THE ROLE OF CANCER CONTROL IN ADVANCING THE EVIDENCE BASE FOR IMPROVING CLINICAL PRACTICE IN THE COMMUNITY

Past, Present and Future

Arnold D. Kaluzny
Donna M. O'Brien

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Preface

In 1971, the United States Congress passed The National Cancer Act, a monumental piece of legislation that initiated an all-out “war on cancer,” then the second leading cause of death in the U.S. The program expanded the role and function of the National Cancer Institute, established in 1937 as one of the 27 National Institutes of Health, and provided the infrastructure to support the advancement of science to conquer what Siddhartha Mukherjee has called the “emperor of all maladies.”

Tucked away in the legislation was a mandate for the NCI director to work in collaboration with other federal, state and local public health agencies and private industry to conduct cancer control research. Supplemental funding was available to focus on the full continuum of cancer care, from prevention to early detection and treatment.

The mandate launched an evolutionary process described in the three articles included here. Together, these papers, published separately during the National Cancer Act’s 50th anniversary year, serve as a trilogy to document the evolution of cancer control and the underlying roles of policy and management in improving cancer care. They also trace the history of the expanding role of cancer control within the NCI and the institute’s efforts to improve clinical practice within a community setting.

The first two papers, “The Expanding Role of Cancer Control and the U.S. National Cancer Institute: Policy Implications for Global Cancer Care” (Elsevier *Journal of Cancer Policy,* 2019) and “How Vision and Leadership Shaped the U.S. National Cancer Institute’s 50-Year Journey to Advance the Evidence Base of Cancer Control and Cancer Care Delivery Research” (Elsevier *Journal of Health Policy,* 2020), provide a retrospective view of the expanding role of cancer control over the past 50 years and the role of vision and leadership in establishing the infrastructure for many of the cancer control programs and databases we now take for granted.

The third paper in the series, “Achieving a Multilevel Evidence-Based Approach to Improve Cancer Care in the Post-COVID Era: What is the Role of Management?” (Elsevier *Journal of Cancer Policy*, 2021), builds upon the two prior papers, providing a prospective approach as we deal with post-pandemic health challenges.

COVID-19 has laid bare the limitations of the existing health care delivery system, with devastating effects on cancer care across the country. The pandemic’s impact clearly illuminated the weaknesses of our care delivery

systems and identified actions, programs and initiatives that may serve as building blocks to redesign those systems. As is often said, “Never let a crisis go to waste. Use it as an opportunity to do the things you once thought were impossible.”

W.E. Deming, a pioneer of quality improvement, noted that delivery problems are system problems, and “the system belongs to management.” Management must take the lead if systemic problems are to be resolved. Within that spirit, we hope this final paper provides a catalyst for collaboration between clinicians and managers, to provide evidence-based cancer care for patients and their families.

Pulling together the three papers was stimulated by the onset of the pandemic. These challenging years not only have demonstrated the limitations of the health care delivery system. They have reminded us of the importance of vision, leadership and well-developed infrastructure. Only with these can we support a multilevel, evidence-based, integrated approach to addressing major health challenges on a global scale.

This is well recognized within the cancer community, and we are grateful for the support provided by Elsevier, the editors of the *Journal of Cancer Policy* and *Journal of Health Policy,* and their invited reviewers. We also wish to thank our editor and friend Linda Kastleman, who helped us focus on what we knew – that the role of cancer control in promoting evidence-based clinical trials in the community was a 50-year process, involving many components, interim events and multiple participants. These three papers, read as a trilogy, effectively illustrate that “the whole is greater than the sum of its parts.”

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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

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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).

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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 eff im-plemented 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 co-munity. 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].

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How vision and leadership shaped the U.S. National Cancer Institute's 50-year journey to advance the evidence base of cancer control and cancer care delivery research

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

[a] Gillings School of Global Public Health, Cecil G. Sheps Center for Health Services Research, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States of America
[b] Strategic Visions in Healthcare LLC, New York, NY, United States of America
[c] International Cancer Expert Corps, Washington, DC, United States of America

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ABSTRACT

In 1971, Congress passed the National Cancer Act, landmark legislation that reorganized the National Institutes of Health's National Cancer Institute (NCI). The Act included a new focus on cancer control, including the requirement that the NCI award research grants and contracts, in collaboration with other public agencies and private industry, to conduct cancer control activities related to the diagnosis, prevention, and treatment of cancer. The requirement placed the NCI at the nexus of a rapidly changing science and a complex and dynamic healthcare delivery system and involved an evolutionary transformation to advance cancer control and cancer care delivery research along the cancer care continuum. Analysis is based on a qualitative ethnographic approach using historical records, oral histories, and targeted interviews. The multimethod approach provided the opportunity to describe the vision, leadership, and struggle to build an infrastructure, expand expertise, and forge collaboration with the NCI and a complex and changing healthcare system. As the 50th anniversary of the National Cancer Act approaches in 2021, the process and these achievements are at risk of being taken for granted or lost in the flow of history. Documenting the process, milestones, and key players provides insight and guidance for continuing to improve cancer care, advance research, and reduce cancer incidence and mortality. Cancer care is a microcosm of the larger healthcare system providing insight and lessons on the importance of developing and maintaining a research infrastructure and the role of multilevel collaboration and partnerships involving both the private and public sectors.

