Journal of Cancer Policy 20 (2019) 100187

Contents lists available at ScienceDirect

Journal of Cancer Policy

journal homepage: www.elsevier.com/locate/jcpo

The expanding role of cancer control & the U.S. National Cancer Institute: Policy implications for global cancer care

Arnold D. Kaluzny[a], Donna M. O'Brien[b,*]

[a] UNC Gillings School of Global Public Health, Senior Research Fellow, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, Chapel Hill, NC, 27599, United States

[b] Strategic Visions in Healthcare, LLC, 250 Park Ave, Suite 700, New York, NY, 10177, United States

ARTICLE INFO

Keywords:
Cancer control
Cancer prevention
Cancer care delivery research
1971 National Cancer Act
2017 World Health Assembly Resolution

ABSTRACT

Throughout the global community, cancer control has been recognized as an important component of cancer care for populations, patients and their families. The United States had a pioneering effort, created as a result of the 1971 National Cancer Act (The War on Cancer), when it mandated that the National Cancer Institute (NCI), in collaboration with other federal, state, and local public health agencies and private industry, conduct cancer control activities that included detection, prevention and treatment of cancer. The paper identifies three signal events in the expanding role of cancer control and their policy implications to improve clinical practice patterns in a community setting: the emergence of cancer control as science; the recognition of the interdependency of cancer control and cancer prevention; and the inclusion of cancer care delivery research and its contribution to the expanding role of cancer control. These events provide insight and guidance to others as they work to implement the 2017 World Health Assembly recommendations to improve the evidence base of cancer prevention and control on a global scale.

1. Introduction

Throughout the global healthcare community, cancer control is being increasingly recognized as an important component for improving health outcomes. With the progress in improving health outcomes in many diseases, cancer is now the leading cause of death in Europe [1] and in the US, it is projected to become the leading cause of death by 2020 [2]. Similar trends are predicted in Low-and-Middle Income Countries (LMICs) which already account for 70% of cancer deaths worldwide [3].

In 2017, the World Health Organization (WHO) World Health Assembly noted that "risk reduction has the potential to prevent around half of all cancers" and urged the promotion of cancer research "to improve the evidence base for cancer prevention and control" [4,5] – a concept pioneered in the United States with the 1971 passage of the National Cancer Act, often described as the War on Cancer [6]. This paper traces the expanding role of cancer control within the U.S. National Cancer Institute and its focus on improving clinical practice patterns within a community setting. A role that places cancer control at the interface between the changing science and delivery system.

Three signal events at the NCI are examined in the evolution of cancer control and their relevance to the implementation of evidence-based cancer control and prevention as recommended by the 2017 World Health Assembly: the emergence of cancer control as science, the recognition of the interdependency of cancer control and cancer prevention in the care continuum; and the inclusion and contribution of cancer care delivery research to improving clinical practice patterns. Understanding these events, the processes involved and the rationale for decisions made, may prove helpful as others work to improve cancer control and prevention on a global scale.

The 1971 National Cancer Act, a visionary and comprehensive legislative achievement often described as the "war on cancer," created the National Cancer Program. The legislation strengthened the National Cancer Institute (NCI), initially established in 1937 as one of 27 institutes within the National Institutes of Health (NIH), and to elevate its importance, designated the NCI director and members of the newly formed National Cancer Advisory Board (NCAB) and President's Cancer Panel as presidential appointments. The legislation authorized the director to provide for the establishment of fifteen new centers for clinical research – the beginning of the NCI-designated Cancer Centers program. It also provided NCI with significant expansion of funding and the organizational and financial flexibility to adapt its structure and

* Corresponding author.
E-mail addresses: arnold_kaluzny@unc.edu (A.D. Kaluzny), dobrien@svhealth.com (D.M. O'Brien).

https://doi.org/10.1016/j.jcpo.2019.100187
Received 29 November 2018; Received in revised form 4 February 2019; Accepted 15 March 2019
Available online 19 March 2019
2213-5383/

expand its focus, including the ability to create additional new cancer centers, and training programs; expand research facilities; establish an international cancer research data bank; and disseminate the results of cancer research.

Tucked away in the 1971 legislation was the requirement that the NCI director work in collaboration with other federal, state, and local public health agencies and private industry, to conduct cancer control activities with supplemental funding "earmarked." [7]. The inclusion of cancer control research and its focus on prevention, early detection, and treatment was a public recognition that NCI needed to address the full continuum of cancer care and that it needed to conduct its research with relevant public and private healthcare delivery system organizations and providers.

