

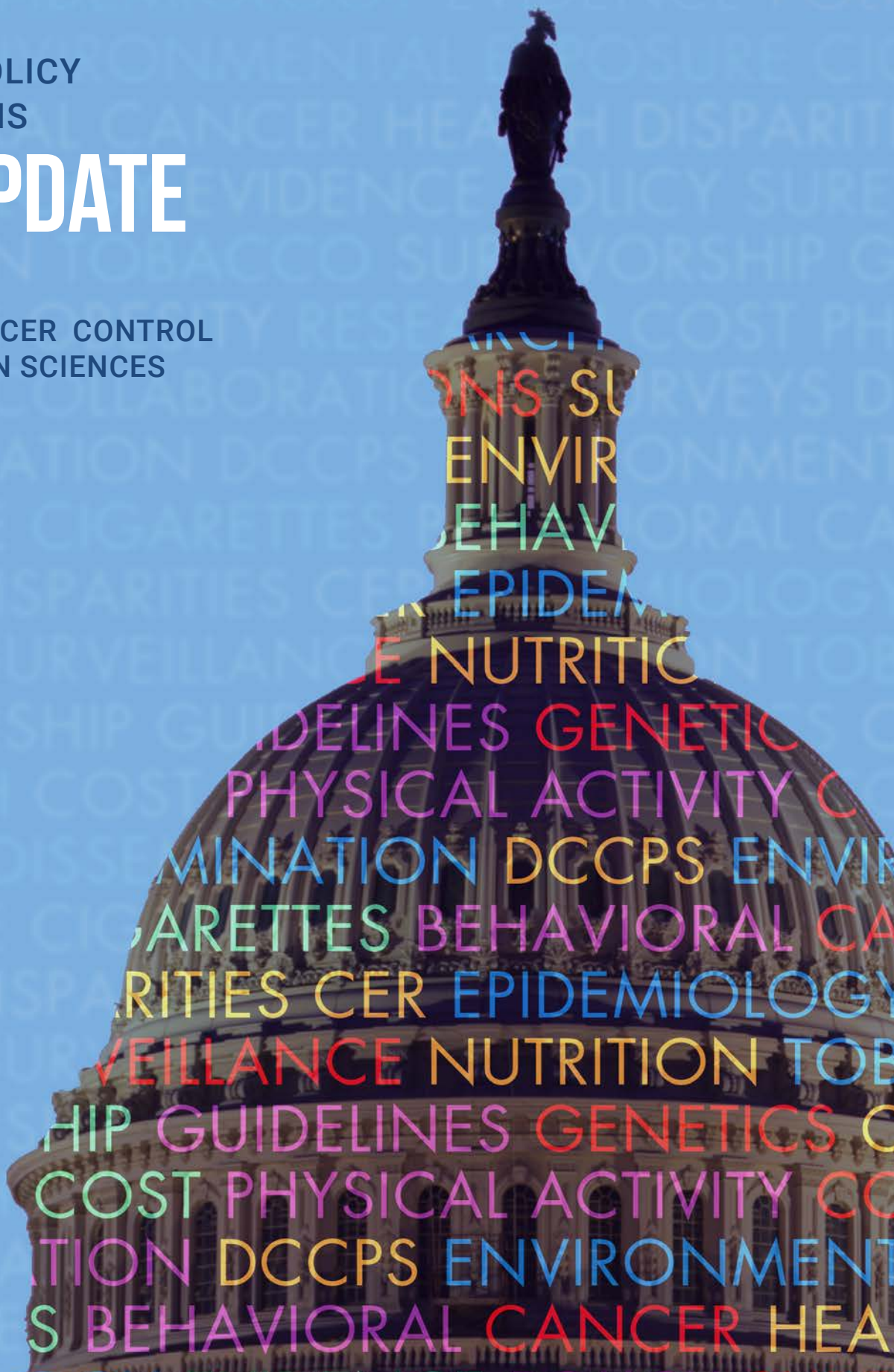


NATIONAL CANCER INSTITUTE

INFORMING POLICY  
AND PROGRAMS

# 2016 UPDATE

DIVISION OF CANCER CONTROL  
AND POPULATION SCIENCES





## OVERVIEW

The Division of Cancer Control and Population Sciences (DCCPS) at the National Cancer Institute (NCI) supports science that helps inform policies and programs aimed at preventing, detecting, and treating cancer. That science includes work to understand and assist those living with a history of cancer, as well as their families. A key focus of this work is evaluating the effect of models of care, incentives, and factors that can be changed to improve care. A portion of the research supported by DCCPS therefore provides policy makers with the practical evidence they need to make effective decisions. The division's long-standing history of collaborating across the National Institutes of Health (NIH), Department of Health and Human Services (HHS), and other agencies makes it uniquely suited to continue to play a role in the generation of evidence to shape and respond to national efforts to improve the value and effectiveness of cancer care. This brief provides examples of the division's research contributions related to public policy and illustrates its role in developing a comprehensive base of scientific evidence for policy makers and public health practitioners.



# EVALUATING STRATEGIES FOR IMPROVING VALUE AND PATIENT OUTCOMES

The passage of health care reform legislation in 2010 focused on improving access to health insurance for the uninsured, particularly young adults, individuals with preexisting conditions, and people who are not offered or cannot afford insurance through their employer. The Centers for Medicare and Medicaid Services, as well as several major insurers, have recently indicated they are exploring the possibility of shifting cancer care from fee-for-service to value-based reimbursement approaches intended to improve patient outcomes and reduce financial burden. These and other changes have been made with the expectation that they would increase access and improve quality. There is a need to evaluate the effect of these changes in incentives on care delivery and outcomes. DCCPS is uniquely positioned to support research that will generate information needed to understand the immediate impact of these reforms and make adjustments if the reforms fail to achieve the stated goals or have unintended adverse consequences.

## Economic burden of cancer and rising health care costs

DCCPS conducts cutting-edge research on the economic burden of cancer and employs some of the nation's top health economists. The division examines the determinants of the cost of cancer care and develops estimates of the overall economic burden of cancer. To prepare this information, DCCPS has worked to develop new methods and is using the most recent data to estimate the cost of cancer care and to provide projections of cost of care in the future based on population trends.