1. Introduction

In 2010, in his Pulitzer Prize-winning "biography" of the disease, Siddhartha Mukherjee [1] described cancer as the "emperor of all maladies." Almost a decade later, the description is still apt. In 2018, in the U.S. alone, cancer claimed nearly 610,000 lives, and 1.7 million people were newly diagnosed with it. Human costs aside, the economic burden of cancer-related healthcare was $147.3 billion in 2017 [2]. That year, the World Health Assembly urged the promotion of cancer research "to improve the evidence base for cancer prevention and control" [3] – a concept pioneered in the United States with the 1971 passage of the National Cancer Act, often referred to as the "War on Cancer" [4,5].

The 1971 legislation led to expansion and reorganization of the NCI and required the NCI director to explore new opportunities to prevent cancer, diagnose it earlier, treat it more efficiently, and improve care and care outcomes [4]. The legislation empowered the NCI to leverage its unique role as a government-funded research institute in making long-term public investments to advance cancer care along the care continuum, employing innovative approaches and establishing relationships with the healthcare delivery system not accessible to the private sector [6].

Scientific discoveries were being made rapidly, and the NCI was called upon to translate the science for clinical application quickly and efficiently within a complex healthcare system. The science – and the complex healthcare system within which it was to be applied – was unimaginable in 1971.

For nearly 50 years, the U.S. National Cancer Institute (NCI) has worked to improve the evidence base of cancer prevention and control [5] and address the reality of a changing healthcare delivery system. While much progress has been made, there continue to be challenges. By 2013, the Institute of Medicine declared that the fragmented cancer care delivery system was "in crisis" [7] and called for new strategies to ensure that high-quality cancer care was offered. This paper is the story of the NCI's organizational evolution in cancer control as it navigated rapid changes in both science and in the healthcare delivery system. It is about vision, leadership and struggle to build an infrastructure, expand expertise, forge collaborations,

* Corresponding author at: 250 Park Ave Suite 700, New York, NY 10177, United States of America.
E-mail address: dobrien@svhealth.com. (D.M. O'Brien).

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and advance new ideas. Given the 50-year anniversary of the National Cancer Act in 2021, this evolution, including the achievements and the roles of individuals is important to document.

2. Methods and materials

The description of the expanding role of cancer control and the emergence of cancer care delivery research are based on a qualitative ethnographic analysis, using historical records, oral histories and targeted interviews, as well as observations by – and in some cases, the participation of – the authors as they were involved in policy decisions and program implementation during the 50-year study period. Historical records included a review of archived minutes of the NCI Board of Scientific Counselors, Board of Scientific Advisors (BSA) and relevant minutes of the NCI National Cancer Advisory Board (NCAB). Oral histories were commissioned and conducted in December 2008 and January 2009. The oral histories and written transcripts are archived in the Office of NIH History. In addition, key NCI personnel were interviewed in spring 2019.

3. Findings

3.1. The formative years

The 1971 legislation required the NCI to award research grants and conduct cancer control activities [4], but did not provide a mandate for funding. Lester Breslow, MD, MPH, director of the California State Health Department, and other public health leaders successfully advocated in 1973 to modify the National Cancer Act to include supplemental funding for cancer control [8].

To carry out the mandate effectively, it was essential that NCI develop new approaches to engage with the healthcare delivery system [9], even as that system and its providers were undergoing fundamental changes. Legislation that enacted Medicare and Medicaid was signed in 1965 [10], and the injection of funding to hospitals and physicians would dramatically change the relationship between hospitals and their management, and physicians [11–13].

3.1.1. New leadership focus on cancer control and prevention

In 1981, Vincent DeVita, MD, director of the NCI's Division of Cancer Treatment, was appointed NCI director. A pioneer in the development of chemotherapy interventions, DeVita brought a dedication to empirical and protocol-based research [14]. He named Peter Greenwald, MD, DrPH, as director of NCI's Division of Resources, Centers and Community Activities (DRCCA). Greenwald, a physician with public health training, was well aware of the effects of a prevailing delivery system upon the implementation of cancer control programs. He had no history of working within NCI, but he and the NCI director shared a passion and respect for empirical research and a conviction that research must benefit society. In an interview, Greenwald recalled a conversation with DeVita:

> "I wanted to do research that led directly to public benefit. To be successful, we needed to change the whole climate, the whole staff [...] I felt that with Vince De Vita's backing, I would be able forcefully to change the nature of cancer control."
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Greenwald's appointment gave new perspective, power, and purpose to the concept of cancer control. Many of the programs did not align with his vision, and DRCCA did not include an identifiable cancer prevention focus. As Greenwald stated:

> "Prevention was falsely defined as anything to do with studying causality, etiology, and epidemiology, with nothing that involved intervening to lower the occurrence of cancer. [...] Research on causality is important, but it is not prevention."
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Greenwald assembled a group of like-minded physicians and researchers to design studies that could provide an empirical basis for prevention and control interventions. Within weeks of Greenwald's appointment, Joe Cullen, PhD, a behavioral scientist from the University of California at Los Angeles, was named the division's deputy director, and Jerome Yates, MD, a medical oncologist from Roswell Park Cancer Institute, was named chief of the Community Oncology and Rehabilitation Branch.