2. The emergence of cancer control as science

While cancer control was part of the 1971 legislation, its definition was ambiguous and for the next decade, it involved a disparate and diffuse set of activities and programmatic initiatives scattered throughout NCI, including at NCI-designated Cancer Centers. Cancer control became a catch-all for various demonstration programs, which were generally absent of empirical research or rigorous evaluation [8].

Cancer control was administratively located in the Division of Resources, Centers and Community Activities (DRCCA) and in 1981 underwent a review examining its programs for evidence of lowering cancer risk and/or contributing to social benefit. Community programs that had access to clinical providers within the community and the general population that failed to provide evidence of improving clinical practice patterns were terminated, including the Community Hospital Oncology Program (CHOP). A community program based on the premise that locally generated practice guidelines would improve the quality of cancer care. An evaluation of CHOP, that included patterns of care, demonstrated no change in practice with the conclusion that physician-generated guidelines represented the lowest common denominator of care [9].

During this time, advances in clinical science and an emphasis on clinical trials at the NCI were making mechanisms to support patient accrual to trials a high priority [10]. Access to the large population of patients in the community setting was needed for its research initiatives, however the NCI had limited involvement with, or access to community hospitals and providers.

In 1981, the Board of Scientific Counselors (BSC) approved and funded a new program – the Community Clinical Oncology Program (CCOP), to engage private practice community oncologists as participants in the NCI clinical trials program [11]. The inclusion of busy private practice oncologists as part of the NCI scientific enterprise providing access to patients in the community was unprecedented, and many thought, ill-advised [12]. Sixty-two providers participated in the first phase of the CCOP program with each provider receiving direct funding from NCI with a requirement to enroll a minimum of 50 patients each year on NCI-approved research protocols. The CCOP accrual performance exceeded expectations [13].

The DCCRA was renamed the Division of Cancer Control and Prevention (DCPC) in 1983. The name change coupled with the implementation and supporting evidence that community oncologists were able to contribute to the NCI research enterprise indicated that henceforward, the role of the division was to advance the evidence base of cancer control and prevention. A role that aligned with the emerging NCI priorities for extending its reach into the community and its belief that physicians in communities could enroll patients in high priority clinical trials and contribute to NCI evidenced-based cancer control research projects.

In 1984 the *Journal of the National Cancer Institute (JNCI)* published a seminal paper [14] that defined cancer control as a science involving the "reduction of cancer incidence, morbidity and mortality through the orderly sequence from research interventions and their impact in a defined population to the broad, systematic applications of the research results." The paper outlined five phases of cancer prevention and control research moving from hypothesis, methods development, controlled intervention trials, defined population studies, and demonstration and implementation studies. This new definition was important for cancer control efforts generally and it had a significant impact on the NCI's focus with the emphasis shifting from demonstration projects to empirically-based research targeting and/or contributing to lowering cancer risk. It was also aligned with NCI's underlying premise that NCI-approved clinical protocols represented the highest quality of care, and that participation in clinical trials, with baseline quality criteria for selection of providers, would also serve to disseminate best practices for clinical care within the community. What followed was a series of actions and programs that provided the infrastructure to support and improve the evidence base for cancer control and prevention focused on improving clinical practice pattern to improve cancer care within the community.

Over the next decade, expertise was expanded in DCPC with the recruitment of behavioral scientists, economists, biostatisticians, and health services researchers, creating the ability to conduct empirical research on health outcomes, practice patterns, and measurement using the national Surveillance, Epidemiology and End Results (SEER) database. This database collects cancer incidence data from population-based cancer registries that cover approximately 34 percent of the U.S. population [15].

With this expertise and data systems in place, cancer control efforts were positioned for greater collaboration with external agencies on broader public health issues to reduce cancer incidence. The data also became available to extramural cancer control researchers. An immediate product of this expanded capacity was the publication of the NCI report *Cancer Control Objectives for the Nation 1985–2000* [16]. It targeted tobacco use, dietary factors, occupational hazard, and cancer causes and called for collaboration between NCI, state, local and federal governments, corporate and union leaders, the healthcare industry, private organizations, schools, and the media to reduce cancer death by as much as fifty percent. The estimates were largely dependent on how fast cigarette smoking would decrease. Unfortunately, the effort to implement the report was weak and was insufficient to have a major impact on smoking rates, but the path to an evidence-based approach to cancer control and the need to collaborate with other agencies and healthcare providers was established.