This information has important policy implications for health care planning and resource allocation. DCCPS researchers have developed and reported to Congress

estimates of both the overall cost of cancer care in the US and specific costs by tumor type and site, sex, age group, geographic location, and phase of care (i.e., initial, continuing, and last year of life). For example, researchers found that the costs of cancer care to Medicare are substantial and vary by tumor site, phase of care, stage at diagnosis, and survival. They also found that 55 percent of families of cancer patients incurred a debt of \$10K or more, so the financial impact of cancer remains an important concern.

These findings suggest that the cost of cancer care involves not only direct expenditures but also indirect costs borne by families, such as lost productivity, job loss, and time costs associated with treatment. DCCPS conducts and supports research to quantify these indirect costs. For example, DCCPS developed models using the human capital approach, which relies on earnings as a measure of productivity, to estimate the value of productivity lost as a result of cancer mortality. A DCCPS study was the first to estimate net patient time costs over the full course of cancer care for 11 of the most common cancer sites. In addition, DCCPS research found that time spent by informal caregivers was substantial. Incorporation of the value of informal caregiver time will be important when evaluating the costs and benefits of cancer control interventions.

In recent years, DCCPS co-funded the [Medical Expenditure Panel Survey \(MEPS\) Experiences with Cancer Survivorship Supplement](#), which, along with the main Medical Expenditure Panel Survey, was used to improve national estimates of the burden of cancer, particularly medical expenditures for patients of all ages. MEPS is the only source of national data on the financial burden of cancer for survivors and has played an important role in describing financial toxicity, a topic that has become a priority for

professional and patient advocacy organizations. Data from the MEPS supplement show that the cost of care among cancer survivors is considerable, even years after diagnosis.

### Improved coverage of preventive health services

DCCPS plans, implements, and maintains a comprehensive research program to promote the appropriate use of effective cancer screening tests, as well as strategies for informed decision making regarding cancer screening technologies, in both community and clinical practice.

For example, the USPSTF has used the evidence from the [Cancer Intervention and Surveillance Modeling Network](#) (CISNET), funded by DCCPS, as they created screening guidelines for lung cancer and revised screening recommendations for breast and colorectal cancers. DCCPS research has also led to creation of guidelines regarding prostate and cervical cancer screening. Since 2001, DCCPS has collaborated with the Agency for Healthcare Research and Quality (AHRQ) to model how changes in screening, risk factors, and optimal use of chemotherapy would influence mortality rates from colorectal cancer. DCCPS worked with AHRQ and the Centers for Medicare and Medicaid Services (CMS) to produce an economic analysis CMS used to inform new coverage of a colorectal screening test, the immunochemical fecal occult blood test (FOBT). DCCPS research also informs the Centers for Disease Control and Prevention's (CDC's) National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which provides access to breast and cervical cancer screening services to underserved women.

Two large randomized screening trials, one in Europe and one in the US, led by NCI, have reported results on the use

of prostate-specific antigen (PSA) screening and prostate cancer mortality. The European Randomized Study of Screening for Prostate Cancer (ERSPC) showed a 20 percent decline in prostate cancer mortality, while the US study – the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) – showed that annual, regular screening compared with the screening already occurring in the US discovered more prostate cancers, but did not lead to further declines in mortality over 7 to 10 years. Leaders of both trials have agreed to work with DCCPS CISNET investigators to examine the trials in detail to determine the causes of the differences. In addition to the marked differences in use of PSA screening in the control groups in the two populations, other issues may play a role as well, such as differing systems of PSA use (e.g., PSA cutoffs and biopsy practices) and treatment practices. CISNET investigators will use the methods of systematic modeling they have developed to reconcile differences between the two trials and assist in translating them for use in the development of public health guidelines for PSA screening. Data from the DCCPS-supported Surveillance, Epidemiology, and End Results (SEER) Program enabled both of these studies.

CISNET members also provided key evidence reports that informed USPSTF's review of recommendations on breast cancer screening. In 2016, a comprehensive analysis from six independent research teams examining breast cancer screening intervals produced a unanimous finding: mammography screening every 2 years for average-risk women ages 50 to 74 offers a favorable balance of benefits to harm. The conclusion was consistent with the same groups' analyses published in 2009, even with newly added data from digital mammography, advanced treatments, and molecular tumor subtypes. The findings, presented to the USPSTF as part of its evidence review for breast cancer

screening recommendations, were published in the *Annals of Internal Medicine* (Jan 12, 2016).

The study above was possible, in part, because of the contributions on current screening practices and outcomes from the DCCPS-funded [Breast Cancer Surveillance Consortium](#) (BCSC), a well-established research resource for studies designed to assess the delivery and quality of breast cancer screening. This large, standardized data set presents a unique opportunity for investigators throughout the country to study how mammography screening performance may be improved and how breast cancer screening relates to changes in disease stage at diagnosis, survival, and mortality. In the past 15 years, BCSC data have had an impact on a wide range of scientific and policy arenas beyond the immediate work of the consortium.

The BCSC is planning studies to assess the influence of state-based legislation that requires the reporting of breast density to women, despite uncertainty about how density is associated with breast cancer risk and what women with dense breasts can do to reduce their risk. These results could guide future legislation. BCSC data on breast density and breast cancer risk have garnered much media attention, as they provide increasing evidence that breast density alone is not adequate justification for supplemental screening. BCSC data are used for Mammography Quality Standards Act (MQSA) compliance activities, as well as quality improvement activities, and the BCSC has worked with the American College of Radiology to develop common data collection forms. BCSC data have been included in several high-level reports by the Government Accountability Office (GAO) and Institute of Medicine (IOM), and they also have been used for USPSTF guideline development.

The [Population-based Research Optimizing Screening through Personalized Regimens](#) (PROSPR) network was

established in 2011 to better understand how to improve the screening process (recruitment, screening, diagnosis, referral for treatment) for breast, colorectal, and cervical cancers. PROSPR has mapped the complex process of three types of cancer screening, which will assist health care administrators and clinicians in identifying opportunities to improve the screening process. Data from the PROSPR colorectal cancer group have shown that physicians' adenoma detection rates have a strong inverse association to colorectal cancer risk, which has implications for designing colorectal cancer screening programs in health systems.

DCCPS experts also support CDC's Guide to Community Preventive Services. The guide is a free resource to help public health planners choose programs and policies to improve health and prevent disease in communities. DCCPS provides a crosswalk between the [Research-tested Intervention Programs](#) (RTIPs) website and the guide to assist with selection of evidence-based interventions that align with the guide recommendations. DCCPS experts participate in literature reviews, oversee the development of new research, and contribute to the development of the guide.

