges represented by non-communicable diseases (along with their associated risk factors such as smoking and obesity), by mental disorders, and by the growing scourge of injury and violence.”²² Frenk has also noted that, paradoxically, recent success in reducing infectious disease and child mortality may contribute to the chronic disease burden in later years:

In health we are victims of our own success. The improvement in basic health conditions . . . enhance[s] the survival of children to reach ages at which non-communicable diseases are more prevalent [P]roblems only of the poor, like many common infections and malnutrition, are no longer the only problems of the poor, who also have the highest rates of many non-communicable diseases, mental disorders, injury, violence, smoking, obesity, and other risk factors.²³

Barry Bloom has echoed this description, noting that chronic diseases are now “the greatest contributor to the global burden of disease,” even as infectious diseases remain destructive.²⁴ Bloom argues convincingly for increased attention to behavioral prevention efforts, highlighting the need to decrease tobacco use, vitamin deficiencies, and weight gain.²⁵ Other estimates of disease are similarly alarming. Katsuri Sen and Ruth Bonita found in 2000 that variation in rates of premature death among populations aged 15 to 60 years is primarily the result of non-communicable diseases and injury.²⁶ An estimate published by the *Lancet* in

21. See, e.g., JoAnne Epping-Jordan et al., *Preventing Chronic Diseases: Taking Stepwise Action*, 366 LANCET 1667, 1667 (2005); Frenk, *supra* note 14, at 954; Derek Yach et al., *The Global Burden of Chronic Diseases: Overcoming Impediments to Prevention and Control*, 291 JAMA 2616, 2617 (2004).

22. See Frenk, *supra* note 14, at 954.

23. *Id.* at 955.

24. Bloom, *supra* note 10.

25. *Id.*

26. Katsuri Sen & Ruth Bonita, *Global Health Status: Two Steps Forward, One Step Back*, 356 LANCET 577, 577 (2000); see also Abdesslam Boutayeb, *The Double Burden of Communicable and Non-Communicable Diseases in Developing Countries*, 100 TRANSACTIONS OF THE ROYAL SOC’Y OF TROPICAL MED. & HYGIENE 191 (2006); Yach et al., *supra* note 21, at 2616.

2005 found that four out of five deaths from chronic disease occur in low-income and middle-income countries.²⁷ There has been inadequate attention to deaths from chronic disease in these settings,²⁸ which are characterized by inadequate access to treatment and a lack of effective prevention programs.²⁹ World Health Organization (“WHO”) personnel such as Frenk and Lee Jong-wook have called on the WHO and national health systems to guide the response to the double burden,³⁰ and the WHO has labeled the prevention of chronic diseases “a vital investment.”³¹

The consequences of this double burden, particularly the impact of chronic disease, are financially and socially devastating. Chronic disease impoverishes individuals and nations, whether by low-level disability over a long period of time³² or by impoverishment caused by out-of-pocket medical expenses where access to subsidized health care is poor.³³ The WHO has estimated, for example, that China alone will lose \$558 billion in national income between 2005 and 2015 due to premature deaths caused by heart disease, stroke, and diabetes.³⁴ Poverty, in turn, drives further illness, disability, and premature death caused by infectious and chronic disease, exacerbating global inequalities in health and wealth.

Health behaviors contribute to both the infectious and the chronic disease halves of this double burden, particularly as “ideas and lifestyles” travel among countries.³⁵ As identified by a variety of research groups and the WHO, behaviors adding most to the global health burden include unprotected sex,

27. Epping-Jordan et al., *supra* note 21, at 1668; *see also* WORLD HEALTH ORG., PREVENTING CHRONIC DISEASES: A VITAL INVESTMENT 3 (2005), *available at* http://www.who.int/chp/chronic_disease_report/full_report.pdf (estimating that 60% of deaths worldwide were due to chronic disease).

28. Yach et al., *supra* note 21, at 2617.

29. Epping-Jordan et al., *supra* note 21, at 1667.

30. *See* Julio Frenk & Octavio Gómez-Dantés, *Globalization and the Challenges to Health Systems*, HEALTH AFF., May/June 2002, at 160, 161; Lee Jong-wook, *Global Health Improvement and WHO: Shaping the Future*, 362 LANCET 2083, 2083 (2003).

31. WORLD HEALTH ORG., *supra* note 27, at 1.

32. *See, e.g.*, Charles H. King & Madeline Dangerfield-Cha, *The Unacknowledged Impact of Chronic Schistosomiasis*, 4 CHRONIC ILLNESS 65, 72 (2008); *see also* WORLD HEALTH ORG., *supra* note 27, at viii.

33. *See, e.g.*, Diane McIntyre, *What Are the Economic Consequences for Households of Illness and of Paying for Health Care in Low- and Middle-Income Country Contexts?*, 62 SOC. SCI. & MED. 858 (2006); Eddy van Doorslaer et al., *Effect of Payments for Health Care on Poverty Estimates in 11 Countries in Asia: An Analysis of Household Survey Data*, 368 LANCET 1357 (2006) (concluding that measures of poverty should not count out-of-pocket medical spending as household consumption and that, if properly measured, poverty rates would rise).

34. WORLD HEALTH ORG., *supra* note 27, at 5.

35. Frenk & Gómez-Dantés, *supra* note 30, at 161.

alcohol use, indoor air pollution, occupational health risks, tobacco use, and physical inactivity.³⁶ Interventions to address these behaviors are an important part of the response to both chronic and infectious diseases.

II. A QUICK PRIMER ON BEHAVIORAL INTERVENTIONS: DEFINITIONS, ORIGINS, AND ACCESS

Addressing disease, whether chronic or infectious, requires an integrated approach consisting of both treatment and prevention,³⁷ including efforts to promote healthy behaviors through behavioral interventions. It is possible to blur the boundary between “behavioral” and “biomedical” interventions, illustrated by hard-to-classify examples such as breastfeeding, vitamin supplementation, condom use, or growth monitoring. However, the basic contours of this argument remain the same: behavioral interventions targeting health choices, such as smoking, diet, physical activity, sexual activity, and hygiene have the potential to make an impact on global disease burden. National health reforms and global health funding streams have acknowledged this in recent years. Consider, for example, Mexico’s *Oportunidades*, a federally funded program that transfers cash incentives directly to families who take enumerated preventive health care actions such as prenatal care, regular checkups for children, cervical cancer screening for women, and diabetes control for adults;³⁸ the growing U.S. National Institutes of Health (“NIH”) prevention research budget,³⁹ and the funding earmarked for behavioral prevention in initiatives such as the President’s Emergency Plan for AIDS Relief.⁴⁰ Effective programs designed specifically to

36. WORLD HEALTH ORG., *supra* note 27, at 6 (estimating at least 2.6 million deaths worldwide each year due to obesity or excess weight; 7.1 million due to raised blood pressure; 4.4 million due to raised cholesterol; and 4.9 million due to tobacco use); Jürgen Rehm et al., *Global Burden of Disease and Injury and Economic Cost Attributable to Alcohol Use and Alcohol-Use Disorders*, 373 LANCET 2223, 2223 (2009); Sen & Bonita, *supra* note 26, at 580; Yach et al., *supra* note 21, at 2616.

37. Of course, the relationship between treatment and prevention is not always dichotomous. As Paul Farmer has noted, treatment *is* prevention in some contexts, such as antiretroviral treatment for HIV infection, which leads to a decrease in viral load and a corresponding decrease in infectiousness. FARMER, *supra* note 1; *see also* Jesús Castilla et al., *Effectiveness of Highly Active Antiretroviral Therapy in Reducing Heterosexual Transmission of HIV*, 40 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 96, 100 (2005).

38. *See* Lia C.H. Fernald, Paul J. Gertler & Lynnette M. Neufeld, *Role of Cash in Conditional Cash Transfer Programmes for Child Health, Growth, and Development: An Analysis of Mexico’s Oportunidades*, 371 LANCET 828, 829-30 (2008) (noting that the program had a \$3.7 billion budget in 2007, covering over five million families); Frenk, *supra* note 14, at 957.

39. NIH Office of Disease Prevention, NIH Prevention Research Budget, <http://prevention.nih.gov/budget.aspx> (last visited Mar. 31, 2010).

40. United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria, 22 U.S.C.A. §

encourage behavior change can be powerful tools in lessening the double burden of disease. The remainder of this section will provide a rough definition of behavioral interventions and identify the main groups that create them: researchers, non-governmental organizations (“NGOs”) and other community groups (for example, schools or community centers), and governments.

A. Behavioral Interventions: Definitions and Origins

A behavioral intervention—“any intervention that has as its expressed purpose changing a person’s health-related attitudes, beliefs, intentions, and behavior so as to enhance his or her health”⁴¹—generally includes some kind of education about health risks and protective behaviors. Studies in social science and psychology, however, have demonstrated that knowledge alone is insufficient to change most health behaviors.⁴² For this reason, behavioral interventions generally include multiple components, such as education sessions, media components, skills training and practice, counseling, group activities, and exercises involving family members, peers, or other social systems. Interventions can target behavior change at a variety of levels, including the individual,⁴³ the family,⁴⁴ social groups such as peer networks or schools,⁴⁵ entire communities,⁴⁶ or even broader levels.⁴⁷

7601 (West 2008).

41. Ralph J. DiClemente, Laura F. Salazar & Richard A. Crosby, *Designing Randomized Controlled Trials in Health Promotion Research*, in RESEARCH METHODS IN HEALTH PROMOTION 129, 129 (Richard A. Crosby, Ralph J. DiClemente & Laura F. Salazar eds., 2006) (defining the term “health promotion program”).

42. See, e.g., ALBERT BANDURA, PRINCIPLES OF BEHAVIOR MODIFICATION (1969).

43. For a discussion of an individual-level intervention, see The EXPLORE Study Team, *Effects of a Behavioural Intervention To Reduce Acquisition of HIV Infection Among Men Who Have Sex with Men: The EXPLORE Randomised Controlled Study*, 364 LANCET 41 (2004).

44. For a discussion of a family-level intervention, see Bonita Stanton et al., *Randomized Trial of a Parent Intervention: Parents Can Make a Difference in Long-Term Adolescent Risk Behaviors, Perceptions, and Knowledge*, 158 ARCHIVES PEDIATRICS & ADOLESCENT MED. 947 (2004).

45. For discussions of social-level interventions, see Karin K. Coyle et al., *Draw the Line/Respect the Line: A Randomized Trial of a Middle School Intervention To Reduce Sexual Risk Behaviors*, 94 AM. J. PUB. HEALTH 843 (2004); and Susan M. Kegeles, Robert B. Hays & Thomas J. Coates, *The Mpowerment Project: A Community-Level HIV Prevention Intervention for Young Gay Men*, 86 AM. J. PUB. HEALTH 1129 (1996).

46. For a discussion of a community-level intervention, see Zunyou Wu et al., *Community-Based Trial To Prevent Drug Use Among Youths in Yunnan, China*, 92 AM. J. PUB. HEALTH 1952 (2002).