Cullen advocated for empirically-based programs that would make the most difference in cancer prevention. During his tenure, NCI enacted a new Smoking Tobacco and Cancer Prevention program to reduce tobacco use [16]. Yates's experience with community oncologists provided him with both a clinical perspective and awareness that physicians wanted access to NCI clinical trials.

The expanding NCI research enterprise called for greater access to patients for clinical trials. The Community Clinical Oncology Program (CCOP), launched in 1981, would effectively engage community oncologists in the NCI clinical trials program with accrual exceeding expectations [17,18]. Leslie Ford, MD, who recently had joined the branch, described the uniqueness and foresight of the program:

> "This was pretty sweeping talk about community oncology to say that physicians practicing in their communities would actually do as well as cancer center and university physicians in terms of quality care."
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3.2. Finding direction

The 1983 name change of DRCCA to the Division of Cancer Prevention and Control (DCPC) supported Greenwald's vision of cancer control – as "a science based upon empirical research that leads to social benefit." In 1984, Greenwald and Cullen published a paper 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."
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The publication made a significant impact on the field. A transformation of the division's culture and operations acknowledged the interface between research and clinical practice, while taking into account the complex and changing healthcare system. Further changes were underway.

Ed Sondik, PhD, who was working at the National Heart, Lung, and Blood Institute, learned that Greenwald was considering a health services research branch to incorporate aspects of economics, operations research, and biometrics. Sondik recently had returned from Stanford University, where he conducted research on medical decision-making under uncertainty – a central focus of operations research [21].

In an interview with Greenwald, Sondik recalled:

> "Whoever is talking about operations research at NIH is my kind of person [...] because there is no activity like that at NIH [...] There are of course the usual analytical sciences, epidemiology, demography, etc. ... [but] ... operations research is focused on decision making [...] and that is quite crucial to health policy."
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Sondik was appointed head of the new Applied Research Branch (ARB) and focused on three areas of research – health services and economics, modeling and statistical methods, and cancer risk assessment.

An immediate product of this new branch was the publication of "Cancer Control Objectives for the Nation 1985–2000" [23]. The report targeted tobacco use, dietary factors, occupational hazards, and other cancer causes to reduce cancer deaths by as much as 50%. Unfortunately, the effort to implement the report was insufficient to have a major impact on smoking rates [24], and tobacco control research would remain an ongoing focus at the NCI. Still, the report and the new definition of cancer control were

catalysts that led to several new research initiatives and productive collaborations between the NCI and state, local and federal governments, corporate leaders, and private organizations.

The national network of the CCOP was expanded in 1987 to include clinical trials for cancer prevention and control and to bring research to underserved populations [24,25]. The CCOP's expansion improved clinical practice [26] and was a model for other research networks [27]. Other evidence-based research efforts quickly followed.

The ambitious Prostate, Lung, Colorectal, and Ovarian (PLCO) Screening Trial [28], launched in 1991, would demonstrate, after 15 years, that screening had no significant effect on prostate, lung or ovarian mortality. For colorectal screening, there was a 21% reduction in incidence and a 26% reduction in mortality. This and other longitudinal colon cancer screening studies have led to public awareness campaigns, reimbursement changes, and enhanced advocacy efforts [29]. The Breast Cancer Surveillance Consortium (BCSC), established in 1994, collected screening data on patients and mammograms to track the relationship of screening to stage of diagnosis, survival, and breast cancer mortality [30] and led to enhanced understanding of clinical practice patterns, such as overutilization of screening [31].

3.2.1. Translating evidence into the reality of clinical practice

In the late 1980s, Samuel Broder, MD, a medical oncologist and AIDS researcher who valued empirical research, succeeded DeVita as director and continued support of the NCI cancer prevention and control research program [32]. Evidence-based studies were challenging well-established guidelines recommending yearly breast cancer screening. By 1992, evidence suggested that annual breast cancer screening for premenopausal women ages 40–49 had little or no effect on mortality and came with attendant harms [33]. The paper reporting these findings set off a chain of events. NCI began a formal review that ultimately led to the presentation of a report at a 1993 meeting of the Board of Scientific Counselors [34].

The interest generated by this topic and the public meeting led to live TV coverage with provider and advocacy groups presenting their perspectives on the risks and benefits of breast cancer screening. The highly controversial statement issued by the Board, in part, stated that:

> "There is general consensus among experts that...To date, randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50."
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In the aftermath, NCI continued to invest in research to evaluate the efficacy of breast cancer screening, but deferred to established expert groups, such as the U.S. Preventive Services Task Force, to make formal recommendations on clinical practice guidelines. The risk-benefit statement is updated periodically.