## HHS development of a national strategy to improve health care quality

NCI-funded studies have provided a strong foundation for Patient-Centered Outcomes Research Institute (PCORI)-funded work, which has cancer as one of the top three conditions in its portfolio. DCCPS has supported comparative effectiveness research (CER) studies and developed the methods and data sets needed to conduct high-quality CER. Results from CER, also known as patient-centered health research, will provide the evidence patients and physicians need to choose between a wide variety of options for diagnosis, treatment, and monitoring.

In addition, DCCPS supports the [Cancer Research Network \(CRN\)](#), a consortium of eight nonprofit research centers based in integrated health care delivery organizations that cover more than 6 million individuals. CRN conducts research on the characteristics of patients, clinicians, communities, and health systems to improve cancer prevention and care. CRN also enables CER through the development of standardized approaches to data collection, data management, and analysis across health systems. The CRN is undertaking preliminary efforts to track implementation of lung cancer screening outside clinical trials, which will give early information about appropriateness of adoption and levels of benefits and harms in a “real world” population. Other projects that DCCPS supports around CER include CISNET, BCSC, and physician surveys.

In response to the President’s Cancer Panel’s report *Accelerating HPV Vaccination Uptake: Urgency for Action to Prevent Cancer*, DCCPS has funded grant supplements to 18 NCI-designated cancer centers to support collaborations with existing state and local coalitions and HPV immunization programs. The goal of this funding is to conduct an environmental scan in order to develop or expand intervention research to increase HPV vaccination uptake in pediatric care settings. These supplements are part of a larger effort that NCI and CDC are undertaking to systematically bring together NCI-designated cancer centers, CDC programs, and state and local health departments and their immunization programs.

For the past several decades, NCI has funded the [Cancer Control Supplement \(CCS\) to the National Health Interview Survey \(NHIS\)](#) to collect data pertaining to knowledge, attitudes, and practices in cancer-related health behaviors, screening, and risk assessment. The NHIS CCS covers

a variety of topics including diet, physical activity, cancer screening, sun protection, tobacco use, genetic testing, and cancer survivorship. These data serve as an official monitoring tool for Healthy People cancer control objectives, which aim to improve the health of all Americans.

In 2014, DCCPS began funding the [Cancer Care Delivery Research \(CCDR\) component of the NCI Community Oncology Research Program \(NCORP\)](#). NCORP is a national network of investigators, cancer care providers, academic institutions, and other organizations that serves as a resource for studying cancer care in the community, where the majority of patients receive care. The goal of NCORP is to generate a broadly applicable evidence base that contributes to improved patient outcomes and a reduction in cancer disparities. This is the first time that health care delivery has been a focus of clinical trials groups, which is a positive step, given those groups have existing capacity to conduct research in the settings where most Americans with cancer receive their treatment.

DCCPS played a leading role in coordinating the development of the [Patient Reported Outcomes Measurement Information System \(PROMIS\)](#), which is a system of highly reliable, precise measures of patient-reported health status for physical, mental, and social well-being. PROMIS serves as a well-validated instrument that sets a standard for the collection of patient-reported data in the research community. More recently, DCCPS has funded the [Person-Centered Assessment Resource \(PCAR\)](#), which provides automated use of four state-of-the-science measurement systems – PROMIS, NIH Toolbox, Neuro-QOL, and ASCQ-Me – that were originally developed as separate NIH programs. PCAR gives researchers and others a single [place](#) to identify key quality-of-life measures.

## TOBACCO CONTROL

### Smoking Cessation within the Context of Lung Cancer Screening

The US Preventive Services Task Force (USPSTF) now recommends that adults ages 55 to 80 who have a 30 pack-year smoking history and currently smoke or have quit smoking within the last 15 years should be screened annually for lung cancer. Furthermore, the Centers for Medicare and Medicaid Services issued a national coverage determination for Medicare coverage. The requirement in the Affordable Care Act that USPSTF prevention recommendations (grade A or B, such as the ones mentioned above) be covered by all basic health insurance plans ensures that a large number of heavy smokers susceptible to lung cancer will present at least once per year for screening. This represents an important point of intervention for behavior modification. RFA-CA-15-011, “[Smoking Cessation within the Context of Lung Cancer Screening \(R01\)](#),” is designed to stimulate research on optimal cigarette smoking cessation approaches delivered in conjunction with lung cancer screening visits in a variety of screening settings.

### State and Community Tobacco Control

The division’s Tobacco Control Research Branch has funded the [State and Community Tobacco Control \(SCTC\) Research Initiative](#) since 2011. The research conducted by the initiative addresses important, understudied aspects of state and community tobacco-control policy and media interventions. The initiative’s four main research areas are secondhand smoke policies, tobacco tax and pricing policies, community and individual behavior related to tobacco advertising and mass media actions to counter tobacco advertising, and tobacco industry practices as they relate to the above three items. SCTC funds one

coordinating center and the following research projects: Brief Interventions to Create Smoke-free Home Policies in Low-income Households; Countering Young Adult Tobacco Marketing in Bars; Maximizing State and Local Policies to Restrict Tobacco Marketing at Point of Sale; Monitoring and Assessing the Impact of Tax and Price Policies on US Tobacco Use; Networks among Tribal Organizations for Clean Air Policies; Nonsmokers and Tobacco Control Norms: Population Surveys and Intervention Studies; and Tobacco Control in a Rapidly Changing Media Environment.

### Family Smoking Prevention and Tobacco Control Act

The landmark Family Smoking Prevention and Tobacco Control Act of 2009 granted the Food and Drug Administration (FDA) authority to regulate the manufacturing, marketing, and distribution of tobacco products. Evidence generated by DCCPS-funded research has contributed to FDA’s ability to make informed decisions as it determines how to implement its regulatory authorities. To inform regulatory policy, in 2013 NIH and FDA announced the creation of 14 [Tobacco Centers of Regulatory Science \(TCORS\)](#), comprising scientists from diverse backgrounds to increase the knowledge across the full spectrum of basic and applied research on tobacco and addiction.