47. See, e.g., Gerry V. Stimson, *AIDS and Injecting Drug Use in the United Kingdom, 1987-1993: The Policy Response and the Prevention of the Epidemic*, 41 SOC. SCI. & MED. 699 (1995). For a brief description of community-level, group-level, and structural interventions, see CDC, *Diffusion of Effective Behavioral Interventions*, <http://www.effectiveinterventions.org/go/>

TRANSFERRING BEHAVIORAL INTERVENTIONS

A useful four-part framework for considering behavioral interventions is to consider 1) the program's design, 2) its actual delivery to participants by program staff, 3) the uptake of program by participants, and 4) the context in which the program takes place.⁴⁸ A behavioral intervention generally takes the form of a written program manual, which can be accompanied by media components such as workbooks or videos. Program manuals specify the curriculum, interactive activities or exercises, and the accompanying media or other components. Interventions are generally delivered by program staff, often including social workers, counselors, teachers, volunteers, NGO staff, students, nurses, doctors, dietitians, community workers, and parents. The extent of training and skills necessary to achieve program effects varies; program staff may need intervention-specific training and access to a program manual or protocol. The effects of behavioral interventions also depend on active uptake and participation levels by the people receiving the program. These participants can be individuals, families, schools, communities, or other groups. In order to change behaviors, participants must actually receive the necessary information and skills training, understand what they receive, and then enact and sustain new behaviors in their own lives.⁴⁹ Contextual factors such as resource availability, program setting, language, and the intervention's cultural fit can also influence design and delivery; successful programs are tailored to the physical, cultural, legal, and social environment.

One example of an effective behavioral intervention is the Focus on Youth program (also called Focus on Kids), which aims to reduce the risk of HIV infection among adolescents. The initial trial of this program, which was developed by a research team at the University of Maryland, took place in low-income African American communities in Baltimore.⁵⁰ The initial intervention consisted of seven weekly meetings at a community center and a full one-day session and celebration at a nearby camping site.⁵¹ The curriculum was based on social cognitive theory and protection motivation theory, and it was delivered by pairs of adults to adolescents aggregated in small single-sex groups. Activities

interventions (last visited Mar. 31, 2010).

48. The design and application of this four-part framework was part of the author's doctoral thesis.

49. See Albert J. Bellg et al., *Enhancing Treatment Fidelity in Health Behavior Change Studies: Best Practices and Recommendations from the NIH Behavior Change Consortium*, 23 HEALTH PSYCHOL. 443, 444 (2004).

50. CDC, A Focus on Kids Intervention: Focus on Youth with ImPACT: Fact Sheet, http://www.effectiveinterventions.org/files/foy_with_Impact_Fact_Sheet.final_08-1027.pdf (last visited Mar. 31, 2010).

51. Bonita Stanton et al., *A Randomized, Controlled Effectiveness Trial of an AIDS Prevention Program for Low-Income African-American Youths*, 150 ARCHIVES PEDIATRICS & ADOLESCENT MED. 363 (1996).

included small group discussions, lectures, videos, games, roleplaying, arts and crafts, and community projects, and the culturally sensitive curriculum focused on decision-making, condom use, communication, family trees, and negotiation skills. Compared to youth who simply viewed videos about AIDS and received condoms, youth enrolled in the Focus on Youth intervention were significantly more likely to report using condoms at six-month follow-up.⁵² Subsequent trials of this program modified it to include booster sessions and a parent-child communication component; this combined program had protective effects at long-term follow-up on risky sexual behavior, alcohol use, marijuana use, crack/cocaine use, and drug selling.⁵³ An adapted version of the program was recently shown to reduce sexual risk behavior among a youth population in the Bahamas.⁵⁴ Interestingly, however, an adapted intervention had no effect on risk behaviors in schools in a rural area of West Virginia. The difference in effectiveness between programs might have been due to school-mandated modifications that eliminated condom practice exercises.⁵⁵ The Centers for Disease Control and Prevention ("CDC") has classified Focus on Youth as an effective behavioral intervention, encouraging its adoption through the Diffusion of Effective Behavioral Interventions ("DEBI") project,⁵⁶ which entails training sessions and ongoing technical assistance. A recent survey of organizations implementing the Focus on Youth program found that it has also been implemented in eleven U.S. states and the District of Columbia, Mexico, Trinidad and Tobago, and Vietnam, and it has been translated into five languages.⁵⁷ Groups in China and Namibia have also implemented adapted

52. *Id.* at 363 (reporting that rates of self-reported condom use were 85% and 61% among intervention and control youths, respectively, at a follow-up six months post-intervention).

53. See Ying Wu et al., *Sustaining and Broadening Intervention Impact: A Longitudinal Randomized Trial of 3 Adolescent Risk Reduction Approaches*, 111 PEDIATRICS e32 (2003) (evaluating the intervention with parental monitoring and booster sessions); see also Bonita F. Stanton et al., *Parental Underestimates of Adolescent Risk Behavior: A Randomized, Controlled Trial of a Parental Monitoring Intervention*, 26 J. ADOLESCENT HEALTH 18 (2000) (evaluating the parental monitoring and communication component only).

54. See Jie Gong et al., *Effects Through 24 Months of an HIV/AIDS Prevention Intervention Program Based on Protection Motivation Theory Among Preadolescents in the Bahamas*, 123 PEDIATRICS e917 (2009).

55. See Bonita F. Stanton et al., *Trial of an Urban Adolescent Sexual Risk-Reduction Intervention for Rural Youth: A Promising but Imperfect Fit*, 38 J. ADOLESCENT HEALTH 55.e25, 55.e35 (2006).

56. CDC, *Diffusion of Effective Behavioral Interventions: Focus on Youth with Informed Parents and Children Together*, <http://www.effectiveinterventions.org/go/interventions/focus-on-youth--impact> (last visited Mar. 31, 2010).

57. Jennifer S. Galbraith et al., *Exploring Implementation and Fidelity of Evidence-Based Behavioral Interventions for HIV Prevention: Lessons Learned from the Focus on Kids Diffusion Case Study*, 36 HEALTH EDUC. BEHAV. 532, 538-39 (2009).

versions of the curriculum.⁵⁸

Behavioral interventions like Focus on Youth are under development in many places, although very few are actually evaluated for effectiveness.⁵⁹ They are generated, broadly, by three groups of people with overlapping incentives. Often, programs are developed directly by academics—public health researchers, medical professors, social and behavioral scientists, and psychologists. Most academics do not seek to make a profit on the interventions that they produce, and many intervention packages are sold by nonprofits after their development.⁶⁰ Because researchers are constrained by the need to continually apply for grants and publish new research findings, they generally have limited time to put into publicizing and disseminating effective programs after evaluating them.

NGOs are another source of health behavior interventions, which are implemented by community-based groups, private health insurers, clinics, hospitals, schools, and professional associations. Incentives for community groups also include a desire to improve the health of target populations, the need for continued funding, positive media attention, and the increased need to provide external funders with measurable outcome data. These program creators are often overburdened and may lack the time and incentives to disseminate interventions, to generate program manuals or other replicable materials, or to publicize programs that appear to be effective.

Finally, local and national governments also generate behavioral interventions, which can be delivered through government-run schools, clinics, mass media, and departments of health and welfare. Governmental incentives can include accountability to citizens, a desire to lessen disease burden and increase national productivity, financial considerations, and international or external pressures; however, these incentives do not generally align with disseminating interventions outside the jurisdiction.

B. Access to Behavioral Interventions: The Ideal and Reality of Intervention Transfer

Intervention transfer refers to the process of identifying a program with

58. *See id.* at 538.

59. *See, e.g.,* Manuel Nebot, *Health Promotion Evaluation and the Principle of Prevention*, 60 J. EPIDEMIOLOGY & COMMUNITY HEALTH 5, 5 (2006) (“While the ‘scientific community’ holds to the principle that all public health must be evidence based, in practice the effectiveness of many health promotion interventions and programmes is not properly assessed.”); *cf.* ROSS C. BROWNSON ET AL., EVIDENCE-BASED PUBLIC HEALTH 7 (2003), available at http://prc.slu.edu/Documents/Chapter_1.pdf (describing that public health interventions have fewer studies for effectiveness than medical studies for pharmaceutical products).

60. *See, e.g.,* ETR Associates, <http://www.etr.org> (last visited Mar. 31, 2010) (describing the work of ETR Associates, a nonprofit organization that evaluates and markets sexual risk reduction programs for young people).

proven effects in one setting, and then modifying that program and implementing it somewhere else. Creators of such programs rarely initiate transfers themselves; decision-makers in new settings often must seek them out independently. At the heart of the transfer process is the ideal of evidence-based practice (“EBP”).⁶¹ Briefly, EBP in public health is a process in which decision-makers formulate a research question, search for responsive and methodologically rigorous evidence, appraise the quality of the evidence, integrate the evidence with the situation at hand, adopt an intervention, and monitor the actual intervention effect.⁶² Relevant considerations for adopting an intervention include appraisal of a program’s acceptability to participants, ease of implementation by practitioners, resource requirements, and cost-effectiveness. Evidence-based practice also *produces* important knowledge about the effectiveness of a given behavioral intervention in a new setting, thereby contributing to the body of evidence. To replicate the protective effects of a behavioral intervention, it is also necessary to balance two competing concerns: *fidelity* (implementing the same program that was used before, or at least the core components responsible for behavior change)⁶³ and *adaptation* (implementing the program in a way that will work in the new setting).⁶⁴ Randomized controlled trials and systematic reviews have shown

61. Introductions to evidence-based practice include BROWNSON ET AL., *supra* note 59; J.A. MUIR-GRAY, EVIDENCE-BASED HEALTHCARE (2001); and DAVID L. SACKETT ET AL., EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM (2000). For a primer on the hierarchy of evidence, see Gordon H. Guyatt et al., *Users’ Guides to the Medical Literature: A Method for Grading Health Care Recommendations*, 274 JAMA 1800 (1995); Centre for Evidence Based Medicine, Levels of Evidence, <http://www.cebm.net/index.aspx?o=1025> (last visited Mar. 31, 2010).

62. See sources cited *supra* note 61 for variations on these steps.

63. Theoretical work in implementation fidelity for behavioral interventions is extensive, including the following highlights: Felipe González Castro, Manuel Barrera, Jr. & Charles R. Martinez, *The Cultural Adaptation of Prevention Interventions: Resolving Tensions Between Fidelity and Fit*, 5 PREVENTION SCI. 41 (2004); Andrew V. Dane & Barry H. Schneider, *Program Integrity in Primary and Early Secondary Prevention: Are Implementation Effects Out of Control?*, 18 CLINICAL PSYCHOL. REV. 23 (1998); Linda Dusenbury et al., *A Review of Research on Fidelity of Implementation: Implications for Drug Abuse in School Settings*, 18 HEALTH EDUC. RES. 237 (2003); Frank J. Moncher & Ronald J. Prinz, *Treatment Fidelity in Outcome Studies*, 11 CLINICAL PSYCHOL. REV. 247 (1991); Barbara Resnick et al., *Examples of Implementation and Evaluation of Treatment Fidelity in the BCC Studies: Where We Are and Where We Need To Go*, 29 ANNALS BEHAV. MED. 46 (2005); William H. Yeaton & Lee Sechrest, *Critical Dimensions in the Choice and Maintenance of Successful Treatments: Strength, Integrity, and Effectiveness*, 49 J. CONSULTING & CLINICAL PSYCHOL. 156 (1981). Opinions differ on how much fidelity is necessary when scaling up effective interventions. See Dane & Schneider, *supra*.