The speed of advancing science, its clinical application, and the changing delivery system have amplified the importance of evidence-based recommendations, which are based not only on scientific evidence but also on an understanding of how care is delivered. How this balance is best achieved remains an ongoing challenge.

3.3. 'Hard and new choices'

In 1995, leadership of the NCI was passed to Richard Klausner, MD, chief of the Cell Biology and Metabolism Branch of the National Institute of Child Health and Human Development, who had spent his professional career at NIH. He set into motion a series of committees to review NCI's major functions. Klausner wanted to close the gap between the "power and beauty of molecular approaches to biology and what happens clinically [36]." He noted that "hard and new choices" were required.

Klausner proposed a reorganization of the NCI that included establishment of two divisions–the Division of Cancer Prevention (DCP) and the Division of Cancer Control and Population Sciences (DCCPS) [37]. Peter Greenwald, former DCPC director, was appointed director of the DCP. The new division would be based on biological markers and the design of chemoprevention agents to reduce cancer risk. DCPC's seven functional research branches, which had produced significant, practice-changing studies in cancer prevention, screening, and public health [38], would move to the new DCP. Missing in the new division was expertise to relate scientific advances to clinical practice and organizational providers.

Greenwald remained committed to the premise that cancer prevention should maintain a link to the delivery system if social benefit were to be achieved, and created a matrix structure to correspond to major cancer disease sites. As he described:

> "The basic structure was fine, but the matrix part did not work very well ... the division lacked the ability to put resources directly into the matrix teams. The organ site and cancer prevention groups remain [...] and matrix teams are created on an ad-hoc basis."
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Barbara Rimer, DrPH, a Duke University social behavioral scientist who recently had completed a term as NCAB chair, was named the first DCCPS director. The appointment of a behavioral scientist as director of a major NCI division, along with the division's name change, acknowledged that the social and behavioral sciences played an important role in understanding a complex and changing delivery system. Robert Hiatt, MD, PhD, an epidemiologist from the University of California at San Francisco and member of the Cancer Control Advisory Committee, was appointed deputy director.

Building on the work of the DCPC and the ARB, Rimer and Hiatt quickly expanded existing databases to monitor practice and utilization patterns and recruited researchers to study social-behavioral interventions and cancer care delivery and outcomes [40]. The Surveillance, Epidemiology, and End Results program was expanded through collaborations with other federal agencies for data linkages [5]. To provide a greater focus on the care continuum, the Office of Cancer Survivorship, recently established to study the unique needs of the growing number of cancer survivors and respond to the expanding advocacy community [41,42], was incorporated into the division [43]. New programs were launched to examine the changing structure and operations of the delivery system, including the Cancer Research Network [44]. Established in 1998 to support cancer control research within integrated healthcare delivery systems, the network became a model for NCI and NIH, incorporating integrated delivery systems into their research programs [45,46].

To study how patient and provider factors influenced outcomes, the division received funding in 2001 for the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS) [47], which examines how cancer patients' and providers' characteristics, beliefs, and behaviors influence treatment and outcomes. The program has contributed important findings that inform quality of life and symptom management issues for people with lung and colon cancer, including the need to implement supportive care strategies beginning at diagnosis [48].

"We knew we needed much bigger numbers and a more diverse base of participants to support research studies," said Robert Croyle, PhD [49]. Croyle had served in the division as associate director of behavioral research, and in 2003, succeeded Rimer as director.

Increasing attention was given to understanding the patient's perspective and the measurement of patient-reported outcomes. In 2004, the division developed the Patient-Reported Outcomes Measurement Information System (PROMIS), an outcomes measurement now used internationally and applied to a wide variety of patient populations [50].

The need to assess and improve cancer screening practices and outcomes in a real-world setting led to the launch in 2011 of the multi-site Population-based Research to Optimize the Screening Process (PROSPR) program, which established an infrastructure and common metrics to study screening across disparate locations for breast, cervical, colorectal, and lung cancer. The program identified the need for greater understanding of factors that drive variation and of ways that new screening technologies and healthcare environment changes in policies and reimbursement were affecting screening. Its re-funding for five years in 2018 will support more

in-depth study of measures for health system-level factors that impact the screening processes, including those that influence access and disparities, and will examine ways to ensure the quality of screening [51].

Recognizing the need for multilevel interventions [52], the division convened a forum to identify needed research, understand the current state of the science, and clarify issues in the conceptualization of this research across scientific disciplines [53]. In 2014, the division was reorganized into four research areas [5] that enable it to continue its unique role in funding the conduct of longitudinal studies with large patient populations, respond to changes in science, and understand the multilevel influence of an increasingly complex delivery system.