With a new definition of cancer control, clear targets, and through the experience of the CCOP, confirmation of the important role of the healthcare delivery system in supporting accrual to clinical trials, the CCOP was expanded. In addition to treatment trials, it would include cancer prevention and control trials, and it would work to address the racial disparities in cancer care and access to clinical trials with the implementation of the Minority-based Community Clinical Oncology Program (MB−CCOP). The DCPC was now actively involved with community hospitals and their affiliated physicians. An external evaluation documented the importance of organizational factors involved but like most evaluations, raised more questions than it addressed [17]. The evaluation did not assess cost or provide an in-depth assessment of factors associated with minority accrual. But there was no turning back, and these issues would continue to be evaluated expanding the evidence base for cancer control and prevention.

Other empirically based programs quickly followed including the *Prostate, Lung, Colorectal and Ovarian (PLCO) Screening Trial* (PLCO) and the Breast Cancer Surveillance Consortium (BCSC). The PLCO was a prospective randomized design trial that ran from 1993 to 2001 with 10 clinical practice screening sites, a central laboratory, a coordinating center, and a biorepository. It assessed whether annual screening for prostate, colorectal, lung and ovarian cancer reduced the respective cancer specific mortality rates. The project was controversial at the time, yet as the results began to appear, it provided the evidence base for present day screening practices. The trial showed screening had no

significant effect on prostate, lung, or ovarian mortality. For colorectal cancer screening, there was a 21 percent reduction in incidence and a 26 percent reduction in mortality [18].

The BCSC was launched in 1994 to address the need to design better screening interventions. This research collaborative network of seven mammography registries with linkages to tumor and/or pathology registries supported by a statistical coordinating center would enhance understanding of breast cancer screening practices in the U.S. and their relation to stage of diagnosis, survival, or breast cancer mortality [19]. The program provided the empirical base for the more comprehensive Population-Based Research to Optimize the Screening Process (PROSPR) program with its extensive network of various types of organizational settings that conduct cervical, colorectal and lung cancer screening, recruitment, screening, diagnosis, referral and treatment within a community setting.

3. The inter-dependency of cancer control and cancer prevention

Cancer control spans the continuum of care from prevention and diagnosis through treatment, survivorship and end of life care. In 1985 a restructuring was underway at the NCI with many advisory committees appointed to review the NCI's major intramural and extramural functions. For cancer control two committees were appointed; one for cancer control and one for cancer prevention. Based on the recommendations of the committee, DCPC was separated into two divisions – the Division of Cancer Control and Population Sciences (DCCPS) and the Division of Cancer Prevention (DCP) [20].

3.1. The Division of Cancer Control and Population Sciences (DCCPS)

The division name change was a recognition of the important role of the social and behavioral sciences and their contribution to understanding the complexity of and changes in the delivery system. Building on the past DCPC efforts, the DCCPS compiled a set of data resources that could be used to study cancer care delivery and outcomes [21]. Data resources included SEER, which was expanded to include a Medicare linkage for a collaboration with the Centers for Medicare and Medicaid; the Congressionally mandated SEER Patterns of Care Program; the Cancer Control Supplement to the National Health Interview Survey, which has enabled study of cancer screening utilization (as well as other cancer control behaviors) in the United States dating back to the late 1980s; and the SEER-CAHPS (Consumer Assessment of Healthcare Provider and Systems) linkage that provides data for studying the care experiences of Medicare enrollees with and without cancer; and the SEER-MHOS (Medicare Health Outcomes Survey) that uniquely provides population level pre and post-diagnosis data on quality of life. These databases advanced cancer care research by providing access for the division and extramural researchers to directly monitor ongoing cancer trends and target social behavioral program interventions.

To better understand the operations of the changing delivery system the division launched several programs that required collaboration with various components of the changing healthcare system. The Cancer Research Network Program (CRN) provided funding for cancer control researchers affiliated with a number of nonprofit integrated healthcare delivery systems to study prevention and screening; epidemiology of prognosis and outcomes; healthcare quality and cost; and communications and dissemination [22]. The participating healthcare systems provided coverage to a significant portion of the U.S. population and pursued research studies in four areas: prevention and screening; epidemiology of prognosis and outcomes; healthcare quality and cost; and communications and dissemination. A critical challenge was the development of a uniform set of quality and cost metrics. Data, typically considered propriety, was essential to meeting CRN research objectives. This level of collaboration between NCI and the healthcare delivery organizations was unprecedented and required the development of trust in the sharing of proprietary analyses in order to support the larger mission of the project. The CRN program became a model for a trans-NIH initiative, the NIH Health Care Systems Research Collaboratory, and its work was integrated into that program.