64. See, e.g., Jeffrey A. Kelly et al., *Transfer of Research-Based HIV Prevention Interventions to Community Service Providers: Fidelity and Adaptation*, 12 AIDS EDUC. & PREVENTION 87 (Supp. A 2000).

many behavioral interventions to be effective for modifying health behaviors,⁶⁵ and transferring these interventions to new settings could have a significant impact on global disease.

Despite the ideal of evidence-based practice, many effective interventions are neglected, and it has been estimated that “penetration of even the most successful interventions rarely surpasses 1% of any target population.”⁶⁶ Reasons for the limited reach of effective behavioral interventions are manifold.

One key limitation of evidence-based practice is the need for training, both to apply the EBP process and to negotiate the public health literature. A large part of the workforce in public health may lack this training.⁶⁷ The public health and social services sectors are largely unregulated in many places, and even trained professionals may not have been exposed to EBP. Governmental officials, community organizers, school personnel, and other practitioners may not know about electronic databases that index published evaluations of programs—which usually do not contain full text reports of published evaluations—and those who successfully search databases may find an overwhelming amount of

65. See, e.g., Laurie M. Anderson et al., *The Effectiveness of Worksite Nutrition and Physical Activity Interventions for Controlling Employee Overweight and Obesity: A Systematic Review*, 37 AM. J. PREVENTIVE MED. 340, 355 (2009) (summarizing trial findings across a range of worksites to show that worksite nutrition and exercise programs can reduce employee weight); Eileen F. Kaner et al., *The Effectiveness of Brief Alcohol Interventions in Primary Care Settings: A Systematic Review*, 28 DRUG & ALCOHOL REV. 301 (2009) (finding that brief interventions delivered in a variety of primary care settings led to significant reductions in alcohol consumption among men); Seth M. Noar, Hulda G. Black & Larson B. Pierce, *Efficacy of Computer Technology-Based HIV Prevention Interventions: A Meta-Analysis*, 23 AIDS 107 (2009) (synthesizing evidence from a variety of populations showing that computer-based HIV prevention programs can have significant impacts on behavior); L.F. Stead & T. Lancaster, *Group Behaviour Therapy Programs for Smoking Cessation*, COCHRANE DATABASE SYSTEMATIC REVIEWS Art. No.: CD001007, 11 (2005) (summarizing evidence from 53 separate trials to show that group therapy is effective for smoking cessation).

66. Peter S. Jensen, *Commentary: The Next Generation Is Overdue*, 42 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 527, 527 (2003) (cited in Mary Jane Rotheram-Borus, Dallas Swendeman & Gary Chovnick, *The Past, Present, and Future of HIV Prevention: Integrating Behavioral, Biomedical, and Structural Intervention Strategies for the Next Generation of HIV Prevention*, 5 ANN. REV. CLINICAL PSYCHOL. 143, 146 (2009)). Research into the actual dissemination of most social interventions is also lacking. See, e.g., Russell E. Glasgow & Karen M. Emmons, *How Can We Increase Translation of Research into Practice? Types of Evidence Needed*, 28 ANN. REV. PUB. HEALTH 413 (2007).

67. See, e.g., BROWNSON ET AL., *supra* note 59, at 7 (“[P]ublic health relies on a variety of disciplines, and there is not a single (or even small number of) academic credential(s) that ‘certifies’ a public health practitioner. In the United States, for example, fewer than half of the 500,000 individuals in the public health workforce have had formal training in a public health discipline such as epidemiology or health promotion.”).

information.⁶⁸ Next, even if an effective program in an analogous setting is discovered and transferred with perfect fidelity, it may not work the same way in the new setting. For example, the “Be Proud! Be Responsible!” sexual risk reduction intervention has repeatedly been shown to have protective effects in urban settings such as Trenton and Philadelphia;⁶⁹ however, a recent implementation of this intervention in a suburban setting has shown no effect on behavior.⁷⁰ Adaptation of programs may be necessary for transfer, but it is difficult to know what to change.⁷¹ Interventions may require trained staff or materials that are unavailable, particularly in low-income settings.⁷² Some programs may be further hampered by cultural or legal constraints; for example, stringent drug paraphernalia laws may limit the effectiveness of needle exchange

68. See, e.g., Cynthia D. Mulrow, *Rationale for Systematic Reviews*, 309 BRIT. MED. J. 597, 597 (1994) (“Over two million articles are published annually in the biomedical literature in over 20,000 journals Clearly, systematic literature review is needed to refine these unmanageable amounts of information.”). To illustrate this problem, when I set out to summarize the evidence for abstinence-based HIV prevention programs, I worked with a team to screen over 20,000 abstracts to find the 52 program evaluations that were responsive to our research question. Kristen Underhill, Paul Montgomery & Don Operario, *Sexual Abstinence Only Programmes To Prevent HIV Infection in High-Income Countries: Systematic Review*, 335 BRIT. MED. J. 248 (2007); Kristen Underhill, Don Operario & Paul Montgomery, *Systematic Review of Abstinence-Plus HIV Prevention Programs in High-Income Countries*, 4 PUB. LIBR. SCI. MED. e275 (Sept. 2007), available at <http://www.plosmedicine.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.0040275&representation=PDF>. Locating full-text copies of these evaluations, appraising study methodology, and aggregating the results took months. Ideally, the systematic reviews we produced should make this evidence available to others in a fraction of that time, but this will depend on whether our reviews are easily accessible.

69. See Centers for Disease Control and Prevention, *Be Proud! Be Responsible!*, http://www.cdc.gov/hiv/topics/research/prs/resources/factsheets/Be_Proud.htm (last visited Mar. 31, 2010) (reviewing primary studies by John and Loretta Sweet Jemmott, the program developers); see also John B. Jemmott, III, et al., *Reducing HIV Risk-Associated Sexual Behavior Among African American Adolescents: Testing the Generality of Intervention Effects*, 27 AM. J. COMMUNITY PSYCHOL. 161 (1999).

70. See Elaine A. Borawski et al., *Taking Be Proud! Be Responsible! to the Suburbs: A Replication Study*, 41 PERSPECTIVES SEXUAL REPROD. HEALTH 12 (2009).

71. See, e.g., Stephanie G. Bell et al., *Challenges in Replicating Interventions*, 40 J. ADOLESCENT HEALTH 514 (2007); Dane & Schneider, *supra* note 63; Kelly et al., *supra* note 64; Rotheram-Borus et al., *supra* note 66, at 146, 153 (“There is no consensus on the level at which to define core elements and the causal mechanisms implied. There are not typically data on the [evidence-based intervention] to identify that specified core elements are indeed the causal mechanisms necessary for behavior change”).

72. See Rotheram-Borus et al., *supra* note 66, at 153 (“Staff persons in agencies who wish to implement [evidence-based interventions] often do not have the skills or capacities to pull a manualized [intervention] off the shelf and implement it effectively.”) (internal references removed).

TRANSFERRING BEHAVIORAL INTERVENTIONS

programs, or criminalization of same-sex sexual activity may limit the effectiveness of programs that aim to build community among men who have sex with men. Finally, even when the EBP process works perfectly and transferred interventions do lead to safer behaviors in the new context, the resources required to make these programs sustainable may be lacking.

Beyond these practical challenges to broadening the access to effective behavior change programs, formal and informal barriers to information-sharing might also inhibit transfer. This Note will now turn to these obstacles.

III. INTELLECTUAL PROPERTY AND BEHAVIORAL INTERVENTIONS: BARRIERS TO TRANSFER

Although behavioral interventions resemble patented medical technologies in some ways, a broader view of the international intellectual property regime will be necessary to identify relevant information-sharing constraints. While there may also be contract restrictions, applicable trade regulations, or potentially even antitrust barriers to the transfer of effective behavioral interventions, this Note focuses only on intellectual property and information-sharing barriers. This Part will outline both formal barriers and informal limitations to the information-sharing necessary to disseminate behavioral interventions. This investigation suggests that although patents, trademarks, and trade secret protections pose few barriers to transfer, copyrights and informal information constraints can be important obstacles to intervention dissemination.

A. Formal Intellectual Property Barriers to the Dissemination of Effective Behavioral Interventions

In domestic law, the broad categories of intellectual property protection are fourfold: 1) copyrights,⁷³ 2) patents,⁷⁴ 3) trademark or trade dress,⁷⁵ and 4) trade secrets, which are protected through a patchwork of state laws and tort doctrines.⁷⁶ These four categories map onto the types of intellectual property

73. See 17 U.S.C. § 102(a)-(b) (2006). Copyrights are awarded for “original works of authorship fixed in any tangible medium of expression” but not for “any idea, procedure, process, system, method of operation, concept, principle, or discovery”

74. See 35 U.S.C. § 101 (2006). Patents are awarded in the United States for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”

75. Protected marks include “corporate and product names, symbols, logos, slogans, pictures and designs, product configurations, colors and even smells.” INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 30 (Robert P. Merges, Peter S. Menell & Mark A. Lemley eds., 2007) [hereinafter INTELLECTUAL PROPERTY]. Domestic trademark regulations in the United States are set forth in the Lanham Act, 15 U.S.C. §§ 1051-1141n (2006).

76. See, e.g., UNIF. TRADE SECRETS ACT § 1(4) (1985). Trade secrets consist of “information,

protected by international agreements. On the international stage, with which this Note is primarily concerned, the most significant agreement on intellectual property rights is the World Trade Organization's ("WTO's") Trade-Related Aspects of Intellectual Property agreement, or TRIPS. Signing nations must comply with or "harmonize" their own law with respect to the entire TRIPS agreement by 2016,⁷⁷ including the enforcement of pharmaceutical patents. Under TRIPS, the categories of intellectual property are sevenfold: patents, copyrights, trademarks, trade secrets or other undisclosed information, geographical indications, industrial designs, and layout designs of integrated circuits.⁷⁸ This Note will deal with only the first four broad categories, which are most relevant to behavior change programs and mirrored by domestic law in TRIPS signing nations. Enforcement of intellectual property rights is not automatic; the owners of intellectual property must instigate private actions to protect those rights using national court systems, and the TRIPS agreement requires nations to provide enforcement mechanisms and penalties sufficient to deter infringement.⁷⁹ In some instances, such as trade secrets, intellectual property cannot formally exist if the owners do not make reasonable prior efforts to maintain secrecy. Penalties for infringement vary by jurisdiction and type of protection, but can include injunctions and monetary damages.

The owners of formal intellectual property rights to behavioral interventions, if such rights exist, could range from private owners like individual investors and institutions to public owners like governments.⁸⁰ Identifying the owners of both interventions and evaluations is important, because if formal intellectual property constraints diminish the dissemination of effective behavioral interventions, non-enforcement by owners may be one way to sidestep such barriers.

including a formula, pattern, compilation, program, device, method, technique, or process" that "derives independent economic value" and "is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

77. See WTO, Understanding the WTO – Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 31, 2010).

78. *Id.*

79. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 [hereinafter TRIPS], available at http://www.wto.org/english/docs_e/legal_e/27-trips.doc.

80. Notably, government-created works cannot receive formal intellectual property protection in some jurisdictions. U.S. federal law explicitly bans copyright protection for any work "prepared by an officer or employee of the United States Government as part of that person's official duties." 17 U.S.C. § 101 (2006). There may be discretion, however, in awarding copyright to "works prepared under Government contract or grant." H.R. REP. NO. 94-1476 (1976) (quoted in INTELLECTUAL PROPERTY, *supra* note 75, at 432). This may be the case for many behavioral interventions and evaluations thereof, which are often produced using governmental funding like NIH grants.