3.4. Building bridges

In 2001, the newly appointed NCI director brought increased attention to the delivery of cancer care and aimed to improve cancer outcomes. Andrew von Eschenbach, MD, a urologic oncologist and cancer center executive, had built his career at MD Anderson Cancer Center in Houston. As he described:

> "Moving to the NCI was like going from boots on the ground, during which I was on the front line every day, involved with day-to-day cancer care, to being a pilot in an AWAC surveillance plane, where I get to see the whole landscape of oncology."
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Based on his clinical experience and now with a new "bird's eye" perspective [54], von Eschenbach set ambitious goals, with emphasis on the rapid acceleration of the discovery–development–delivery cycle and the application of nanotechnology, genomics, proteomics, and bioinformatics as they affect the full continuum of cancer care [55].

In 2005, von Eschenbach recruited John Niederhuber, MD, a surgeon with experience in basic sciences, to be deputy director. Niederhuber, who had served as NCAB chair and as director of the University of Wisconsin Comprehensive Cancer Center, accepted the position on condition that he could develop a program to expand community hospitals' ability to provide state-of-the-art cancer care [56]. Shortly after Niederhuber's arrival, however, President George W. Bush appointed von Eschenbach to lead the U.S. Food and Drug Administration, and Niederhuber subsequently was appointed NCI director in 2006.

3.4.1. Science at a crossroads

Cancer research was at a crossroads. Large clinical trials required significant resources, while new funds were critical to advancing basic science and technologies associated with the sequencing of the genome, an event which, by all measures, represented a paradigm shift in cancer research [57]. NCI was operating under considerable financial constraints, and Niederhuber was forced to make difficult choices.

At that time, the NCI had approved a large prospective clinical study (STELLAR), estimated to cost between $50 million and $100 million, to culminate a 20-year research program evaluating chemotherapy agents for breast cancer prevention. Despite its having been approved in an extensive review process, with the unlikely prospect that a pharmaceutical company would undertake such a project given the limited return on investment, the director appointed an ad-hoc panel to reconsider the project [58]. At the June 14, 2006, meeting of the NCAB, the panel reported that it could not "offer strong endorsement of the trial as it was presented for funding [59]." While scientists on both sides were critical of the way in which the matter was handled [60], the decision was an inflection point for the NCI, in which the well-established standards of clinical trials were suspended to accommodate a rapidly evolving science [61].

3.4.2. Partnering with the healthcare delivery system

In 2007, Niederhuber, based on his commitment to expand the capacity of community hospitals to provide state-of-the-art cancer care and growing interest in "precision oncology," initiated the NCI Community Cancer Centers Program (NCCCP) pilot, a public-private partnership with 16 community hospitals [62], later expanded to 30 hospitals. The program was met with mixed reviews when presented to the NCAB and the Board of Scientific Advisors. Some felt the concept was "comprehensive and ambitious" and "addressed major healthcare issues of the time." Others were skeptical that community hospitals would make the matching investment or wondered how the NCCCP was different from the well-established CCOP [55].

NCCCP was based in the Office of the NCI director, as its scope cut across several NCI divisions and centers. Unlike other NCI programs, it required the direct involvement of hospital management, as management controlled resources. Program oversight was managed by committee, with representatives from each hospital and from participating NCI divisions and centers. The result was a learning collaborative that facilitated rapid development and dissemination of strategies to achieve program goals [55].

An evaluation showed that program goals and co-investment requirements were met or exceeded [63–65]. Organizational factors associated with improved outcomes included the direct involvement of executive management, strengthened alignment between hospitals and their cancer specialty physicians, development of collaborative learning among participating hospitals, and access to NCI expertise for benchmarking and sharing best practices [66].

3.4.3. Aligning NCI research programs to strengthen the relationship with the delivery system

In 2010, Harold Varmus, MD, succeeded Niederhuber as NCI director [67]. A Nobel laureate, former NIH director, and president of Memorial Sloan Kettering Cancer Center, Varmus quickly moved to emphasize a basic science agenda within NCI, prioritizing research project grants for investigator-initiated biomedical research. He named Greenwald associate director for cancer prevention in the Office of the NCI Director and appointed Barnett Kramer, MD, MPH, director of DCP. Kramer recently had retired as director of the NIH Office of Disease Prevention.

In a time of limited resources and increased investment in basic sciences, NCI in 2012 made the decision to merge NCCCP and CCOP, with Douglas Lowy, MD, deputy director of the NCI [68], facilitating this planning process. The new program, the NCI Community Oncology Research Program (NCORP), would be based within DCP, but would have an associate director from the DCCPS. As Kramer noted:

> "Collaboration is the key. Building on our past collaboration with DCCPS, now more formalized through NCORP, DCP has access to broader expertise in health services and access to the delivery system to advance prevention and control research."
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3.4.4. Cancer care delivery research (CCDR)

Researchers from DCCPS and DCP worked together to document their understanding of the healthcare system's structure, processes, and role in cancer care and research. For purposes of clarifying the NCORP research agenda, the group defined cancer care delivery 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."
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Launched in 2014, NCORP has been effective in clinical trial accrual and in its unique role as a community-based laboratory to advance the evidence base of cancer prevention and control, including the conduct of complex delivery-system-based studies for cancer control that can inform health policy and value-based care [71,72]. Based upon an external review, NCORP was approved for funding with a new six-year award made in 2019 [73,74].

