TBM

NEWS FROM NIH

News from the NIH: research to evaluate "natural experiments" related to obesity and diabetes

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Obesity is a major contributor to many serious health conditions that increase morbidity and reduce quality of life. For example, obesity is a significant risk factor for diabetes, cardiovascular disease, and certain forms of cancer. The prevalence of obesity in children and adults in the USA has dramatically increased in the past four decades [1, 2]. Although some cities and states are showing reductions in rates of childhood obesity, the prevalence is still far above 1970 levels [3–5]. Diabetes currently affects an estimated 25.8 million people in the USA and another 79 million Americans are estimated to be at greatly increased risk of developing diabetes in the next several years [6]. Further, most adults with diabetes in the USA are not meeting the recommended goals for diabetes care [7]. Overweight, obesity, and/or excessive weight gain during pregnancy are also contributing to rising rates of gestational diabetes mellitus which in turn increases risk of future type 2 diabetes in the mother and child. In addition to the considerable impairments to health and quality of life with these conditions, there are also serious economic consequences. The estimated current annual cost of diabetes alone in the USA is $245 billion dollars per year with $176 billion in direct medical costs and the remainder related to reduced productivity [8].

The increasing challenges of obesity and its related health conditions in our society also coincide with a dynamic time for health care in the USA, including changing consumer demands (employers and individuals) and the pressing need to deliver evidence-based care, improve health outcomes for all Americans, and control costs. In communities and in health-care settings, many of the policy and programmatic changes are evidence-informed, but often little is known about population-level effects. Rigorous scientific evaluation of these "natural experiments" can help to more rapidly build an evidence base to inform key stakeholders and policy makers.

Evaluation research generally, and rigorous evaluation of natural experiments specifically, is increasingly recognized as an important and appropriate approach to health-related research, particularly in the context of policy and environmental [9, 10] change. The term experiment in natural experiments is something of a misnomer as the implementation of these public health and health-care system policies and programs are not often designed as true experiments. Generally, the term natural experiment refers to an exposure or change that is not directly manipulated by the researcher, but rather the result of policy or program interventions that are varied in their implementation along a number of possible dimensions, such as time, geography, or content. Research that evaluates the real-world implementation of polices and program has some challenges such as the potential for bias, confounding, and threats to casual inference. Despite these limitations, the data from natural experiment research offers unique opportunities to enrich the evidence base and can offer advantages not provided by other research designs, such as improved external validity. This research can provide important data about the impact of a policy or program in real-world settings and populations; see for example the well-known study on the impact of education on health outcomes by Lleras-Muney [11]. Often, these are data that would be very difficult, potentially unethical, and often cost prohibitive to collect in the context of an investigator-initiated randomized experiment [12]. Natural experiment research also allows for the assessment of potential unintended consequences or subgroup differences in response to the program or policy and measurement of implementation fidelity, variability, and process.

Since 2010, several institutes and centers (ICs) at the National Institutes of Health have jointly issued funding opportunity announcements intended to support rigorous evaluation of natural experiments related to obesity and/or diabetes outcomes, including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); National Cancer Institute (NCI); *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Aging (NIA); and the Office of Behavioral and Social Sciences Research (OBSSR). In these funding opportunity announcements, policies are broadly defined to include public policies at local, state, and federal levels of government and organizational level policies, such as those implemented by large organizations, worksites, or school districts. Polices can be formal such as laws and regulations or informal such as guidelines and procedures. Pro-

gram is defined as a set of activities initiated by governmental or other organizational bodies to enhance obesity prevention and control.

OBESITY POLICY AND PROGRAM EVALUATION

- PA 13-110 (R01): http://grants.nih.gov/grants/guide/pa-files/PA-13-110.html, participating ICs include NIDDK, NCI, NICHD, NHLBI, NIA, and OBSSR.
- PAR 12-257 (R01): http://grants.nih.gov/grants/guide/pa-files/PAR-12-257.html, participating ICs include NIDDK, NICHD, NCI, NIA, and OBSSR.

These FOAs solicit evaluation research on policy and environmental interventions that can be expected to improve obesity-related behaviors such as energy intake and physical activity level. Examples include, but are not limited to, healthy food outlets in underserved areas, calorie labeling requirements, taxes on unhealthy foods or beverages, after school and summer programs, and modifications to the built environment to encourage active transportation or leisure physical activity, such as biking infrastructure, multi-use trails, sidewalks, and parks and recreation facilities. PAR 12-257 uses an accelerated review/award process to support time-sensitive research to evaluate a new policy or program expected to influence obesity-related behaviors. The goal is that eligible applications selected for funding will be awarded within 3–4 months after the application submission/receipt date. PAR 12-257 is intended to support research where evaluation of an obesity-related policy and/or program offers an uncommon and scientifically compelling research opportunity that will only be available if the research is initiated with minimum delay.

SCHOOL NUTRITION AND PHYSICAL ACTIVITY POLICIES, OBESOGENIC BEHAVIORS, AND WEIGHT OUTCOMES

- PA 13-100 (R01): http://grants.nih.gov/grants/guide/pa-files/PA-13-100.html, participating ICs include NICHD, NCI, NHLBI, and OBSSR.
- PA 13-098 (R21): http://grants.nih.gov/grants/guide/PA-files/PA-13-098.html, participating ICs include NICHD, NCI, NHLBI, and OBSSR.
- PA 13-099 (R03): http://grants.nih.gov/grants/guide/PA-files/PA-13-099.html, participating ICs include NICHD, NCI, and OBSSR.