1. Copyrights

Copyrights may be the most significant formal barriers to the process of transferring effective behavioral interventions. Copyrights are automatically awarded to most literary and artistic work, without the need for application, and are not contingent on expensive prosecution processes. Under the Berne Convention, the term of copyright is limited to fifty years after the death of the author.⁸¹ Because all written program manuals and program evaluations are “literary work,” copyrights are pervasive in the field of behavioral interventions. As upheld under the TRIPS agreement, copyrights can impede the transfer of behavioral interventions in two important ways.

First, copyrights on published evaluations of program effectiveness prevent others from identifying evidence-based interventions that might work in a given setting. Although the open-access movement among academic publications is a beneficial trend, many full-text papers remain inaccessible to non-subscribers.

Second, copyrights inhibit access to program manuals and materials. Barriers to accessing program materials affect the processes of *deciding* which intervention to use and of *implementing* the intervention that is selected. As the previous Part noted, effective replication requires fidelity—something that is impossible without access to the correct program materials and instructions, even if those original materials require adaptation. The costs of acquiring copyrighted program manuals and materials can make interventions inaccessible to nonprofit organizations seeking to implement evidence-based programs.⁸² Costs of

81. Berne Convention for the Protection of Literary and Artistic Works, art. 7(1), Sept. 9, 1886, revised July 24, 1971, 25 U.S.T. 1341, 1161 U.N.T.S. 3, available at http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html.

82. See, e.g., Rosemary C. Veniegas et al., *HIV Prevention Technology Transfer: Challenges and Strategies in the Real World*, 99 AM. J. PUB. HEALTH S124, S126, S128 tbl.3, S129 (2009) (finding based on a survey of community-based organizations that inaccessibility of manuals and intervention information can inhibit intervention transfer; also noting that a lack of intervention materials during the selection phase led organizations to choose and acquire programs that they were “underprepared to carry out”); see also Alice A. Gandelman, Linda M. DeSantis & Cornelis A. Rietmeijer, *Assessing Community Needs and Agency Capacity—An Integral Part of Implementing Effective Evidence-Based Interventions*, 18 AIDS EDUC. & PREVENTION 32, 38 (Supp. A 2006) (noting that the average prevention budget of AIDS organizations is “typically not enough to implement one, much less more than one EBI [evidence-based intervention]”); Robin Lin Miller, *Innovation in HIV Prevention: Organizational and Intervention Characteristics Affecting Program Adoption*, 29 AM. J. COMMUNITY PSYCHOL. 621, 639 (2001) (reporting a survey of community-based organizations, which found that money “dictated whether programs were deemed feasible”; also noting that many organizational representatives “talked about programs they hoped to adopt, if they could secure the financial support to do so”). Program materials form only part of the costs of implementing an evidence-based intervention. Debra P. Ritzwoller et al., *Costing Behavioral Interventions: A Practical Guide to Enhance Translation*, 37 ANNALS BEHAV.

implementation may be higher when materials are branded and licensed for a profit.⁸³ Depending on the format of the intervention, entire programs may be copyrighted. For example, some behavioral interventions are in the form of self-help booklets, videos, theater productions, or computer software.⁸⁴ Passing costs onto consumers is often unrealistic for interventions addressing ill health, which is largely shaped by poverty and a scarcity of prevention resources.

The remedies for copyright enforcement depend on the place of enforcement, but they can include actual damages, statutory damages, lost royalties or licensing fees, attorneys' fees, and injunctions, with some prosecution possible under the criminal law. The costs of legal actions to monitor infringement and enforce copyrights offset this barrier to some extent; it may well be prohibitively expensive for most owners of copyrights to protect their intervention materials. However, the *de facto* consequences of copyrights—namely that most published evaluations and intervention materials are not freely accessible to the public—may be the most significant barrier faced in intervention transfer.

2. Patent Protection

Some behavioral interventions could arguably be described as “processes,” which are eligible for twenty-year patent protection under TRIPS if they “are new, involve an inventive step and are capable of industrial application.”⁸⁵ The requirement of industrial application⁸⁶ would present little obstacle to patenting behavioral interventions. Provisions denying patents on the grounds of public policy are also likely inapplicable; while public policy concerns limit the patentability of inventions whose commercial exploitation could prove dangerous

MED. 218 (2009) (enumerating different costs involved in delivering a behavioral intervention). However, broadening access to program materials can improve feasibility and help organizations select programs that match their actual capacity.

83. For example, the costs of licensing multisystemic therapy and receiving mandatory supervision have been well documented by a Canadian study team. See A.W. LESCHIED & ALISON CUNNINGHAM, SEEKING EFFECTIVE INTERVENTIONS FOR SERIOUS YOUNG OFFENDERS: INTERIM RESULTS OF A FOUR-YEAR RANDOMIZED STUDY OF MULTISYSTEMIC THERAPY IN ONTARIO, CANADA 118-125 (2002), available at <http://www.lfcc.on.ca/seeking.html> (documenting licensing fees, site fees, continued supervision fees, and high per-client costs).

84. Computer programs are copyrightable as “literary works” in the United States. See 17 U.S.C. §§ 101, 117 (2006). Copyrightability and ease of enforcing copyrights for computer programs in other jurisdictions vary.

85. TRIPS, *supra* note 79, § 5, art. 27(1).

86. The “industrial application” requirement in TRIPS is defined to be synonymous with the term “useful.” TRIPS, *supra* note 79, § 5, art. 27(1), n.5. This aligns with the U.S. patent requirement of utility, and it would almost certainly be satisfied by a program that produces public health improvements.

to human life,⁸⁷ this exception does not enable governments to deny patent protection on the grounds that inventions are *helpful* to public health.⁸⁸ Despite the lack of formal barriers to patents on the grounds of utility and public policy, intervention developers are unlikely to seek and obtain patents due to patentability of subject matter and practical obstacles to obtaining and enforcing patents.

First, even if they are described as processes, behavioral interventions likely would not qualify as patentable processes in most jurisdictions. The text of TRIPS suggests that processes that qualify for patents should lead directly to physical, commercial products, because process patents confer the right “to prevent third parties not having the owner’s consent from . . . using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.”⁸⁹ The lack of a physical product may well be a terminal deficiency for patenting behavioral interventions. Under U.S. patent law, for example, a behavioral intervention would likely not qualify for a process patent.⁹⁰

Next, even if behavioral interventions were readily classifiable as patentable processes, there remain practical reasons why program developers might not seek or receive patents. First, obtaining and enforcing a patent requires time and resources that may be unavailable or counter to the incentives of many, though not all program developers.⁹¹ Second, as Milby et al. identify, evaluations of

87. TRIPS, *supra* note 79, § 5, art. 27(2).

88. See INTELLECTUAL PROPERTY, *supra* note 75, at 347. TRIPS also permits governments to deny patent protection for “diagnostic, therapeutic, and surgical methods for the treatment of humans.” TRIPS, *supra* note 79, § 5, art. 27(3)(a). Behavioral interventions may be denied patents on these grounds if they are classified as therapeutic; however, the patenting of drugs suggests that this rationale alone is often insufficient to prevent patenting. In the United States, patents may be awarded for medical treatment processes; however, these patents do not confer the right to seek monetary or injunctive relief from any licensed medical practitioner for infringement. *See* 35 U.S.C. § 287(c) (2006). If behavioral interventions fell under this type of designation, patents would present no bar to dissemination.

89. TRIPS, *supra* note 79, § 5, art. 28(1)(b).

90. The standard definition of a patentable process is “an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” *Cochrane v. Deener*, 19 U.S. 780, 788 (1877). Behavioral interventions would not pass the “machine-or-transformation” test as articulated in *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009). They would also have failed the older *State Street Bank* test, which requires that patent-eligible processes produce “a useful, concrete, and tangible result.” *State St. Bank v. Signature Fin. Group*, 149 F.3d 1368, 1375 (Fed. Cir. 1998). At a stretch, some behavioral interventions might be classified as methods of carrying out business, which are indeed patentable in some jurisdictions, including the United States. *Id.* However, the *Bilski* opinion appears to hold these processes to the same standard of eligibility, which would likely present an insurmountable barrier. *In re Bilski*, 545 F.3d at 960.

91. As discussed in Part II.A, program developers are generally academic researchers,

behavioral interventions are usually published;⁹² in many jurisdictions, such publication is a bar to the receipt of a patent, because it undermines the requirement that the invention be “new.”⁹³ Finally, the delivery of a behavioral intervention to human participants would constitute a “public use” of the invention, which would also undermine the novelty requirement for patent eligibility. It would be impossible to pilot or to evaluate a behavioral intervention without such use, thereby erecting statutory barriers to patenting an intervention in the United States.⁹⁴ Fourth, processes invented using governmental funding may not be patentable due to statutory bars in various jurisdictions; this could disqualify a large number of behavioral interventions. Fifth, it may be difficult for behavioral interventions to fulfill the “inventive step” requirement in TRIPS, which is synonymous with the “non-obviousness” requirement that is a lynchpin of patent law in the United States and elsewhere.⁹⁵ “Prior art” for these

governmental institutions, and nonprofit organizations; when they create new programs, these groups tend to be motivated respectively by publications and career advancement, accountability to constituents and funders, and community concerns—none of which align exactly with patenting. Patenting an intervention would require secrecy during program development, which does not comport with the incentive for publications and career advancement among researchers. There may be public policy barriers to patenting interventions created by governmental institutions, whose accountability to constituents may prevent profiting from the sales of a patented intervention. NGOs may simply lack the resources necessary for a lengthy patent prosecution process, and in some fields of behavioral intervention (for example, HIV prevention), NGOs that develop new programs may be familiar enough with the detrimental health effects of pharmaceutical patents that they may choose not to patent or enforce patents for their own work. For all program developers, the expected return for patenting a behavioral intervention may be small in comparison to the cost of patent prosecution, given that program purchasers tend to be nonprofit institutions with limited budgets for new program materials.

92. Jesse B. Milby et al., *A Progressive Process for Technology Transfer of a Complex, Effective Psychosocial Intervention: Methods and Preliminary Results*, 6 ADDICTIVE DISORDERS & THEIR TREATMENT 187, 187 (2007) (“In behavioral science, especially research supported by the US government, [transferring behavioral interventions to practice settings] rarely involves intellectual property protection, because most science and technology findings are published in journal literature.”).

93. TRIPS, *supra* note 79, § 5, art. 27(1). Under U.S. law, for example, if a printed publication occurs more than one year before an attempt to patent a process, that publication can be a bar to patenting. *See, e.g.*, 35 U.S.C. § 102(b) (2006); *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986) (holding that publication in a doctoral thesis in Germany was a bar to patenting an invention in the United States).

94. *See, e.g.*, *Egbert v. Lippman*, 104 U.S. 333, 333 (1881). The “experimental use” exception to the public use bar, however, might help someone seeking to patent a behavioral intervention despite its prior use in an effectiveness trial. *See, e.g.*, *City of Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877).