4. Discussion

Today's pressing issues in prevention and control little resemble those identified in NCI's formative years [7,75,76]. Cancer prevention and control research in the U.S. now incorporates the multi-level complexity [77,78] of the financing and delivery of cancer care, focusing upon rescinding ineffective, low-value, or harmful practices [79–81]; continuing tobacco control efforts [82]; better engagement of patients in decision making and meeting the needs of "cancer survivors" [83–85]; reducing disparities [86,87]; and assessing new reimbursement models for value-based care [88–90]. These issues suggest a "new frontier"– one requiring new methods and access to large datasets and analytical capacity as advanced by Norman "Ned" Sharpless, MD who was appointed Director of the NCI in 2017 [91].

In 2016, the U.S. Cancer Moonshot initiative was launched [92], and Congress passed the 21st Century Cures Act [93]. These initiatives, which provide $1.8 billion over seven years, expand research opportunities, including the basic concept of cancer control, precision prevention and early detection, expansion of clinical trials, enhanced data sharing, and implementation sciences. The complexity of advancing the science and improving the evidence base of cancer prevention and control through greater collaboration among various federal agencies was documented in a 2019 report issued by the U.S. National Academies of Sciences, Engineering and Medicine (NASEM) [94].

For the future, to optimize that value of cancer control and cancer care delivery research at the NCI it will be important to:

- Maintain a strong infrastructure. The public sector and the NIH/NCI have played an important role in many clinical practice advances that are now taken for granted. With funding from Congress, the NCI has provided the infrastructure and served as a catalyst for advances along the cancer continuum. More than ever, these efforts are needed to meet the challenges of an advancing science, clinical application and a complex and evolving healthcare system.

  The value of this infrastructure became evident with the COVID-19 pandemic, as the NCI rapidly mobilized on many levels [95]. Patients on clinical trials became an urgent priority with NCI, and its investigators quickly "re-imagined" ways to manage the care of these patients so their treatment was not compromised. They also recognized that some lessons learned may carry forward as new best practices. With cancer patients at particular risk, cancer control and cancer care delivery studies were immediately established and made available through the NCORP and other clinical trial programs. The NCI COVID-19 Cancer Patient Study (NCCAPS), a large cohort natural history study, is tracking how the disease develops and changes in patients undergoing treatment for cancer and the immediate and long-term effects [96]. Maintaining an infrastructure to be ready for conducting studies such as this is essential for making progress.
- Expand on partnerships. The NASEM report called for coordination of cancer control efforts across various federal agencies so that relevant issues, such as quality, scientific advances, safety, and cost and payment, could be addressed in an integrated way across the sectors involved in the delivery of care. Actions and funding to facilitate these partnerships are needed.

  Partnering with providers is also critical. Programs such as the NCORP, with its national network of community oncologists and healthcare organizations and systems, offer the capacity to collaborate with the clinical community to develop evidence-based interventions across the full continuum of care. Such interventions include evaluation to improve care processes, assess alternative reimbursement models, and study new care delivery models as changes in science and the health system accelerate at an unprecedented rate. Finding ways to expedite the timeframe for the study of these urgent issues, as has happened for COVID-19, will be important for leveraging the value of these programs.

These efforts built upon the 1971 National Cancer Act, and after nearly a half-century, the NCI, in its historic and catalytic role as a government-funded research institute, has been joined in its efforts by other public [97] and private-sector organizations [98] and professional associations [99] that contribute to progress. Much remains to be done. Yet the expanding evidence base of cancer prevention and control and the integration of cutting-edge science with public and private-sector vision and leadership have transformed cancer care and the lives of those facing cancer. The challenge moving forward is to leverage what has been accomplished, in collaboration with efforts in the public and private sectors, and more fully to engage those in the healthcare system as partners in research along the full care continuum – from risk assessment and prevention through survivorship and end of life [100].

5. Conclusions

When the 1971 National Cancer Act was passed, the language of a "war on cancer," with the implication of being able to *win* that war, was used to mobilize support for consequential legislation that has led to new knowledge, prevention and better outcomes for patients. However, the complexity of the disease – and the challenges of making excellent cancer care more universal through both basic and cancer control research – made it clear that transformation would not be immediate. Six years later, Benno Schmidt Sr., a key player in the passage of the National Cancer Act and chair of the first President's Cancer Panel (PCP), would note in his 1977 PCP report that the national cancer program was a vast undertaking requiring patience and constancy of support by Congress, the federal administration, and the public.

Moving forward, continuing advances in science and clinical application within a changing healthcare system will present unrelenting challenges to the provision of high-quality health and cancer care. Though the challenges are significant, the NCI, with its committed leadership, expertise and infrastructure, and with increased efforts to forge partnerships, will continue to play a central and catalytic role in expanding the evidence base of cancer control and cancer care delivery research. Despite this half-century of phenomenal progress, the complexity of cancer remains and calls for continued study of its implications for the continuum of cancer care and the changing healthcare system. "The goal," as expressed by Schmidt decades ago and still true today, "is the course we travel together, and the end is only the beginning." [101].