Evidence-based cancer control and prevention programs also require an understanding of the characteristics and beliefs of cancer patients and providers. The newly formed DCCPS launched the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS) to examine how characteristics and beliefs of cancer patients and providers influenced treatment and outcomes and evaluated the effects of specific therapy on patient survival and quality of life and satisfaction to provide important supplemental data for randomized trials. Over 10,000 lung and colon cancer patients participated in this program which collected data on medical treatments, patient reported outcomes, and quality of follow up care and health outcomes for long term survivors providing valuable information for clinical practice [23].

Throughout the period, DCCPS would reorganize from time to time to align with the changing science and delivery system. In 2014 it organized into four program research areas: Healthcare Delivery; Surveillance; Epidemiology and Genomics; and Behavioral Research. These areas build on several prior initiatives dealing directly with various components of the healthcare delivery system, including the earlier described PROSPR screening program that built on the BCSC network of providers to study cancer recruitment, screening. diagnosis, referral and treatment for cervical, colorectal and lung cancer in a community setting [24]. In 2017 the division launched the Cancer Center Cessation Initiative with the long-term goal of helping the NCI-designated cancer centers build and implement sustainable tobacco cessation treatment programs [25].

3.2. The Division of Cancer prevention (DCP)

The designation of a separate DCP provided the opportunity to focus on advancing the science of prevention. The newly formed division would include the PLCO and CCOP/MBCCOP, as well as research groups: Biometry, Nutrition, Early Detection and Research Network (EDRN), and the Chemo preventive Agent Development Research Group (CADRG). These research groups had been part of the DCPC and were responsible for significant studies in practice changes for cancer prevention and public health. The CCOP became a research platform that supported 33% of the accrual to NCI trials including the Breast Cancer Prevention Trial the first ever definitive demonstration of the efficacy of a chemoprevention agent in a major cancer [26, 27]. With the role of evidence-based cancer prevention well established, subsequent trials followed for prostate, bowel, and lung.

Missing in the newly constituted DCP however, was the expertise in health services research, economics, risk assessment, and operations research; disciplines with linkages to the changing healthcare system that were needed to effectively translate advances in the science of prevention to clinical and organizational providers. Prevention research is part of the continuum of care and required an interdisciplinary approach that would bring together a range of scientific disciplines and collaboration with the clinical community.

Committed to the objective of maintaining a link to the delivery system, the division re-organized and implemented a matrix structure building on the seven existing DCP functional units with new organ site research groups for lung and upper digestive cancer, breast and gynecologic cancer and prostate and urologic cancer. These organ site groups would design, develop, implement and monitor research efforts for the specific organ site and provide an organizational link with the relevant clinical community. Project teams were developing state-of-the-art care concepts that would build on the expertise of the functional units and the organ site research groups. The concept and basic structure were sound, but the division lacked the ability to support the teams. The organ site and cancer prevention groups remain, but teams are formed on an ad-hoc basis [28].

3.3. The challenges of separating cancer prevention and control

The separation of cancer prevention and cancer control created new opportunities and organizational challenges. It permitted each division to focus on advancing the underlying science with the infrastructure to support its various programs. For DCP, this included identifying biomarkers, chemo preventive agents, and advancing the science of nutrition. For DCCPS, this included expanding knowledge on the changing structure and economics of cancer care delivery, surveillance, epidemiology, behavioral science, and cancer survivorship.

The separation, however limited the potential of both divisions. DCP, as an example, did not have the ability to effectively translate advances such as nutritional and chemoprevention interventions to targeted populations or easy access to the relevant delivery systems. DCCPS – while having an expanding knowledge base of the operation and economics of healthcare delivery, surveillance, epidemiology, behavioral science, and access to the major components of the healthcare system – lacked the ready access to facilitate and disseminate evidence-based preventive interventions to the population at risk. Finding ways for the two divisions to collaborate was increasingly important.

Cancer control involves the full continuum of care, yet program components most often operate as discrete rather than integrated parts. The ongoing advances in science and the changes in the healthcare system further challenge the ability of cancer control to translate advances to patients, their families and the population at risk. New approaches to facilitate collaboration were required.