95. TRIPS, *supra* note 79, § 5, art. 27(1), n.5 (describing the inventive step requirement); *see also* INTELLECTUAL PROPERTY, *supra* note 75, at 347.

interventions—which would consist of prior programs aimed at behavior change—may render most types of program activities obvious. Sixth, although the improvement of health behaviors is undoubtedly “useful,” the *demonstration* of utility may be a difficult requirement for a behavioral intervention. Evaluations of behavioral interventions are expensive, lengthy, and usually published. The effects of a behavioral intervention, unlike the results of most patented processes, are likely to vary widely and may not be entirely reliable. Finally, even if an intervention *did* receive a process patent and *were* enforced, compulsory license exceptions to the TRIPS agreement may apply for particularly effective interventions, although power dynamics among states could make compulsory licensing politically or economically costly.⁹⁶ TRIPS also contains a provision enabling case-by-case review of “Other Use Without Authorization of the Right Holder,” conditional on “adequate remuneration” for the patentee.⁹⁷

Importantly, interventions that integrate a technological component, such as a software program or electronic reminder device, may involve patented *pieces*. For example, patents have been awarded to a hand-held computer device that prompts users to exercise and provides meal suggestions,⁹⁸ to Weight Watchers software and hardware that help users follow program guidelines,⁹⁹ to a Weight Watchers calculator,¹⁰⁰ and to software that enables users to see what they might look like in clothing if they lose weight according to a specified regimen.¹⁰¹ Patents may be a bar to transferring these types of interventions, if the technological piece is a core component responsible for intervention effects.

3. Trademarks

Trademark protection, which TRIPS permits for “any sign, or any combination of signs, capable of distinguishing the goods or services of one

96. See, e.g., Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 32 J.L. MED. & ETHICS 209, 210 (2009) (summarizing some of the economic and political “secondary effects” of issuing a compulsory license, including loss of investment, litigation by pharmaceutical corporations, and possible trade sanctions).

97. TRIPS, *supra* note 79, § 5, art. 31, 31(h).

98. Apparatus To Control Diet and Weight Using Human Behavior Modification Techniques, U.S. Patent No. 5,673,691 (filed Jan. 2, 1996) (issued Oct. 7, 1997).

99. Weight Control System Having Varying Meal Plans and Meal Planning Schemes, U.S. Patent No. 7,361,143 (filed Mar. 10, 2004) (issued Apr. 22, 2008).

100. Process for Controlling Body Weight, U.S. Patent No. 6,878,885 (filed Oct. 14, 2003) (issued Apr. 12, 2005).

101. Diet and Exercise Planning and Motivation Including Apparel Purchases Based on Future Appearance, U.S. Patent No. 7,328,119 (filed May 2, 2005) (issued Feb. 5, 2008).

undertaking from those of other undertakings,”¹⁰² largely originated from the impulse to protect consumers by identifying the source of the goods and services they purchased. This form of intellectual property protection has now evolved to protect the companies who have registered their trademarks, and trademarks themselves are increasingly bought, sold, and licensed as goods in their own right. The term of trademark protection is potentially unlimited, and TRIPS permits indefinite renewals of trademark registrations for terms of at least seven years each.¹⁰³

Trademark protection applies less readily to most behavioral interventions. Although some commercially marketed behavioral interventions, such as Weight Watchers, have registered marks, trademark protection is unlikely to bar most intervention dissemination. Generally the name or logo of a behavioral intervention is unlikely to be an “essential component” for program effectiveness, and therefore marks need not be transferred with other key components of the intervention.¹⁰⁴ If the original program materials were used, the trademarks would refer correctly to the source of the goods, and so their use would not be infringing. People who purchase trademarked goods may use them as they choose, and organizations who deliver behavioral interventions often do so without making a profit. Likelihood of confusion is the touchstone for trademark infringement,¹⁰⁵ which is unlikely for the vast majority of behavioral interventions that are limited in fame and geographical scope.

Given these caveats, it is *possible*, but not probable, that developers of behavioral interventions may seek to avoid the dilution of their own program names, logos, or identities by others seeking to duplicate and package them elsewhere. These types of claims, however, would be offset by the same factors mentioned above. Policing trademark infringement is expensive and may be counter to the incentives or financial capacity of program developers, given that initial trademark registration costs time and money, and trademarks can lapse if they are not defended rigorously by filing new legal actions against infringers.¹⁰⁶ There can also be “exceptions” to trademark rights in the interests of third parties,¹⁰⁷ and prosecution would be legally difficult given the need to prove a

102. TRIPS, *supra* note 79, § 2, art. 15.

103. TRIPS, *supra* note 79, § 2, art. 18.

104. For example, a recent study of 34 organizations implementing the Focus on Youth program found that 11 (32%) changed the program name. Galbraith et al., *supra* note 57, at 539. If an intervention’s trademark is protected, implementation of the exact same program under a different mark may qualify as reverse passing off, however, which could rise to claims of false designation of origin by any person “who believes that he or she is likely to be damaged by such act.” 15 U.S.C. § 1125(a) (2006).

105. TRIPS, *supra* note 79, § 2, art. 16.

106. For a fuller discussion of this point, see *supra* note 91.

107. TRIPS, *supra* note 79, § 2, art. 17.

likelihood of confusion between the original and the copycat. Finally, even if trademarks were vigorously enforced, the penalties would be limited to rebranding and discontinuing of the trademark, trade dress, or service mark; no delivery of interventions could be enjoined. For these reasons, it appears that trademarks are not a major barrier to the transfer of behavioral interventions.

4. Trade Secret Protection

Trade secrecy is often discussed apart from the other three forms of intellectual property law, in part because it is difficult to define. The nature of a trade secret—called “Undisclosed Information” in TRIPS—can be any information that fulfills three conditions: 1) it must be “secret in the sense that it is not . . . generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question”; 2) it must “ha[ve] commercial value because it is secret”; and 3) it must “ha[ve] been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.”¹⁰⁸ State parties to TRIPS agree to “protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”¹⁰⁹ Although patents and copyrights are finite and require disclosure of the innovation, trade secret protection depends on non-disclosure and is limited only by the duration of reasonable efforts to maintain secrecy. These efforts can include non-disclosure agreements, implied secrecy, and contracts. Remedies for disclosing trade secrets may vary, but can include injunctions, damages, and attorney’s fees.¹¹⁰ In some ways, it is tempting to suggest that information barriers in the transfer of behavioral interventions are most akin to trade secrecy. Much of the information about actual implementation is only known to program developers and staff, especially if there are deviations from a written manual. Trade secrecy is available to processes and other information that escapes easy classification among the patent, copyright, and trademark domains, which may make this type of protection more appropriate for complex interventions. Contracts to protect the dissemination of implementation information are possible, and many behavioral interventions have commercial value.

Practically, however, trade secret protection will not formally apply to most

108. TRIPS, *supra* note 79, § 7, art. 39(2)(a)-(c).

109. TRIPS, *supra* note 79, § 7, art. 39(3).

110. UNIF. TRADE SECRETS ACT §§ 2-4 (1985). The Uniform Trade Secrets Act has been adopted by 45 states, the District of Columbia, and the U.S. Virgin Islands. *See* Uniform Law Commissioners, A Few Facts About the Uniform Trade Secrets Act, http://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-utsa.asp (last visited Mar. 31, 2010).

behavioral interventions because secrecy will be impossible to maintain. Most obviously, interventions must involve participants that observe the workings of the program and could potentially disclose or replicate it outside the intervention setting, making a claim of secrecy difficult to uphold.¹¹¹ The availability or sale of intervention manuals or protocols, the inclusion of intervention details in published evaluations, or the presentation of intervention plans to academic conferences or funding bodies are also barriers to proving secrecy. Reverse engineering of programs based on publicly accessible information would be permissible, and misappropriation or dishonest commercial practices may be difficult to prove given the exposure of program participants. Finally, so many different strategies have been tested for behavioral interventions that, although each program on its own is unique, it would likely be very difficult to show that any specific intervention component were not “readily accessible to persons within the circles that normally deal with the kind of information in question”¹¹²

On the balance, therefore, it is very unlikely that formal trade secrecy protections will inhibit the transfer of behavioral interventions, although we can draw similarities between trade secrets and the types of de facto information barriers already existing in this field. This Note will now sketch the outlines of these informal barriers.

B. Informal Constraints on the Availability of Information

Information about behavioral intervention programs is rarely widely available. Many behavioral intervention programs are not tested, while completed evaluations may go unpublished. Studies showing evidence of harm or no effect could help program adopters weed out ineffective or detrimental interventions; however, evaluations with such findings are even less likely to be written or published. This is due in part to the biases of journals in selecting pieces for publication,¹¹³ and in part because program developers or funders may be reluctant to release findings suggesting that their programs are ineffective.

111. Programs could potentially ask participants to sign nondisclosure contracts as a condition of participation, but this is unlikely to be acceptable in practice.

112. TRIPS, *supra* note 79, § 7, art. 39(2)(a). One exception to the general lack of trade secret protection may be interventions that involve the provision of food according to specific recipes, which may be likely only for behavioral interventions that involve weight loss. Weight Watchers recipes have been deemed trade secrets. *See* Weight Watchers Int’l, Inc. v. Stouffer Corp., 744 F. Supp. 1259, 1280 (S.D.N.Y. 1990).

113. This is the problem of publication bias, which refers to the tendency of journals to be more accepting of papers reporting statistically significant findings. The seminal article on this topic is Kay Dickersin, *The Existence of Publication Bias and Risk Factors for Its Occurrence*, 263 JAMA 1385 (1990); *see also* Kay Dickersin, *How Important Is Publication Bias? A Synthesis of Available Data*, 9 AIDS EDUC. & PREVENTION 15 (Supp. A 1997).

Another information barrier is the lack of data about how programs are actually implemented. Although methods for monitoring program implementation are improving, much of the information about participant attendance, program staff activity, use of program materials, and relevant contextual details is not gathered. Poor metrics exist for this type of data.¹¹⁴ Journals do not have space to publish all of this information, and funders are unlikely to demand it along with other metrics of program accomplishment. This lack of reporting results in a de facto monopoly on relevant information, much of which may be eventually lost due to turnovers in program staff or management.

Program developers and researchers rarely have the time, resources, or expertise to devote to disseminating their intervention. Program manuals and materials are not made available for free, and cost-free distribution of materials is particularly unthinkable when programs are branded, sold, and licensed. Technical assistance to help others adopt an intervention can be expensive, time-consuming, and hard to provide. There are also few good guides available to help program adopters adapt an intervention to fit a new setting. Although some procedures to adapt interventions for transfer are under study,¹¹⁵ it is still very difficult to determine which intervention components can and cannot be modified while retaining the program's effectiveness.

Even with all of these constraints on information availability, the information that *is* available is disorganized and overwhelming. Databases like PubMed¹¹⁶ and PsycINFO,¹¹⁷ where articles are abstracted, can be daunting. The type of systematic literature search and evidence assessment that EBP requires is time-consuming and skills-based. As discussed above, potential program adopters may lack the time and skills necessary to find, evaluate, and use the information already available. There is no centralized database for behavioral intervention evaluations or program materials; there is also no mandatory prospective registration database for trials of behavioral interventions, which contributes to the potential for bias in conducting and reporting evaluations. CENTRAL¹¹⁸ and Clinicaltrials.gov¹¹⁹ have made a start in this area, but registration is either optional or tied to specific funding requirements. Similarly,

114. Dane & Schneider, *supra* note 63.

115. See Bell et al., *supra* note 71; Russell E. Glasgow et al., *Evaluating the Public Health Impact of Health Promotion Interventions: The RE-AIM Framework*, 89 AM. J. PUB. HEALTH 1322 (1999).