CRediT authorship contribution statement

ADK and DOB were involved in the conceptualization, research, interviews, document review and the writing and editing of the manuscript.

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Achieving a multilevel evidence-based approach to improve cancer care in the U.S. post-COVID era: What is the role of management?

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

[a] Strategic Visions in Healthcare, New York, NY, United States
[b] Gillings School of Global Public Health, Sheps Center for Health Services Research, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States
[c] International Cancer Expert Corps, Washington, DC, United States

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ABSTRACT

In 2013, the Institute of Medicine already had declared the state of U.S. cancer care as "a delivery system in crisis." Beginning in early 2020, the ongoing COVID-19 pandemic has dramatically revealed the fragile nature of the U.S. health system. As a microcosm of that larger health system, cancer care can provide us with opportunities for innovative thinking and new solutions.

This paper describes a series of public and private-sector cancer care initiatives that are the building blocks for a multilevel evidence-based approach to improve cancer care in the post-COVID era. Achieving these objectives requires significant managerial policy decisions, some risk taking, and the development of organizational strategies that involve collaboration within the managerial and clinical leadership. Such strategies should reflect adaptability to navigate the complex and changing science, policy and financing environment, while retaining the central values of patient-centered care. As suggested by Edward Deming, an early pioneer in quality-improvement initiatives, the problems are with the system, and the system belongs to management.

Though future challenges are undefined and likely to be significant, the foundational elements of a multilevel, evidence-based approach for improving cancer care are established and able to be built upon and will offer application in the post-COVID era.

1. Introduction

In 2018, nearly 610,000 people in the U.S. died after enduring the agonies and indignities of cancer, while another 1.7 million people in the U.S. were newly diagnosed with some form of the disease [1]. Human costs aside, the economic burden of cancer-related health care is projected to be $246 billion in the U.S. by 2030 [2], with cancer replacing heart disease as the number one cause of death in high-income countries [3]. Yet, as early as 2013, the Institute of Medicine had warned of a cancer care "delivery system in crisis" [4]. The U.S. response to the COVID-19 crisis has dramatically revealed the inability of the delivery system to meet the health needs of the population. Notably, COVID-19 challenged cancer and heart disease as a leading cause of death in 2020 [5]. Both cancer care and pandemic control require a well-managed and integrated health care system that can support patients and families across the continuum from prevention to end of life.

Behind the IOM's disparaging evaluation of the country's cancer care delivery system and the health system at large [6,7], particularly evident when faced with the challenges of COVID-19, are efforts within the cancer care community to design an integrated and evidence-based approach to improving health care. These research and clinical program efforts, which involve both the public and private sectors, operate at the interface between evolving science, its clinical application, and a changing health care system, one that represents a microcosm of the larger health care system [8], with implications for both management and the clinical community. As Dr. Harvey Fineberg, in his closing days as president of the IOM, reminded the clinical, research and managerial communities, "If we can solve the problems of cancer care, then we have the key to solving health care more broadly."

2. Building blocks for a multilevel evidence-based approach for the delivery of cancer care

The Triple Aim [9], an initiative launched in 2007 by the Institute for

* Corresponding author at: 250 Park Ave, Suite 700, New York, NY, 10177, United States.
E-mail address: dobrien@svhealth.com (D.M. O'Brien).

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Healthcare Improvement, posits that improvement of the U.S. health system requires simultaneous activities in three areas – enhancing the experience of care, improving the health of the population and reducing the per capita cost of care. Drawing upon the Triple Aim framework, the following narrative outlines ongoing initiatives for improving the delivery of cancer care, with carryover to the larger health care system. These actions require a multilevel [10] approach providing a roadmap to identify existing building blocks within the delivery system and opportunities for future action, placing management and clinical leadership at the interface of the advancing science, its clinical application and a changing health care system. As suggested by Edward Deming [11], the problems are with the system, and the system belongs to management.

2.1. Improving the experience of care

Cancer is a complex set of diseases, and the U.S. and other countries have made significant investments in the study of cancer control and treatment. Still, serious challenges – dramatized by the advent of COVID-19 – are presented by the speed of scientific advancement and the unremitting need for clinical application along the care continuum. Cancer patients and their families find themselves plunged into a delivery system facing extraordinary change. Influenced by professional associations, advocacy groups, payers, the pharmaceutical industry, technology companies, and national, state and local policy and regulatory agencies, the system comprises an array of organizations and clinical providers. During the pandemic and its cycles of resurgence, patients and providers also have had to address hospital capacity challenges for non COVID-19 patients and adapt to virtual visits, via telehealth, with many postponing cancer screening, which will result in later-stage diagnoses [12].

The prospect for the patient is overwhelming and frightening. Nearly all who enter into the care delivery system will experience periods of frustration and despair, and many will face significant financial hardship. Often, the "system" is little more than an illusion, as it inhibits the effective transfer and application of advancing science to improve patient-centered care along the full continuum from prevention to end of life. Because it is so prevalent and costly, cancer care in the COVID-19 era dramatizes the disjointedness of the health care delivery and payment systems.