### Warning labels for modified-risk tobacco products

The FDA’s [Tobacco Products Scientific Advisory Committee \(TPSAC\)](#) concluded in April 2015 that milder health warnings suggested by Swedish Match in its reduced-risk application for snus do not fully convey the product’s health risks. This was the first application to be considered by the FDA under



guidelines for modified-risk tobacco products. Although the TPSAC recommendations are not binding, subsequent approval is unlikely. A DCCPS scientist participates as an ex-officio member of the committee.

## Smoking cessation

DCCPS-funded research has contributed to the strong evidence base regarding effective treatments and interventions for tobacco dependence. The Federal Employee Health Benefit Program continues to offer smoking cessation programs and medications without co-payments or coinsurance to its beneficiaries. Research is also informing CMS as it develops policies regarding smoking cessation as a covered benefit among recipients. For example, in June 2010, CMS proposed to expand coverage for tobacco cessation counseling to all Medicare beneficiaries who use tobacco.

## Secondhand smoke

DCCPS-funded research has shown that smoke-free laws benefit nonsmokers by eliminating exposure to tobacco smoke and benefit smokers by providing an environment that encourages and facilitates quitting. As of October 2015, 36 states, Washington, DC, and Puerto Rico had enacted comprehensive smoke-free laws. Several of the US territories also have enacted comprehensive smoke-free laws. Since 2007, NCI policy has required that all meetings and conferences primarily organized by NCI be held in a jurisdiction that has adopted a comprehensive smoke-free policy.

Smoke-free policies can make a large public health impact when implemented in multi-unit housing settings. DCCPS scientists participate on a federal interagency workgroup (comprising the US Department of Housing and Urban

Development [HUD], CDC, NCI, and the Environmental Protection Agency [EPA]), which has convened periodically since 2013 to share current research, disseminate the evidence base, discuss local-level implementation, and encourage the use of NCI smoking cessation resources as part of any implementation efforts. In support of HUD's 2015 proposed rule to ban smoking in public housing, this workgroup continues to identify opportunities for collaboration between HHS and other federal agencies while the proposed rule is under consideration and as part of an overall implementation strategy once the rule is finalized.

## Tracking tobacco use, cessation practices, and tobacco control policies

The [Tobacco Use Supplement to the Current Population Survey \(TUS-CPS\)](#) is an NCI-sponsored survey of tobacco use and policy information that has been administered triennially as part of the US Census Bureau's CPS since 1992 and is available for public use. Between 2001 and 2007, NCI co-sponsored the survey with CDC. The 2010-11 data are the most recent public-use data available for analysis. The 2014-15 TUS-CPS, cosponsored with FDA, has been fielded, and data will be available in 2016. Because of its large, nationally representative sample, the TUS-CPS is a key source of national-level and state-level data on smoking, other tobacco use, policy, and intervention information in US households. A unique feature is the ability to link other social and economic Census Bureau and Bureau of Labor Statistics data and other sponsor-supported supplement data to the TUS-CPS data. Many of these data can also be linked to cancer and other cause-specific mortality data through the National Longitudinal Mortality Study. NCI and CDC staff, as well as the general extramural community, have conducted and continue to conduct research using this data resource.

# A HEALTHIER GENERATION

A renewed emphasis on improving health behaviors has been spearheaded by the Let’s Move Initiative, The President’s Challenge, the HHS Small Step Initiative, and, most recently, the Surgeon General’s Call to Action on Walking and Walkability, which DCCPS staff helped to draft and promote. In addition to these initiatives, DCCPS supports and provides a wide range of research to help inform ongoing public health efforts across the US and the world.

## Setting national objectives for promoting health and preventing disease

The Healthy People 2020 initiative provides science-based, 10-year national objectives for promoting health and preventing disease. DCCPS co-leads the Healthy People 2020 Cancer Chapter Workgroup with CDC. Since 1979, Healthy People has set and monitored national health objectives to meet a broad range of health needs, encourage collaborations across sectors, guide individuals toward making informed health decisions, and measure the impact of our prevention activity. With oversight from the NIH Office of Disease Prevention, the Cancer Workgroup has representation from the DCCPS Office of the Director, the NIH Office of Minority Health, the NIH Office of Research on Women’s Health, the National Center for Health Statistics (NCHS), AHRQ, the American Cancer Society, and C-Change, and works toward setting new objectives and targets for the next decade while measuring progress from the past decade. DCCPS staff have also worked to develop and evaluate objectives related to nutrition and physical activity.

## Making healthier dietary choices

The Dietary Guidelines for Americans (DGAs) are jointly issued and updated every 5 years by the Departments of Agriculture (USDA) and HHS. They form the basis for federal nutrition policy and provide authoritative dietary advice to promote health and reduce risk for major chronic diseases. To be effective, these guidelines require an extensive evidence base to ensure the most accurate and up-to-date information is included. DCCPS-supported researchers developed methodologies for estimating usual dietary intake distributions and identifying sources of key dietary constituents, including added sugars, and the resulting data have proven to be critical for the recent and upcoming versions of the guidelines. In addition, DCCPS worked with researchers at USDA to develop the [Healthy Eating Index](#) (HEI), a measure of dietary quality, which assesses conformance to the DGAs and has been used in hundreds of studies, including the evaluation of USDA’s multi-billion dollar food assistance programs.

The DCCPS research portfolio includes studies aimed at understanding behaviors and barriers, along with effective interventions to increase the availability of healthy food in the home, at schools, and in childcare settings. In addition, DCCPS has supported research on school nutrition policy, including changes in food laws across states and in elementary schools, and the impact these changes have on behaviors and reducing obesity.

The division has supported the 2007 [Food Attitude and Behaviors](#) (FAB) Survey and, since 2003, the School Nutrition Policy Classification System, which provides an empirical and regularly updated scoring system used by researchers, policy makers, and the public to evaluate and track changes in state laws related to school nutrition.

## Reversing the childhood obesity trend

Obesity is a well-established risk factor for chronic diseases, including heart disease, diabetes, and cancer. Between 1980 and 2004, the prevalence of obesity more than tripled among children, and today nearly one-third of all children in the US are overweight or obese. Recognizing the need to focus attention on reversing that alarming trend, HHS, the Surgeon General, and the White House Task Force on Childhood Obesity have focused renewed attention on the childhood obesity epidemic and the need to implement coordinated obesity prevention efforts. Aiding in this national effort, DCCPS participates in the [National Collaborative on Childhood Obesity Research](#) (NCCOR), a partnership of CDC, NIH, the USDA, and the Robert Wood Johnson Foundation. NCI has the lead role for NIH in NCCOR, which seeks to improve the efficiency, effectiveness, and application of childhood obesity research by developing common measures and methods, evaluating and identifying effective interventions, and assessing policy and environmental changes related to childhood obesity.