116. See NCBI, PubMed, <http://www.ncbi.nlm.nih.gov/pubmed> (last visited Mar. 31, 2010).

117. See APA Databases, PsycINFO, <http://www.apa.org/psycinfo> (last visited Mar. 31, 2010).

118. The Cochrane Library, The Cochrane Central Register of Controlled Trials, http://www.mrw.interscience.wiley.com/cochrane/cochrane_clcentral_articles_fs.html (last visited Mar. 31, 2010).

119. Clinicaltrials.gov, Home, <http://clinicaltrials.gov> (last visited Mar. 31, 2010).

there is no single organization tasked with identifying effective behavior change programs for different types of settings and participants. Individual organizations such as the CDC Prevention Research Synthesis Project, NICE, or the Cochrane Library have made a start towards gathering program evidence; however, these research institutions are more dedicated to comparing research findings across groups of programs than matching individual interventions to settings and participant groups. Few of these research institutions have the type of global recognition necessary to reach most communities in the developing world, and none has made program evaluations available alongside the materials necessary to deliver the interventions in practice.

IV. SYSTEMIC SOLUTIONS

The previous section identified many needs. Among these, we need incentives for researchers, funders, and program developers to provide open access to program materials and evaluations to people who implement behavior change programs: community organizers, schools, local and national departments of health, hospitals, and other groups. We need incentives for transferability trials, for the publication of non-significant or iatrogenic effects, and for methods that enable more systematic adaptation of effective programs, all of which have been neglected by academic journals and institutional research funders. We need ways to distill the evaluations and materials that are already available, so that groups can identify and make use of this information. And we need to centralize some of these functions in a way that can be publicized and that conveys legitimacy on a global scale.

How can we fulfill these needs in a way that is systemic—that is, in a way that does not place the obligation entirely on program developers and program adopters?¹²⁰ This section will outline some suggestions for changing the incentive structure at several levels of global health governance.

A. The World Health Organization

The World Health Organization (WHO) has been consistently cast as the central figure and repository for hope in the systems of global health governance envisioned by leading global health experts.¹²¹ The WHO possesses the

120. Program developers and adopters play critical roles in disseminating interventions; however, this section specifically addresses actors who can influence broader incentive structures for program development and dissemination.

121. See Bloom, *supra* note 10; Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: A Proposed Model for Global Health Governance*, 298 JAMA 225 (2007); Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEORGETOWN L.J. 331 (2008); Dean T. Jamison, Julio Frenk & Felicia Knaul, *International Collective Action in Health: Objectives,*

worldwide recognition, expertise, and humanitarian legitimacy necessary to encourage changes in the incentives listed above, and it has the capacity to make information available to communities worldwide. The WHO receives a relatively stable funding stream¹²² and has the technical capacity to host large quantities of information online; it also has the linguistic capacity to translate much of that material into the most widely understood languages. Furthermore, the WHO is perceived to have scientific and political authority to distinguish among effective and ineffective interventions without bias, and the WHO has the technical expertise needed to appraise the evaluation evidence and contextual factors that might help match programs to settings where they would be effective.

It seems that the WHO could help facilitate the transfer of effective behavioral interventions in several ways, all of which would fall under Frenk's conception of the WHO's "core functions"¹²³ and the need for information-sharing among states.¹²⁴ First, the WHO could host an online registry of evaluations of behavior change programs; at first, the registry could be limited to randomized controlled trials, but it may also be desirable to include other study methods. Ideally, registration would be prospective and would include contact information for the study personnel; after an evaluation concluded, the registry could be updated with study outcomes, published and unpublished evaluation reports, process evaluations, and other relevant information about the implementation of the program, including costs and acceptability. The registry could be searchable based on a variety of criteria, such as target health behaviors, the type of participant, the location of the evaluation, other evaluations of the same or similar programs, and characteristics of the intervention. The initial formation of the database should include past evaluations, both published and unpublished, which would require some pressure on the international copyright regime and individual researchers or institutions. To encourage registration, the WHO could work with national governments, academic journals, and research funders to require registration and sharing as a condition of funding projects or impact evaluations.

Second, the WHO could link the database of *evaluations* with a searchable database of *intervention materials*. These materials could include program manuals, worksheets or workbooks, intervention videos, and otherwise copyrightable materials that are necessary to select and adopt interventions for use. The two databases should work in tandem, such that groups trying to select a

Function, and Rationale, 351 LANCET 514 (1998).

122. The WHO is funded primarily by assessed contributions from member states, although a growing proportion of funds are voluntary contributions by other donors. See WORLD HEALTH ORG., MEDIUM-TERM STRATEGIC PLAN 11-13 (2009), available at http://apps.who.int/gb/ebwha/pdf_files/AMTSP-PPB/a-mtsp_2en.pdf.

123. Jamison et al., *supra* note 121, at 514.

124. Frenk & Gómez-Dantés, *supra* note 30.

program can move easily from program evaluations (seeing which ones have worked, and where they worked before) to program materials (seeing which ones are feasible, and then getting the materials for implementation). Although this would likely take up a great deal of space, programming time, and IT resources, this would be the most direct way to get program materials into the hands of people who can use them. This information should be universally accessible (not just accessible to organizations that develop or deliver interventions), because open access may also enable potential program participants to identify and suggest effective programs.

Third, regardless of whether it is possible to host full-text evaluations and materials, the WHO can be instrumental in identifying behavioral interventions that are known to be effective, along with the contexts in which those programs were shown to have protective effects. This process would mitigate the problems of insufficient time and expertise by people who develop, evaluate, or seek to adopt the programs, and it would create a centralized repository of information and recommendations that would be perceived as scientifically authoritative. Creating a publicly accessible repository of strategies that have been evaluated with evidence of *ineffectiveness or harm* may be equally valuable, since this could help avoid the financial and opportunity costs associated with the delivery of ineffective programs.

Fourth, the WHO could also pressure journals, program developers, and researchers to release copyright on past evaluations and program materials so that they could be included in the trial registry and the database. The WHO could apply this pressure by issuing position statements, sending open letters to journal editors and research institutions, encouraging researchers to submit articles to journals that have favorable open-access policies, discussing the availability of behavioral intervention materials at international scientific meetings, encouraging research funders to require open access to program materials, and ensuring that its own scientists make published evaluations and program materials available online.

Fifth, the WHO could suggest a systematic approach for adapting behavioral interventions for use in new settings, particularly given its expertise in advising a variety of state and local governments in similar questions. Any kind of adaptation guidance would need to be framed at a very high level of generality to be useful for a majority of interventions, but this would help fill the guidance gap in program adaptation strategies.

Sixth, to the extent that copyrights prevent the sharing of behavioral intervention materials and published evaluations, the WHO might be instrumental in developing an open-access license permitting the sharing of such materials, similar to the Creative Commons licensing scheme.¹²⁵ The availability

125. See, e.g., Creative Commons, About Licenses, <http://creativecommons.org/>

and potential popularity of an open-access license for behavioral intervention materials may help to change norms of information-sharing among researchers and program developers, and providing legal language to insist on appropriate attribution could also help to align information-sharing with program creators' career goals.

B. Scholarly Journals and Academic Institutions

Because academic institutions and scholarly journals provide powerful incentives for researchers who develop and evaluate behavioral interventions, and because they have widespread reputations for scientific legitimacy, these groups can significantly encourage the release of program evaluations and materials. For example, journals can make published evaluations of behavioral interventions available for free through publishing on PubMed Central, making the material available on their websites at no cost, or permitting authors to release reports to a central registry like the WHO database proposed above. This could be complicated, however, without some protection for royalties in place. If journals must forego some royalties or other profits to make evaluations accessible immediately, a lag time may be necessary to prevent a chilling effect on the publication of program evaluations. To foster the sharing of intervention manuals and other materials, journals could request that manuals of evaluated programs be made available for free or a discounted cost online as a condition of publication, providing links to the materials in published reports. Journals could also revise reporting requirements for primary studies, requiring researchers to include more information about implementation in original program reports.¹²⁶ Finally, journals could announce and fulfill a commitment to publishing more transferability trials and adaptation research on effective programs.

Like journals, academic institutions could also require their researchers to

about/licenses (last visited Mar. 31, 2010) (providing standard licenses that enable copyright owners to customize the level of copyright protection applied to their copyrighted materials). Several open-access journals, including the PLoS (Public Library of Science) collection, already use Creative Commons licensing to permit free distribution and sharing of published program evaluations. See Creative Commons, About: Who Uses CC?, <http://creativecommons.org/about/who-uses-cc> (last visited Mar. 31, 2010). Crafting a license that specifically applies to health promotion programs might seek to encompass many different types of copyrighted materials (for example, intervention booklets, videos, and posters), and it could tailor privileges to their health-related justifications.

126. See Don C. Des Jarlais et al., *Improving the Reporting Quality of Nonrandomized Evaluations of Behavioral and Public Health Interventions: The TREND Statement*, 94 AM. J. PUB. HEALTH 361 (2004); David Moher et al., *The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomised Trials*, 357 LANCET 1191 (2001); David Moher et al., *Improving the Quality of Reports of Meta-Analyses of Randomised Controlled Trials: the QUOROM Statement*, 354 LANCET 1896 (1999).

make program information available online, and they could host intervention content on their institutional website (or at least allow it to be made available to a centralized database). Academic institutions generally contain the Institutional Review Boards (“IRBs”) that approve most institution-based research, and those IRBs could also play a role in requiring public release of evaluation results and program materials as a condition of approving research. The fact that most programs are un-patented (despite copyright protection) may help in encouraging universities to adopt pro-transfer policies. Journals and academic institutions might choose to refrain from enforcing copyrights that might be violated by groups that make behavioral intervention materials available for free elsewhere. They could also reach out to service providers to diminish some of the demand-side barriers to identify effective programs, such as by running workshops to teach providers skills for locating and appraising evidence of program effectiveness.

C. Funders of Research and Programs

Research and program funders wield some of the same sticks and carrots as academic institutions and journals; reaching out through funders also has the capacity to incentivize both academic *and* non-academic researchers. To improve *supply*-side information shortages, funders of research and intervention trials can require NGOs and researchers to make program materials and evaluations available online free of charge, either on their own websites or through central databases. They can also encourage the conduct and publication of methodologically rigorous and well-reported program evaluations. Funders of groups seeking to adopt behavioral interventions can also nurture the *demand* side of intervention transfer by fostering evidence-based practice. For example, funders could provide training in evidence-based practice, require grantees to show an evidence base for intervention programming, and suggest promising interventions for implementation.