4. The emergence of cancer care delivery research

With 85 percent of cancer patients cared for in the community setting [29] and new opportunities presented with the sequencing of the Human Genome in 2005, a challenge facing the NCI was to assure that community hospitals and their affiliated physicians were better prepared to realize the potential of the advancing science and contribute to it. This coupled with the expanding disparities in various segments of the population led to the implementation of the NCI Community Centers Program (NCCCP). A pilot project involving 30 community hospitals and their affiliated physicians [30] to explore the best methods to enhance access to care with a focus on reducing cancer disparities, improving the quality of care, and expanding research particularly the capacity to support precision medicine. To address the range of community settings and the need to reach underserved populations, selection criteria included cohorts that would reflect urban, suburban, and rural locations, and a requirement that the organizations have a history and demonstrated access to specific underserved populations designated for tracking by U.S. Office of Management and Budget for race and ethnicity [31]. Tracking of data for rural populations, patients over 65, and insurance status was also included. This program design facilitated the ability to make addressing disparities a requirement that cut across all components of the program and created the foundation for evaluation of the extent to which program interventions influenced different underserved populations [32]. A unique feature of this program was its design as a public-private partnership that required at least a 1:1 co- investment by the hospital, and the active participation of executive management along with physician leadership and relevant clinical staff. The required co-investment and the inclusion of executive management created a sense of ownership in the program contributing to its success. An external evaluation tracked performance in quality, access and research measures, and in addition monitored the actual cost of the program including the matching of funds, management participation and the organizational factors that facilitated or inhibited program objectives. The program met or exceeded its objectives: concordance with evidence-based cancer quality measures improved, particularly for underserved populations; accrual to clinical trials increased for underserved populations; and the co-investment exceeded the requirement with 3.2 dollars invested for every NCI dollar. Co-investment was an important indicator and provided a sense of ownership contributing to program sustainability independent of NCI funding [32,33].

One of the by-products of the NCCCP was the identification of various operational challenges and research opportunities in the provision of care and expansion of research within a community setting that would benefit from further research. In one example the NCI worked with NCCCP hospitals to develop a clinical trial screening log that would promote broader screening of patients to reach underserved populations and track barriers to accrual. This initiative identified patient and provider level barriers for further study including variation by subpopulations [34].

To provide these research opportunities and building on the experience of the NCCCP and the well-established CCOP network as an accrual mechanism, the two programs were merged in 2014 to create the NCI Community Oncology Research Program (NCORP). With the launch of the NCORP, researchers from the DCCPS, joined with colleagues from the DCP and defined and documented the importance of understanding the structure and processes of the health system and its role in cancer care and research. NCCCP had demonstrated the value of a research network of hospitals, health systems and their affiliated physicians for identifying quality improvement opportunities through sharing information and strategies to improve cancer care in the community setting.

Based on this experience, the collaborating team from DCP and DCCPS adapted the well-accepted definition of health services research [35] to cancer care and research as *"the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and healthcare provider and patient behaviors affect access to cancer care, the quality and cost of cancer care, and ultimately the health and well-being of cancer patients and survivors*" [36]. This paper provided the scientific rationale for the inclusion of cancer care delivery research as an integral component of the developing NCORP research agenda. An agenda that required all participating provider and research organizations to engage in cancer care delivery research. This forged a formal programmatic working relationship between DCP and DCCPS. A relationship that expands the role and function of cancer control and provides the opportunity to better address the challenges of a changing healthcare system.

5. Conclusion

What lessons can be learned from the evolution of cancer control that may be relevant to others as they embark on the journey to "improve the evidence base" of cancer prevention and control. As Thomas Friedman the Pulitzer Prize winning journalist and author declared "the world is flat," [37] that is, various economic, political and social forces are reducing the traditional geographic boundaries and are opening a flow of concepts and social and economic opportunities across the world.

Four cross cutting themes on lessons learned for cancer control are worthy of note:

The role of infrastructure to support cancer control research – Improving the evidence base for cancer prevention and control requires an infrastructure to support the effort. An infrastructure that provides access to appropriate disciplines including behavioral and social sciences, operations and health services research and the ability to collaborate with clinical personnel in the design and evaluation of cancer prevention and control programs. As illustrated in the U.S. experience, investment provided the essential infrastructure to support a 46-year history of advances in cancer research and the application of that knowledge and technology to improve cancer care [38].