American youth consumes approximately one third of their energy intake while at school [13]. Schools also represent an ideal opportunity for children to increase their physical activity given the 6–7 h spent there each day [14]. Despite numerous recommendations for environmental- and policy-level strategies to combat obesity, the focus of most obesity-prevention strategies in the school context has been limited to the individual level. To date, such individually based intervention strategies have resulted in relatively modest changes in behavior. Given the high cost of such interventions, they have limited opportunities to significantly impact obesity at the population level. School-based policy strategies are increasingly being proposed and implemented in order to reduce childhood obesity rates; there is a critical need to build the scientific knowledge base to inform policy development and implementation in this rapidly developing field.

These FOAs support research to (1) evaluate how policies (federal, state, and school district levels) can influence school physical activity and nutrition environments, youths' obesogenic behaviors (e.g., nutrition and physical activity behaviors), and weight outcomes; (2) understand how schools are implementing these policies and examine multilevel influences on adoption and implementation at various levels (e.g., federal, state, school district, and school); and (3) understand the synergistic or counteractive effect of school nutrition and physical activity polices on the home and community environment and body weight.

EVALUATING NATURAL EXPERIMENTS IN HEALTH CARE TO IMPROVE DIABETES PREVENTION AND TREATMENT

- PAR 13-365 (R18): http://grants.nih.gov/grants/guide/pa-files/PAR-13-365.html, participating IC is NIDDK.

Health-care delivery organizations are implementing new models of care (e.g., innovative teams, appointment models, registries, or referral patterns), treatment supports (e.g., patient navigators and reminders for more rapid medication intensification), and incentive strategies (e.g., pay for performance and reduced co-pay). These health-care changes include rapidly evolving electronic resources in health care and increasingly sophisticated methods to validate, link, and analyze these large data sets. Also, many employers are making changes or implementing programs designed to complement health-care coverage to improve health, lower costs, reduce absenteeism, and increase productivity (e.g., worksite wellness programs and incentives).

The goal of research supported by this FOA is to maximize what can be learned from health-care policies and programs that are planned or recently implemented. Research support is for the evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of NIH grant funding. Further, the intent is to support evaluation of policies or programs that are large enough in scale to allow the results to have some generalizability outside of the specific setting of implementation. Research in response to this FOA may focus on programs or policies that target the patient, family, health-care team, health-care system, or some combination.

Many policy and environmental interventions appear to be promising strategies to reduce obesity rates in children and adults. However, without rigorous evaluation, it is difficult to determine which approach (or combination of approaches) may be effective and for whom. The evaluation of natural experiments offers the opportunity to learn from these interventions and build an evidence base that can inform policy makers and stakeholders at local, state, and federal levels. The funding announcements highlighted above reflect the commitment of the National Institutes of Health to support research to evaluate natural experiments as a means to more rapidly inform population health-focused obesity prevention and control.

Disclaimer: The opinions expressed herein and the interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official recommendation, interpretation, or policy of the National Institutes of Health or the US Government.

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010. *JAMA*. 2012; 307(5): 483-490.
2. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. *JAMA*. 2012; 307(5): 491-497.
3. Centers for Disease Control and Prevention. Vital signs: obesity among low-income, preschool-aged children—United States, 2008-2011. *MMWR Morb Mortal Wkly Rep*. 2013; 62(31): 629-634.
4. Fryar CD, Carroll MD, Ogden CL. Prevalence of obesity among children and adolescents: United States, trends 1963-1965 through 2009-2010. National Center for Health Statistics; 2012. Available at: http://www.cdc.gov/nchs/data/hestat/obesity_child_09_10/obesity_child_09_10.htm. Accessed 25 Nov 2013.
5. Health policy snapshot: declining childhood obesity rates—where are we seeing the most progress? Robert Wood Johnson Foundation; 2012. Available at: http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf401163. Accessed 25 Nov 2013.
6. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information on Diabets and Prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.
7. Ali MK, Bullard KM, Saaddine JB, Cowie CC, Imperatore G, Gregg EW. Achievement of goals in US diabetes care, 1999-2010. *N Engl J Med*. 2013; 368(17): 1613-1624.
8. American Diabetes Association. Economic costs of diabetes in the US in 2012. *Diabetes Care*. 2013; 36(4): 1033-1046.
9. Craig P, Cooper C, Gunnell D, et al. Using natural experiments to evaluate population health interventions: new Medical Research Council guidance. *J Epidemiol Community Health*. 2012; 66(12): 1182-1186.
10. Glasgow RE, Emmons KM. How can we increase translation of research into practice? Types of evidence needed. *Annu Rev Public Health*. 2007; 28: 413-433.
11. Lleras-Muney A. The relationship between education and adult mortality in the United States. *Rev Econ Stud*. 2005; 72: 189-221.
12. McKinnon RA, Orleans CT, Kumanyika SK, et al. Considerations for an obesity policy research agenda. *Am J Prev Med*. 2009; 36(4): 351-357.
13. Briefel RR, Wilson A, Gleason PM. Consumption of low-nutrient, energy-dense foods and beverages at school, home, and other locations among school lunch participants and nonparticipants. *J Am Diet Assoc*. 2009; 109(2 Suppl): S79-S90.
14. Physical Activity Guidelines for Americans Midcourse Report Subcommittee of the President's Council on Fitness, Sports & Nutrition. Physical Activity Guidelines for Americans Midcourse Report: Strategies to Increase Physical Activity Among Youth. Washington, DC: U.S. Department of Health and Human Services, 2012.