## Increasing physical activity

The HHS Physical Activity Guidelines (2008) were the first-ever such guidelines released for Americans. They describe the types and amounts of physical activity that offer substantial health benefits. DCCPS-funded investigators served on the committee, and a DCCPS staff member coordinated the process for HHS. DCCPS staff members were also on the subcommittee of the President's Council on Fitness, Sports and Nutrition that developed the Physical Activity Guidelines Midcourse Report: Strategies to Increase Physical Activity among Youth. DCCPS stimulated novel research in the evaluation of physical activity through the Improving Diet and Physical Activity Assessment program

announcements. DCCPS also funds a number of research initiatives that focus on enhancing the research base for physical activity and its effects on cancer, including mechanisms of physical activity behavior change, physical activity in women with infants, the protective effects of physical activity on adolescent smoking prevention, and active video games and sustainable physical activity. In addition, DCCPS is leading efforts to examine the role of physical activity in modulating cancer recurrence and survival outcomes through its mechanisms, initiatives, and support of a clinical trial to test the hypothesis that reducing obesity will increase survival time.

The DCCPS-supported [Transdisciplinary Research on Energetics and Cancer](#) (TREC) initiative fostered transdisciplinary research to elucidate underlying biological mechanisms of obesity and cancer, explore new biomarkers, develop potential for genetics/genomics to advance individualized treatment, expand translational research focus, add particular emphasis on cancer survivors, and strengthen use and integration of theoretical constructs.

In addition, DCCPS has supported a range of research and tool development on school physical education policy, including the Physical Education-related Policy Classification System (PERSPCS). The PERSPCS provides a platform for the evaluation of physical education laws across states and the associations between state physical education staffing and curriculum standards with reported school practices. The PERSPCS and the School Nutrition Policy Classification System form the [Classification of Laws Associated with School Students](#) (C.L.A.S.S.). Consisting of two databases, C.L.A.S.S. is a resource for researchers, policy makers, and school officials interested in improving school nutrition and physical education as a means to

address childhood obesity. The C.L.A.S.S. data have been used in numerous publications and is a listed resource in the 2013 IOM Report Evaluating Obesity Prevention Efforts: A Plan for Measuring Progress (2013).

DCCPS also created the [Standardized Questionnaires of Walking and Bicycling Database](#) website, a database containing questionnaire items and a list of validation studies for standardized items concerning walking and

biking from multiple national and international physical activity questionnaires. The purpose of this database is to provide easy access to a large number of items that assess duration and frequency of walking and bicycling in the non-disabled adult population. This research provides federal agencies the evidence they need to implement programs to improve the healthy choices of the youngest generation.



## BREAST CANCER AND THE ENVIRONMENT

The US public has long been concerned about whether chemical and physical exposures increase the risk of breast cancer. This concern has led to proactive research initiatives led by NCI and the National Institute of Environmental Health Sciences (NIEHS) and several public laws that directed NCI and NIEHS research on this topic.

### Breast Cancer and Environmental Research Act of 2008

In 2008, Congress passed Public Law (PL) 110-354, the Breast Cancer and Environmental Research Act. PL 110-354 required the Secretary of the US Department of Health and Human Services (HHS) to establish an [Interagency Breast Cancer and Environmental Research Coordinating Committee](#) (IBCERCC). It also authorized funding for research activities aimed at determining the genomic and environmental etiology of breast cancer. NCI shared responsibility with lead agency NIEHS in implementing the act by managing the IBCERCC. This committee's primary objectives were to review federal research activities on environmental factors that may be related to the etiology of breast cancer, summarize advances in understanding the environmental etiology of breast cancer, and make recommendations to the HHS Secretary regarding research gaps and needs. Published in February 2013, the [IBCERCC report](#) contained seven recommendations: 1) prioritize prevention, 2) transform how research is conducted, 3) intensify the study of chemical and physical factors, 4) plan strategically across federal agencies, 5) engage public stakeholders, 6) train transdisciplinary researchers, and 7) translate and communicate science to society.

### Breast Cancer and the Environment Research Program

To address how environmental exposures and personal susceptibility factors influence breast cancer risk, NIEHS and NCI co-funded the [Breast Cancer and the Environment Research Program](#) (BCERP) in 2003. BCERP was renewed for a third phase in October 2015, with similar overarching objectives as the previous two phases and a scientific agenda that is responsive to the IBCERCC recommendations. BCERP emphasizes a transdisciplinary approach and timely dissemination of scientific findings facilitated by community partnerships for the prevention of breast cancer.

BCERP aims to study environmental exposures that may predispose a woman to breast cancer throughout her life, with a focus on specific periods of time, referred to as “windows of susceptibility,” when the developing breast may be more vulnerable to environmental exposures. Initially, BCERP addressed multiple factors that may influence pubertal onset and long-term risk of breast cancer, with laboratory studies aimed at understanding biological mechanisms in rodents and tissue culture models, and with population studies focused on pubertal development in young girls. The program has since evolved to include other critical breast developmental periods, from in utero to postmenopause as well as intermediary markers of breast cancer risk (e.g., breast density).

### Public Law 103-43 to investigate potential environmental risks for breast cancer through the Long Island Breast Cancer Study Project

Prior to initiating BCERP, NCI, in collaboration with NIEHS, funded and coordinated the [Long Island Breast Cancer Study Project](#) (LIBCSP) in response to Public Law 103-

43. LIBCSP, which began in 1993, was a multi-study effort to investigate whether environmental factors were responsible for breast cancer in selected counties in New York and Connecticut. Collectively, LIBCSP consisted of more than 10 studies and the development of a research tool, the [Geographic Information System for Breast Cancer Studies on Long Island](#) (LI GIS), which was archived in 2014. The project included human population studies, the establishment of a family breast and ovarian cancer registry, and laboratory research on mechanisms of action and susceptibility in development of breast cancer. The studies did not identify any environmental factors that could be responsible for the elevated incidence of breast cancer on Long Island.