The contribution of data and databases – Cancer control in the U.S. has benefited from the NCI investment in supporting and

maintaining databases. These data provide the basis for tracking major indices of incidence and mortality. Equally important is tracking clinical practice patterns in collaboration with various professional association/specialty groups such as the American Society of Clinical Oncology or the American College of Surgeons Commission on Cancer, which inform the design of interventions that reflect state-of-the-art care or that assess ongoing changes within the delivery system as field experiments.

Design and invest in programs that link the advancing science to a complex and changing health system – With cancer control at the interface of advancing science and the changing delivery system, it is in a position to facilitate collaboration involving an array of organizations and clinical providers across the care continuum. Collaboration that requires an understanding of, and the ability to manage the multilevel factors involved across the care continuum [39,40]. The expanding role of cancer control has provided evidence that:

- the voluntary participation of community oncologists in developing guidelines to improve care (CHOP) did not improve clinical practice patterns. The process resulted in guidelines that were not based on evidence and represented the lowest possible denominator on which the participants could agree.
- involving community oncologists and providing access to NCI evidence-based clinical trials for treatment and, for cancer prevention and control trials (CCOP), and then to reach minority populations (MBCCOP) were proven successful in improving practice patterns. The CCOP provided direct NCI funding for the community providers to build capacity to support evidence-based trials.
- involving community hospitals and their executive management through co-investment in a public-private partnership that spanned the full cancer continuum (the NCCCP) improved practice patterns and increased underserved accrual. The public-private partnership with an infrastructure that facilitated bi-directional interaction enabled "interactive learning." The NCI team presented evidence-based interventions and the participating hospitals provided feedback on adapting these interventions so that they could be effectively implemented in a community setting. This structured interaction around patient-centered care across the continuum transcended the program-based approach of the NCI and facilitated improved outcomes and the establishment of new evidence-based best practices for dissemination to other community hospitals. It also became an approach that formed the basis for new relationships between NCI-designated cancer centers and community hospitals [41].
-While CCDR is a new component of NCORP with many studies yet to be completed, its inclusion offers the opportunity to engage the broader health services research community to conduct research on the operational challenges of providing quality care within the comunity. An opportunity that will expand the evidence base of cancer control and its contribution to improving care along the full care continuum.

Each of these interventions provided evidence leading to more refined efforts to manage the interface between the changing science and healthcare providers.

The importance of managing the process and measuring outcomes – the underlying challenge in each of these initiatives is the need to manage the effort such that the collaboration was mutually beneficial resulting in clinical outcomes that could be evaluated and quantified through primary data, available databases, and tracking changes in clinical practice patterns. Framing initiatives to achieve mutually defined priorities is necessary but not sufficient. The parties need to be engaged in a meaningful manner, whether as in the case of the NCCCP in which co-investment provided a sense of ownership or with the CCOP providing community oncologists the opportunity to participate in NCI clinical trials and thus be part of the larger NCI research enterprise advancing the frontiers of cancer care.

These four lesson-learned themes cannot be separated from the larger issues facing the healthcare system on a global scale. Cancer care provides a microcosm of the issues facing healthcare in general. As described by Harvey Fineberg in his closing days as the President of the Institute of Medicine, a component of the National Academy of Science, while addressing U.S. healthcare but equally applicable to all who work to improve the evidence base of cancer control and prevention "If we can find a way to solve the problems of cancer care, then we have the key to solving healthcare more broadly" [42].

Disclosure

The authors received no funding for this paper. Both authors have received consulting fees in the past from the National Cancer Institute. There have been no consulting relationships to disclose since 2014.

Acknowledgments

We ae indebted to our NCI colleagues who have over the years given us the privilege and opportunity to observe, and in some cases contribute to NCI efforts to meet the challenges of a changing healthcare system. Special thanks to Dr. Peter Greenwald (retired) a pioneer in the implementation of evidence-based cancer control and prevention programs. Dr. Barry Kramer the director (retired) of the DCP and Dr. Robert Croyle the director of DCCPS who provided valuable insight and documentation to our effort to describe and understand a major organizational transformation in the evolution of cancer control and its impact on cancer policy. Our thanks also to the anonymous reviewers for their detailed comments and to our colleagues Kathleen Igo, Alice Saunders, Loria Leadbetter, and Phyllis Shaw for their help in manuscript preparation and accessing references.

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