Research funders could also contribute to the production of knowledge about how interventions are transferred to new settings, including ways to support organizations in delivering new programs. As an example, the National Institute of Mental Health has funded a study of a technology exchange system that aims to help community-based organizations implement the MPowerment Project, an HIV prevention program for young men who have sex with men.¹²⁷ Research

127. See Gregory M. Rebhook et al., *Translating Research into Practice: The Dissemination and Initial Implementation of an Evidence-Based HIV Prevention Program*, 18 AIDS EDUC. & PREVENTION 119, 121 (Supp. A 2006). This article provides an excellent overview of the intervention dissemination process, from initial program development to widespread implementation. See also U.S. Department of Health and Human Services, Project Information, Project Number 5R01MH065196-08, http://projectreporter.nih.gov/project_info_description.cfm

fundes could also require the evaluators of behavioral interventions to collect and maintain field notes related to program implementation, which may require the collection of additional data beyond the usual evaluation protocol.¹²⁸

D. Governments and Regulators of Research

National governments can be involved in the process of disseminating behavioral interventions in at least four ways: as actors in the international and national legal process, as providers of behavioral interventions, as funders of research and locally delivered programs, and as regulators of federally funded research.

As actors in the international legal process, state governments can press for the WHO to take on the functions outlined above. They can also collectively pursue modifications to the international legal regime to ensure that effective behavioral interventions can be identified and disseminated, although this may be politically difficult. At a national level, lawmakers may also seek modifications or exceptions to national copyright laws, or even simply call attention to the ways that behavior change interventions could be used contribute to health improvements in local communities.

As organizations that adopt, modify, fund, and deliver behavioral interventions, governments can take on a direct role in publicizing program materials and evaluations, as well as ensuring that the interventions they finance are empirically supported. The Diffusion of Effective Behavioral Interventions (“DEBI”) project, which began in 1999 and is run by the CDC,¹²⁹ could provide a model for this process. The DEBI initiative identifies effective programs for HIV prevention based on pre-specified criteria, including the methodological rigor of the program evaluation and a clear description of the intervention’s key components.¹³⁰ The DEBI initiative then provides applicants, usually community-

?aid=7667249&icde=2795168 (last visited Mar. 31, 2010) (outlining the study description).

128. For a discussion of the types of program implementation data that are most useful for dissemination, see Agatha N. Eke et al., *Preparing Effective Behavioral Interventions To Be Used by Prevention Providers: The Role of Researchers During HIV Prevention Research Trials*, 18 AIDS EDUC. & PREVENTION 44, 50 tbl.2 (2006).

129. Centers for Disease Control and Prevention, About DEBI, <http://www.effectiveinterventions.org/go/about-debi> (last visited Mar. 31, 2010). The DEBI program works with the Replicating Effective Programs initiative (which packages program materials for dissemination), and the Prevention Research Synthesis initiative (which identifies evidence-based programs and reviews evidence of program effectiveness). See Eke et al., *supra* note 128, at 45-46; Centers for Disease Control and Prevention, Replicating Effective Programs Plus, http://www.cdc.gov/hiv/topics/prev_prog/rep (last visited Mar. 31, 2010).

130. See Cynthia M. Lyles et al., *Evidence-Based HIV Behavioral Prevention From the Perspective of the CDC’s HIV/AIDS Prevention Research Synthesis Team*, 18 AIDS EDUC. & PREVENTION 21, 24 (Supp. A 2006) (listing criteria for a best-evidence behavioral intervention).

based organizations, with training sessions and program materials without charge.¹³¹ Various city health departments and other funders now require their grantees to implement interventions selected from the DEBI project or the CDC's list of effective behavioral interventions.¹³² To date, over 10,000 people and 5,000 agencies have received DEBI training to deliver evidence-based HIV prevention programs.¹³³ Despite the successes of the DEBI project, there are drawbacks as well; for example, although the list of DEBI-supported interventions is growing, there remain population groups for whom no intervention has yet been identified. Organizations and researchers who work with these groups must adapt DEBI-supported interventions to the new population, rather than developing a new program that may be more appropriate.¹³⁴ However, overall the DEBI project is a successful demonstration of how governments can take a more active role in minimizing barriers to the identification and dissemination of effective programs. Scaling up the DEBI project to address health risks other than HIV may be a promising new trajectory, and the initiative could serve as a model for efforts by other governments, funders, and possibly the WHO.

As funders and regulators of research, governments could also require the disclosure of intervention materials and evaluations as a condition of funding. For example, governmental review of applications for NIH funding already requires a rigorous evidence base, and the NIH Public Access policy requires that the public gain access to evaluations of NIH-funded programs.¹³⁵ If this policy were extended to intervention manuals and materials, this would facilitate the dissemination of effective programs. Regulations governing the conduct of research on human subjects in the United States do not address the accessibility of program evaluations and materials;¹³⁶ however, it may be useful for IRBs who approve research efforts to consider researchers' commitments to make intervention materials and evaluations accessible after the evaluation is complete.¹³⁷

131. See Diffusion of Effective Behavioral Interventions (DEBI) Project, Frequently Asked Questions (FAQs) – General, <http://www.effectiveinterventions.org/go/general-faqs> (last visited Mar. 31, 2010).

132. McKleroy et al., *supra* note 19, at 60.

133. See Diffusion of Effective Behavioral Interventions (DEBI) Project, Welcome, <http://effectiveinterventions.org/> (last visited Mar. 31, 2010).

134. See, e.g., *Adapting CDC DEBI List for Target Audiences Is a Major Issue Among CBOs. Translation Changes Can Affect Funding*, 20 AIDS ALERT 75 (2005) (outlining difficulties in the translation process).

135. See U.S. Department of Health and Human Services, Public Access Policy, <http://publicaccess.nih.gov/> (last visited Mar. 31, 2010).

136. Protection of Human Subjects, 45 C.F.R. § 46 (2009).

137. Other national and international ethics groups, such as the World Medical Association, could apply similar pressure by making subsequent dissemination a priority in their ethical

TRANSFERRING BEHAVIORAL INTERVENTIONS

V. COUNTERING OBJECTIONS TO THE PROJECT OF BROADENING ACCESS TO BEHAVIORAL INTERVENTIONS

The solutions this Note proposed in the previous section are vulnerable to a wide variety of criticisms. This section will acknowledge and attempt to counter at least the most significant objections to the proposals above. These objections include logistical problems in broadening access to behavioral intervention materials, the possibility that later implementers may change programs in ways that diminish their effects, difficulties with the larger project of transferring interventions to new settings, the problem of preserving incentives for innovation, and the possibility that increased focus on behavioral interventions may distract from underlying causes of ill health and health inequalities.

A. Logistic Problems in Information-Sharing

There are clear logistical challenges involved in broadening access to program evaluations and materials, most particularly in the suggested WHO database effort, but also more broadly in the process of transferring behavioral interventions at all. The information required to deliver a behavior change program—including program evaluations, program manuals, program materials, and information about actual implementation and context during evaluations—is vast, complex, and sometimes difficult to collect. Not all programs have manuals. Most researchers do not collect or report data on participant attendance or contextual factors affecting implementation. We lack good instruments for monitoring program delivery or uptake during trials. Process evaluations, which assess how programs are implemented, are becoming more prevalent, but still do not complement the majority of effectiveness studies. The groups that implement behavior change programs might be reluctant to release some implementation details. (For example, consider an NGO that delivers an effective anti-smoking program in schools but must creatively persuade school administrators to give them access. These persuasion techniques might be useful to other groups, but there are good reasons why the NGO may be reluctant to release them). Detractors from this Note's proposal may well argue that there is simply too much information, and that even if the information could be gathered into a single database, the sheer quantity of detail would overwhelm the technological capacity of the database and the ability of users to find what they need. It is time-consuming to identify effective behavior change programs, and setting up and publicizing a database will take time and resources. People in developing countries who are in a position to adopt evidence-based behavior change programs may lack access to the Internet or may have connections that have

guidance to researchers. Professional associations such as the American Public Health Association could also contribute to this effort.

insufficient power to download large files (for example, program manuals and videos). It may also be conceptually challenging to identify what behavioral interventions should qualify for the database, given that all behaviors are related to health in some way (for example, consider the earlier example of efforts to encourage recycling—is this a health behavior change program?). And many of the people who are in a position to adopt effective behavior change programs are new to the idea of evidence-based practice in the first place, suggesting that the database might fall short of its full potential at first.

Many of these criticisms are viable. However, the database approach is not meant to be a total solution—indeed, simply making program materials available will not ensure that they are used. The WHO could mitigate some of these problems by making the database user-friendly and by taking the lead in identifying interventions that were effective. Although not all programs are manual-based, many are, particularly those that have been evaluated and shown to be effective. Even if we cannot make *all* of the relevant information available, we can certainly improve on what is available now. Our metrics for evaluating program implementation and translating research to practice are improving all the time, and the Internet and open-access movement are opening up unprecedented possibilities to make more of that information available to others. Internet access is increasing, and many improvements can be made in the communities that already have access to the web; the involvement of governments in encouraging evidence-based practice could be one way to mitigate the technological barriers to accessing information. It is true that the WHO efforts and other suggestions advanced here would be expensive; however, the economic burdens of chronic disease are also weighty, and prevention is cheaper than treatment.¹³⁸ If improving access to behavior change programs can improve health behaviors and minimize the disease burden to even a small extent, this could very well be worth the expense.

B. Risks of Adapting Interventions: The Dilution of Program Effects

Dilution refers to the possibility that modifications to an effective program will diminish effects on behaviors. For example, participants may look at program materials online, then decide that they do not need to attend in-person program sessions, despite in-person sessions actually being more effective. Program creators may also worry that publicly accessible materials will be used to implement their interventions incompletely or badly, thereby diluting program effects or giving the program a bad reputation. Communities where programs are implemented poorly may believe they are receiving an effective intervention,

138. See, e.g., Robert Beaglehole et al., *Prevention of Chronic Diseases: A Call to Action*, 370 LANCET 2152 (2007) (outlining the economic imperative for improving preventive services in global health).

when in fact they are not. These fears invoke intellectual property doctrines such as dilution of trademark¹³⁹ and the “moral rights” element of copyright.¹⁴⁰ Similar concerns may well be harnessed by licensing systems that limit who can deliver certain interventions.

These risks, however, seem worth running. Not all programs will work everywhere, but it seems unjust to deny new groups the opportunity to identify, duplicate, and experiment with programs that have been effective in the past. This is especially true when the actions that would be necessary to give them that opportunity (for example, making evaluations and materials available online) are minimal. The original rationales for trademarks, copyrights, and patents—where fears of imitation and dilution are acute—were either to protect the consumer (trademarks) or to encourage innovation because it is in the interest of the greater good (copyrights and patents). Here, those with most at stake are not program developers and researchers, but the individuals who could benefit from behavioral interventions and should be given that opportunity. Programs should evolve over time to remain effective in a changing social context, and open access to behavioral intervention materials will enable that change.

C. Drawbacks to the General Goal of Intervention Transfer

Because health behaviors and interventions that target them are influenced by context, there are ways to criticize the entire project of transferring effective programs, particularly when that transfer requires crossing borders. Adaptation is difficult, and it raises concerns about community “ownership” of imported programs, as well as about imperialism when behavior change programs are transported from high-income to low-income settings. Spending our time, energy, and resources to facilitate the transfer of interventions may be misguided from the first, some may argue.