### Northeast and Mid-Atlantic Breast Cancer Study

In response to a request of the 1992 Senate Appropriations Committee, DCCPS assumed lead responsibility at NIH, and was joined by NIEHS, in funding research on factors that may have contributed to high breast cancer mortality rates in the northeastern and mid-Atlantic regions of the US. The six collaborating projects of the [Northeast and Mid-Atlantic Breast Cancer Study](#) found no association between breast cancer risk and blood levels of organochlorine compounds. Data from the studies were analyzed separately and in combination.

## PRACTICAL DATA AND EVIDENCE FOR POLICY MAKERS

DCCPS develops multiple tools to provide the evidence that policy makers and public health officials need to develop thoughtful and comprehensive public health programs. The data and evidence available cover a wide range of topics, including quality of cancer care, the economic burden of cancer, geographic information systems, statistical methods, communication science, tobacco control, and the translation of research into practice.

### Implementation Science

The DCCPS Implementation Science (IS) Team supports the evidence-based implementation of policy and practice by advancing the science of implementation itself. In addition to supporting the generation and execution of dissemination and implementation research studies, the IS team develops and maintains several resources to support evidence-based practice implementation, including Web-based data and successfully tested research models through [Cancer Control P.L.A.N.E.T.](#) and [Research-tested Intervention Programs](#) (RTIPs). An online community of practice, [Research to Reality](#) (R2R), links researchers with public policy practitioners to facilitate the uptake of research-tested interventions. The team offers training programs to promote a scientific approach to implementation of research findings, guidelines, and policies. In addition, they provide consultation and assistance to other sections of DCCPS and to grant applicants.

### Health Information National Trends Survey

The [Health Information National Trends Survey](#) (HINTS) collects nationally representative data about the American public's need for, access to, and use of health- and cancer-related information. The Health Information Technology for

Economic and Consumer Health (HITECH) Act calls for the "meaningful use" of health information technology within medical practice. To help HHS define "meaningful use," DCCPS researchers have partnered with the Office of the National Coordinator for Health Information Technology to use HINTS items to serve as a policy-informing benchmark on the public's awareness of, and benefits from, this significant legislative activity.

### Surveillance, Epidemiology, and End Results Program

The National Cancer Act of 1971 mandated the collection, analysis, and dissemination of data useful in the prevention, diagnosis, and treatment of cancer, which led to the establishment of the [Surveillance, Epidemiology, and End Results](#) (SEER) Program in 1973. SEER is the authoritative source of information on cancer incidence and survival in the US, and currently collects and publishes cancer incidence and survival data from population-based cancer registries covering approximately 30 percent of the US population. It is also the key source for current estimates and future projections of cancer prevalence, the number of Americans who are currently—or will become—cancer survivors, information vital to state and federal planning and spending.

### Annual Report to the Nation on the Status of Cancer

Produced in collaboration with the American Cancer Society, CDC, and the North American Association of Central Cancer Registries, and relying on data from NCI's SEER Program, the [Annual Report to the Nation on the Status of Cancer](#) provides an update on cancer occurrence and trends in the US. Each report includes a Special

Features section, providing an in-depth look at particular cancer trends. Past reports have featured topics such as trends in liver cancer; breast cancer; prevalence of comorbidity among lung, colorectal, breast, or prostate cancer patients; HPV-associated cancers and HPV vaccination coverage level; cancers associated with excess weight and lack of sufficient physical activity; and tumors of the brain and other nervous system, to name a few examples.

### Cancer Trends Progress Report

Providing a summary of our nation's progress against cancer, the [Cancer Trends Progress Report](#) includes key measures of progress along the cancer control continuum, from prevention to end of life, and uses national trend data to illustrate where advances have been made. The content, design, and production of this report are the results of a collaboration of federal and state agency partners, consumer advocates, the American Cancer Society, and others.

### State Cancer Profiles website

Produced in collaboration with CDC, [State Cancer Profiles](#) is a comprehensive system of interactive maps and graphs that enable the investigation of cancer trends at national, state, and county levels. The goal of the site is to provide a system to characterize the cancer burden in a standardized manner, integrate surveillance into cancer control planning, characterize areas and demographic groups, and expose health disparities.

### Tobacco Control Monograph Series

Established in 1991, [the series](#) of 20 tobacco control monographs provides ongoing and timely information about emerging public health issues in smoking and tobacco use control. The series reduces the time between availability of information from research projects and the publication and wide dissemination of this information and enhances the rapidity with which NCI can use findings from research trials to reduce cancer morbidity and mortality.

### National Health and Nutrition Examination Survey

DCCPS funded the inclusion of accelerometer devices in the National Health and Nutrition Examination Survey (NHANES) 2003-2006 to obtain objective measures of physical activity. These data are the basis of more than 100 published articles, including six directly related to cancer risk of cancer survivors. For NHANES 2011-2014, DCCPS supported, with additional NIH funding, the inclusion of wrist-worn accelerometer devices and measures of muscle strength. The accelerometer devices will provide an objective measure of sleep quantity and quality, in addition to data on physical activity-related movement.



## INTERNATIONAL POLICY IMPACT

### International Agency for Research on Cancer

The World Health Organization's (WHO) International Agency for Research on Cancer (IARC) convenes expert panels to evaluate the world's scientific research on environmental agents to determine whether exposure to those agents causes cancer. Experts from NCI and DCCPS are frequently called upon to serve on these panels. The resulting reports are highly authoritative and used extensively worldwide to provide the scientific basis for public health action and for regulatory purposes. Working with other organizations, DCCPS and IARC also support workshops on topics of joint interest, such as guidelines for assessing evidence for gene-environment interactions.

### Framework Convention on Tobacco Control

The WHO Framework Convention on Tobacco Control (WHO FCTC) is the first treaty negotiated under the auspices of WHO. The FCTC was developed in response to the globalization of the tobacco epidemic and is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. DCCPS is funding a number of projects, including evaluating the effectiveness of tobacco control policies in high- versus low-income countries, and, through the support of a special journal issue, is working to stimulate the field of global tobacco research to inform future practice and the implementation of the FCTC. A DCCPS scientist is a member of two WHO committees that inform the FCTC: the Study Group on Tobacco Regulation and the Tobacco Laboratory Network.

### WHO Workshop on Research Priorities to Advance the FCTC Workshop: Research-to-Policy in Low- and Middle-Income Countries (LMICs)

NCI, along with the Society for Research on Nicotine and Tobacco (SRNT) and the Mayo Clinic, sponsored a full-day preconference meeting, held March 17, 2015, at the 16th World Conference on Tobacco or Health. NCI and SRNT provided support for a special issue of Nicotine and Tobacco Research in 2013 to identify critical research priorities in support of the WHO Framework Convention on Tobacco Control (FCTC), with a focus on LMICs. The goal of this workshop, [Research-to-Policy in Low- and Middle-Income Countries \(LMICs\)](#), was to present findings from the special issue and to explore how to build research capacity and foster communication and collaboration between researchers and public health practitioners in LMICs. Participants also took part in a process to identify a small number of research priorities that are both feasible and responsive to the needs of LMICs. NCI's priorities in global tobacco control research were presented with analyses of the DCCPS research portfolio and current grants and training programs.

### Smokeless Tobacco and Public Health: A Global Perspective

NCI and CDC issued [Smokeless Tobacco and Public Health: A Global Perspective](#), the first-ever report on the global use and impact of smokeless tobacco, which found that more than 300 million people in at least 70 countries use these products. The report was released at the National Conference on Smoking or Health in Mumbai, India, on December 15, 2014. Representatives from the government of India and WHO participated in the release and accompanying scientific symposium. Thirty-two leading

experts from around the world contributed to the report. In addition to detailing the serious and well-documented health effects of smokeless tobacco products, the report also examines the distinct challenges and policy solutions in reducing the burden of smokeless tobacco use. For example, a wide range of smokeless tobacco products with different characteristics are in use around the world, yet limited data are available detailing the contents of these products, how they are used, and their prevalence within different population groups. The report identifies key research gaps and makes recommendations for capacity building in research and surveillance of smokeless tobacco use, with the aim of reducing the burden of smokeless tobacco use worldwide.

### World Health Organization pregnancy guideline

Tobacco use and second-hand smoke (SHS) exposure during pregnancy have adverse health effects on women and infants. Potential increases in tobacco use and SHS exposure among pregnant women threaten to undermine improvements in maternal and child health outcomes

achieved in the past 50 years. Currently, most low- and middle-income countries lack up-to-date, evidence-based guidelines for identifying and managing tobacco use and exposure to SHS in pregnancy. Furthermore, many existing guidelines do not include all forms of tobacco use or measures to limit maternal SHS exposure. With support from NCI and CDC, the World Health Organization developed [WHO Recommendations for the Prevention and Management of Tobacco Use and Second-hand Smoke Exposure in Pregnancy](#) to help fill these gaps. The primary objective of these guidelines is to reduce tobacco use and SHS exposure in pregnant women by providing evidence-based recommendations to health care providers and other related service providers. (These recommendations are part of a larger project of the WHO Noncommunicable Diseases and Mental Health cluster, which aims to make recommendations regarding the management of substance abuse in pregnancy, covering tobacco, alcohol, and other psychoactive substances.) NCI and CDC provided both financial and technical expertise in support of the guideline, which was published in 2013.

## LOOKING AHEAD: THE POLICY HORIZON

### Environmental health and toxins

In 2010, the President's Cancer Panel reported findings and conclusions based on testimony from 45 experts from academia, government, industry, and the environmental and cancer advocacy communities, as well as from members of the public, related to environmental causes of cancer. The report called for information sharing and coordination across agencies. Among other findings, it determined that radiation exposure from medical sources is underappreciated. DCCPS maintains a steadfast commitment to support research on low-dose radiation and cancer as well as research focused on assessing and identifying risks that could affect an individual's chances of getting cancer. Additionally, DCCPS added a new section on environmental chemical carcinogens to our Cancer Trends Progress Report, including biomarker data on exposure trends in the general population to four known carcinogens: arsenic, benzene, cadmium, and nitrate.

### Combining cancer epidemiology and economics

Due to changes in cancer-related risk factors, improvements in diagnostic procedures and treatments, and the aging of the population in most developed countries, cancer accounts for a major and increasing proportion of national health care expenditures. At a 2010 international and interdisciplinary meeting in Rome, Italy, health economists, statisticians, and epidemiologists from multiple European countries, the US, and Canada 1) compared and discussed different methodologies developed in country-specific contexts, in terms of data availability, prevention and health care policies, and health care systems, and 2) improved the dialogue among fields of research, with the common aim to estimate present and

future costs of cancer. Measuring the burden of disease will continue to be of great interest to public health researchers and policy makers.

### Benefits of screening evolves with advances in treatment and screening technology

The recent intense debate surrounding the updated USPSTF recommendations on breast cancer are a reflection of a broader discussion about the net benefits of broad-based population screening for cancers in general. These debates focus on the effect of screening on not only those who will develop cancer but also those who will remain free of cancer. As technologies and treatments improve, the potential benefits and harms of screening for those who have cancer must be continually assessed against the harms to those who will never get it. This comparison must be considered in the context of the modern era of targeted cancer therapies, which focus only on those with cancer and promise more specific effects on cancer with less-toxic effects on the patient. DCCPS will continue to conduct and support the research that examines the role of various screening modalities in preventive health care.

### Value

Value is an important factor in providing cancer care, as cost of care can be a major burden on patients and families. The American Society of Clinical Oncology (ASCO) defines value in cancer care by looking at clinical benefit (efficacy), toxicity (safety), and cost (efficiency). The director of the Congressional Budget Office (CBO) has stated that comparative clinical effectiveness research, combined with changes in payment incentives, "offers a promising mechanism for reducing health care costs to a significant degree over the long term while maintaining or improving

the health of Americans.” America’s Health Insurance Plans, a trade association representing health insurance plans, has urged Congress to give CMS the authority to use comparative effectiveness and cost-effectiveness information in its coverage and reimbursement decisions. Costs are not always easy to define or measure. The total treatment costs may differ, sometimes dramatically, depending upon which perspective (e.g., patient, government payer, private insurer, society) is taken in the analysis and which costs are included. Much of the controversy surrounding whether costs should be included in comparative effectiveness research lies in the questions, “When, how, and by whom will the research results be used to make decisions?” The issue is most controversial if results that include costs are used to make insurance reimbursement, pricing, or coverage decisions. The inclusion of costs in research tends to be less controversial when the results are not directly linked to medical and health policy decision making. DCCPS will address these cost-of-care questions by continuing to fund comparative effectiveness research and through the division’s support of the Medical Expenditure Survey (MEPS), a set of large-scale surveys of families and individuals, their medical providers, and employers across the US. MEPS is the most complete source of data on the cost and use of health care and health insurance coverage.