However, these counterarguments may be answered in a few ways. First, there is empirical evidence that some programs work in a variety of settings. Consider, for example, the Focus on Kids intervention described earlier, which has had protective effects in communities as diverse as inner-city Baltimore and the Bahamas.¹⁴¹ Another good example is the Becoming a Responsible Teen intervention, which has shown protective effects for sexual risk behavior among

139. Under U.S. law, trademark dilution refers to the use of a famous mark (a mark “widely recognized by the general consuming public”) that, despite the absence of competition and likelihood of confusion, “impairs the distinctiveness” or “harms the reputation” of the famous mark. 15 U.S.C. § 1125 (2)(A)-(C) (2006).

140. For an overview discussion of moral rights in copyright law, see Cyril P. Rigamonti, *Deconstructing Moral Rights*, 47 HARV. INT’L L.J. 353 (2006).

141. See sources cited *supra*, notes 51-55.

African-American adolescents in urban areas,¹⁴² ethnically diverse young males in juvenile detention facilities,¹⁴³ and primarily white youth in residential substance abuse treatment centers.¹⁴⁴ The Incredible Years¹⁴⁵ and Triple P¹⁴⁶ parenting programs for antisocial behavior in young children have shown effects among diverse communities in the United States, Germany, Canada, Australia, Switzerland, Jamaica, New Zealand, Norway, Portugal, Wales, Scotland, and Sweden. Weight Watchers, a familiar commercial program, has had a significant effect on weight loss in randomized controlled trials in the United States and the United Kingdom.¹⁴⁷ Adaptations of the Project RESPECT intervention for HIV prevention have shown promise among female sex workers in China,¹⁴⁸ adult heterosexual men and women in a variety of U.S. cities,¹⁴⁹ African American and Latina adolescents,¹⁵⁰ and men who have sex with men.¹⁵¹

Second, we might consider the migration of “lifestyles.” If unhealthy

142. See Janet S. St. Lawrence et al., *Cognitive-Behavioral Intervention To Reduce African American Adolescents' Risk for HIV Infection*, 63 J. CONSULTING & CLINICAL PSYCHOL. 221 (1995).

143. See Janet S. St. Lawrence et al., *Sexual Risk Reduction and Anger Management Interventions for Incarcerated Male Adolescents: A Randomized Controlled Trial of Two Interventions*, 24 J. SEX EDUC. & THERAPY 9 (1999).

144. See Janet S. St. Lawrence et al., *Reducing STD and HIV Risk Behavior of Substance-Dependent Adolescents: A Randomized Controlled Trial*, 70 J. CONSULTING & CLINICAL PSYCHOL. 1010 (2002).

145. See The Incredible Years, Library: Incredible Years Research Outside the USA, http://www.incredibleyears.com/library/show_countries.asp (last visited Mar. 31, 2010) (providing links to effectiveness studies in various program locations).

146. See Ireen de Graaf et al., *Effectiveness of the Triple P Positive Parenting Program for Behavioral Problems in Children: A Meta-Analysis*, 32 BEHAVIOR MODIFICATION 714 (2008).

147. See, e.g., Michael L. Dansinger et al., *Comparison of the Atkins, Ornish, Weight Watchers, and Zone Diets for Weight Loss and Heart Disease Risk Reduction: A Randomized Trial*, 293 JAMA 43 (2005); Stanley Heshka et al., *Weight Loss with Self-Help Compared with a Structured Commercial Program*, 289 JAMA 1792 (2003); Helen Truby et al., *Randomised Controlled Trial of Four Commercial Weight Loss Programmes in the UK: Initial Findings from the BBC "Diet Trials"*, 332 BRIT. MED. J. 1309 (2006).

148. See Xiaoming Li et al., *Short-Term Effect of a Cultural Adaptation of Voluntary Counseling and Testing Among Female Sex Workers in China: A Quasi-Experimental Trial*, 18 AIDS EDUC. & PREVENTION 406 (2006).

149. See Mary L. Kamb et al., *Efficacy of Risk-Reduction Counseling To Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases*, 280 JAMA 1161 (1998).

150. See Carol Royce, Paula Perlmutter Silverman & Beatrice Krauss, *A Brief, Low-Cost, Theory-Based Intervention To Promote Dual Method Use by Black and Latina Female Adolescents: A Randomized Clinical Trial*, 34 HEALTH EDUC. & BEHAV. 608 (2007).

151. See Beryl A. Koblin et al., *Effects of a Behavioural Intervention To Reduce Acquisition of HIV Infection Among Men Who Have Sex with Men: The EXPLORE Randomised Controlled Study*, 364 LANCET 41 (2004).

behaviors are in fact traveling from place to place (and from high-income to low-income settings), it may be a very good starting point to see if the same types of things that “work” in one area work in another. Third, this Note has already outlined how barriers to intervention transfer also *limit our knowledge* about program effectiveness in different settings. If we cannot try interventions in different places, we cannot speak definitively about whether they retain their effectiveness. Increasing the availability of program evaluations and materials will enable interventions to be evaluated in other settings, and if the criticism does indeed hold true—that is, if a program is non-transferable—then that will be valuable knowledge as well.

Finally, even if the wholesale transportation of programs to other settings is not viable, simply having a repository of behavior change strategies could well be valuable. The database may spur program adopters to use parts of other interventions, to adapt or evaluate their own, or to gauge how close their own interventions are to programs in other settings. If the database included a listing of program settings or a networking component that enabled different groups to contact one another, it could be even more useful for this purpose.

D. Preserving Incentives for Innovation in Behavioral Interventions

It is possible that making program materials available at a lower cost will diminish the incentives to create new or more precisely tailored programs. Potential program developers may worry about the loss of reputation or profits, while others might use program materials that are inappropriate for their setting without making adaptations or developing a more appropriate intervention.

Neither of these arguments is fully persuasive. To answer the first objection, many incentives remain for program developers beyond program reputation and profits. These include publication, career advancement, research funding, program funding in one’s own setting, and the renown that comes from developing a program that is recognized as effective. Those who develop effective behavior-change interventions are also motivated by genuine regard for health, and many of these developers would welcome broader dissemination of their interventions. Those who do want to sell their own programs for a profit might be more concerned; however, programs that are already sold for profit could opt out of databases of program materials. Total coverage is not necessary for this initiative to be valuable—even making *some* effective programs available for free would be a good start. To answer the second objection, it also seems unlikely that making existing programs available will hinder creative efforts entirely. Those who consider using a program in a new setting will almost always want to change *some* details, either to make the program a better fit for the new setting, or to foster community ownership of the intervention. Groups who wish to create programs out of whole cloth could also benefit from access to strategies that have proven effective in the past—a database of program materials may in

fact inspire creativity, enabling combinations of program components that would not have been identified otherwise.

E. Concern that an Increased Focus on Behavioral Interventions May Distract Attention from Underlying Causes of Health Inequalities

It is possible to challenge the entire premise of behavioral interventions, holding that behavior is socially constituted and depends on resources, education, environment, laws, and other factors that are often beyond individuals' control. Even perfectly healthy behaviors cannot guarantee disease prevention. It might be argued that emphasizing behavior change is therefore unrealistic, as it unduly "blames people" for their circumstances, and diverts attention and resources from efforts to change the social determinants of behavior and illness.

To be sure, some behavioral interventions may take an unfairly individualistic view of health behaviors or expect too much of participants. But this criticism does not apply to all interventions. We should not conflate the effects of interventions with access to effective interventions. When programs prove to be ineffective, then they should be discontinued. When programs are unrealistic, they should not be used. But some interventions do help people make better choices, and we should to maximize accessibility to those programs. Many interventions are specifically developed in light of the contextual determinants of health behaviors, and as we gain knowledge about the ways that context affects the choices we make, interventions may improve further.

It is also unpersuasive to argue that focusing on health behaviors is a distraction from the broader determinants of health inequalities. This argument has arisen before—for example, to argue that providing antiretroviral medication to people in low-income countries is inefficient or detracts from the larger project of reducing the inequalities that contribute to HIV risk.¹⁵² It would be unethical to deny people downstream interventions simply because we want to focus on the upstream determinants of their problems. The provision of health behavior services is already widespread, and we have a duty to make those interventions as effective as possible.

Finally, we should be wary of undermining the agency of people in low-income settings. Behavioral choices are indeed influenced by social factors, but people choose among the options they have. Even among people who are constrained to engage in activities that are detrimental to health, it may be

152. Dr. Paul Wise and Dr. James Orbinski have separately outlined the flaws of this argument in lectures at Yale. James J. Orbinski, Assoc. Professor of Med. & Political Sci., Univ. of Toronto, Guest Lecture in the Yale University Global Health Ethics, Politics, and Economics Course (Apr. 16, 2009); Paul H. Wise, Richard E. Behrman Professor of Child Health and Soc'y, Professor of Pediatrics, Stanford Univ., Guest Lecture in the Yale University Global Health Ethics, Politics, and Economics Course (Feb. 12, 2009).

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possible to engage in these behaviors in ways that minimize those detrimental effects. Interventions that take this approach often fall under the category of harm-minimization, a concept common in HIV prevention programs. For example, interventions that encourage injection drug users to avoid using non-sterile injection equipment can minimize the health risks of injecting, even if intervention participants do not reduce drug use.¹⁵³ When we say that health behavior interventions are unrealistic and distracting, we walk a fine line between recognizing the real ways that context influences behavior, and denying outright the agency and capability of individuals in low-income settings.

CONCLUSION

Health behaviors matter in global health, and they can exacerbate risk for both infectious and chronic diseases. Obesity, heart disease, diabetes, some cancers, sexually-transmitted infections, and many other conditions are in part related to modifiable behaviors. Although behavioral choices are constrained by contextual factors and constitute only one component of disease risk, improving health behaviors can have a beneficial effect on health outcomes.

Behavioral interventions, complex programs that can involve media and interpersonal components, are designed to help participants engage in healthier behaviors. Through the work of community groups, social and public health researchers, governments, and NGOs, we now know that although some of these programs are ineffective, many behavioral interventions can improve health behaviors and outcomes and retain their effectiveness in a variety of settings. Given the prevalence of health risk behaviors and increases in unhealthy lifestyles,¹⁵⁴ the transfer of effective behavioral interventions can improve global health. But there are information barriers, both formal and informal, that stop us from getting those interventions to people who could benefit from them. Although patents, trademarks, and trade secrecy protection are not particularly significant barriers to dissemination, copyrights and informal barriers are formidable. Transferring interventions requires access to information about program effects and program implementation, and much of that information is either copyrighted or inaccessible.

To lower these barriers, this Note proposes an initiative by the WHO to identify effective programs, to make evaluations accessible, and to make the actual program materials and manuals available online at no cost. This initiative should be supplemented by efforts to incentivize information-sharing among program developers, program adopters, and researchers—and these efforts would benefit from the participation of academic institutions, scholarly journals,

153. See Alex Wodak & Leah McLeod, *The Role of Harm Reduction in Controlling HIV Among Injecting Drug Users*, 22 AIDS S81 (2009).

154. See, e.g., Frenk and Gómez-Dantés, *supra* note 30.

research and program funders, IRBs, national and local governments, and researchers and program developers themselves. If we can improve the dissemination of effective behavioral interventions, we may make a start toward reducing behavioral risks and the role they play in the global disease burden.

This argument and its proposed resolution have flaws. However, the central goal of this Note is to identify and respond to a gap in theory and knowledge. Given the salience of health behaviors in many global health problems, the formal and informal barriers inhibiting the dissemination of effective behavioral interventions should not go unquestioned. This Note aims to make a start towards that goal.