### Patient-reported outcomes

Over the past couple of years, there has been rapidly increasing interest in capturing patient-reported outcomes and incorporating these measures into clinical care. The [SEER-Medicare Health Outcomes Survey](#) and the SEER-Consumer Assessment of Healthcare Providers and Systems linked databases enable research that delves into important issues of health-related quality of life and

patients’ experiences with care, respectively. Looking ahead, several DCCPS initiatives are well positioned to contribute to our understanding of cancer patients’ and survivors’ experiences when assessing quality of care, evaluating new drugs, and ensuring patients achieve the outcomes they value. The [Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events](#) (PRO-CTCAE), an electronic-based system for patients on cancer clinical trials to self-report symptomatic toxicities, was developed to complement and extend the Common Terminology Criteria for Adverse Events (CTCAE), NCI’s system for clinician grading of treatment-related adverse effects in cancer clinical trials. PRO-CTCAE is applicable in cancer clinical trials where a precise description of the symptomatic toxicities experienced by patients is needed to better understand treatment tolerability. We anticipate that in coming years, the PRO-CTCAE will be integrated into many or most NCI clinical trials and will eventually be used to characterize new treatments during the FDA approval process. The Patient Reported Outcomes Measurement Information System® (PROMIS®), which assesses patient-reported health status for physical, mental, and social well-being, has the potential to be used for quality measurement and reimbursement by practices, as well as CMS and other payers. PROMIS is also part of a larger effort called HealthMeasures, which provides automated use of PROMIS and three other measurement systems, promotes their uptake in the scientific and clinical communities, and transitions toward a sustainable resource that allows for maintenance of these measurement systems into the future.



## Health IT

Despite modern advances in health information technology (IT), the way in which evidence on cancer screening, early detection, and treatment is gathered and applied has not moved forward as rapidly as needed. Individuals and institutions working both in cancer research and treatment could take better advantage of existing resources and create new mechanisms for assessing and sharing information on the effectiveness and value of each individual treatment. DCCPS is engaging the broader community of scientists and practitioners to develop innovative Web-based tools and applications that leverage cancer-relevant data and build upon the behavioral and communication science evidence base to inform cancer prevention and control. The division's [PopSciGrid Community Health Portal](#) is one example of an evolving platform that demonstrates how health behavior, policy, and demographic data can be integrated, visualized, and communicated to help empower communities and support new avenues of research and policy for cancer prevention and control. As a proof of concept for cyber-enabled population health research, the portal is designed to encourage multidisciplinary collaboration, data harmonization, and development of new computational methods to rapidly analyze and identify longitudinal, multi-level patterns in health-related data. The ability to combine data across the diverse cancer registration systems in the US has also been a top priority for NCI, which led to the implementation of the coding system known as Collaborative Staging System version 2. An expert team developed an algorithm for computing stage across the various existing systems (SEER, AJCC, etc.), an important advancement for determining patient prognosis.

Given the accumulating evidence suggesting that connected health approaches could lead the way to better health outcomes, the President's Cancer Panel (PCP) selected this topic for its 2016 report, *The Connected Cancer Patient: Vision for the Future and Recommendations for Action*. The chief of the Health Communication and Informatics Research Branch of DCCPS, Bradford Hesse, PhD, served as co-chair of the PCP workshops that were convened to explore and recommend concrete actions that could accelerate the development of a patient-centered approach to cancer prevention, treatment, and survivorship in order to maximize the potential of connected health technologies. Outcomes of these workshops, which will be highlighted in the report, will be critical in guiding health information IT policy and practice moving forward.

## Cancer survival statistics

DCCPS supports research and participates in international meetings to improve the statistical methods used to determine survival rates. Current research is focused on developing more accurate models that consider a variety of factors that may influence survival, such as co-morbidities. The research will provide more reliable and efficient statistical methods that can facilitate scientists' understanding of cancer, as well as help inform public health research and priorities.

## Genomics and health policy

DCCPS increasingly funds research in public health genomics, a new multidisciplinary field concerned with the effective and responsible use of genome-based technologies for the benefit of population health. This research helps inform policies and activities of various government groups such as FDA, CMS, AHRQ, and

CDC. It provides data for independent evidence review panels, such as the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group, an independent multidisciplinary committee sponsored by CDC, which makes recommendations on the use of genomic applications in medicine and public health. EGAPP has already addressed several topics related to cancer and, given that more than two-thirds of new genomic applications used in clinical practice are cancer related, the panel is likely to address more in the near future. In addition, a DCCPS senior scientist participates in the Institute of Medicine (IOM) Roundtable on Genomics-Based Research for Health. In light of DCCPS' work in genomics, the division is well suited to provide advice on the medical, ethical, legal, and social implications of genomic technologies.

### Health equity

Achieving health equity is the goal of Healthy People 2020 and has been a major thrust of all the programs within DCCPS since its inception. The division has a very broad-based perspective in funding and conducting research on adverse health conditions that exist among specific population groups to inform prevention and intervention programs. These population groups may be characterized by gender, age, race, ethnicity, education, income, social class, disability, geographic location, or sexual orientation. Looking to the future, we hope to increase our investment in developing interventions for underserved and disadvantaged populations who face the excess burden of those social determinants of health that are mostly responsible for health inequities. Given that these social factors are avoidable and can be eliminated, they can be addressed through a complement of scientific activities that will reduce the burden of these factors, inform policy, and improve overall health.

## PARTNERS

Agency for Healthcare Research and Quality

American Cancer Society

Cancer Information Service, NCI

Centers for Disease Control and Prevention

Centers for Medicare and Medicaid Services

Department of Veterans Affairs

Food and Drug Administration

Institute of Medicine

National Heart Lung and Blood Institute

National Institute for Environmental Health Sciences

National Institute on Aging

National Institute on Alcohol Abuse and Alcoholism

National Institute on Drug Abuse

NIH Office of Behavioral and Social Sciences Research

North American Association of Central Cancer Registries

Public Health Institute

Robert Wood Johnson Foundation

US Census Bureau

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