Patient-centeredness is at the heart of improving the experience of cancer care. It involves multi-specialty clinical management; concordance with evidence-based measures; support services, such as psychosocial care, palliative care, and symptom management; access to targeted therapies and clinical trials; culturally tailored care; and timely access. The public sector has been a catalyst for efforts to enhance patient-centered care for cancer patients.

The Patient-Centered Outcome Research Institute (PCORI) was launched in the U.S. as an independent nongovernmental organization in 2010 to fund research along the full continuum of care, including cancer care, to assess options to improve quality and relevance and provide evidence to help inform patients, clinicians, managers and policy makers. Since inception, the institute has provided more than $350 million in funding to support 89 comparative effectiveness studies related to cancer that are able to inform evidence-based approaches and offer guidance to policy makers and payers [13].

The National Cancer Institute (NCI), the leading cancer research organization in the world, has been conducting cancer control research since the passage of the National Cancer Act in 1971, with an expanding portfolio of evidence-based interventions to improve cancer care [14]. In 2014, the NCI, as part of a reorganization of community-based clinical programs, launched the NCI Community Oncology Research Program (NCORP). This program was centered on expanding clinical trials in the community but it also included research about the delivery of cancer care [15], examining ways in which social factors, financing systems and organizational structure and processes, health technologies, and health care provider and patient behaviors affect access, quality and cost of care, and patient-reported outcomes on quality of life for cancer patients and their families [16]. The explicit recognition of the need to more directly engage with the delivery system provided the opportunity to leverage and develop a research relationship with the large network of hospitals and the associated physicians within NCORP.

Rapid advances in genomics, computational sciences and digital medicine – and continued study of patient-reported outcomes – require even greater collaboration and investment across government agencies and with providers within the delivery system. Several ongoing efforts are providing opportunities to link real-time clinical and genomic databases to create study populations such that we can better understand disease processes and the effectiveness of targeted approaches for prevention and improving care [17].

2.2. Health of the population

Cancer care and health care generally are influenced by many factors beyond the clinical provision of care – such as the determinants of health outcomes, including biologic, behavioral, social, economic, institutional, and policy factors. These involve multiple levels and an array of organizations that represent an "organizational field" [18] responsible for forces that affect utilization of health care and delivery system operations. Operating within a larger "open market" system, health care organizations and physicians are the repository for many health problems enabled by political and economic elements that promote consumption at the expense of health [19], while also enabling uneven access to health care.

Beginning in 1998, the CDC's National Comprehensive Cancer Control Program recognized the importance of these external forces. In collaboration with state and local governments, the American Cancer Society and a cadre of public health personnel helped develop state cancer plans, national programs, and many cancer education and screening programs across the country [20]. These were unprecedented policy initiatives that made a measurable impact on early detection and treatment of cancer [21].

2.2.1. Social determinants of health and cancer disparities

Increasing attention is being given to the influence of social determinants of health on cancer outcomes and strategies that must be addressed within the care delivery, policy, and payment environments [22]. In 2003, in collaboration with the National Institute of Environmental Health Sciences, the National Institute on Aging, and the Office of Behavioral and Social Sciences, NCI launched a broad NIH effort to study determinants of population health disparities, with findings that led to specific community-based interventions to address cancer screening disparities [23,24]. NCI has continued to expand these efforts to improve the health of the population and address the challenges of cancer disparities [26].

2.2.2. Collaborative studies

Progress in improving cancer outcomes requires prospective longitudinal patient clinical data for studies. In 2018, NCI launched the Connect Study, a longitudinal study in collaboration with five integrated delivery systems [25]. The study will accrue patients who have no history of cancer, and researchers will collect electronic medical record (EMR), environment, behavioral, genomic, and microbiome data, so as to better understand the etiology of cancer to inform new approaches for prevention and early detection.

2.2.3. Private sector initiatives

While the public sector and integrated delivery systems primarily have funded efforts to improve the health of the population, the private sector also has initiated some innovative projects. One example is a regional lung cancer screening clinical trial launched jointly by the Barnes-Jewish Christian (BJC) Collaborative [26]. The multi-state

collaborative involves eight independent not-for-profit health systems in Missouri and Illinois participating in a clinical trial, which aims to increase primary care provider referrals for low-dose CT lung cancer screening. Undertaking a multi-site study for lung cancer screening is complex to plan and conduct. This initiative is successful for several reasons, including executive-management support from each health system; multi-level education and planning; engagement by primary care physicians and specialists; access to research expertise and centralized administrative staff at Washington University School of Medicine [27].

Other developments are occurring within the complex, market-driven healthcare delivery and payment system that are leading to more significant change. A pharmacy company has acquired a major health insurance company [28], and employers are becoming more proactive, contracting and collaborating directly with providers [29]. An early employer effort to promote cancer prevention is the Cancer Gold Standard program, launched in 2001, which now has more than 200 participating employers representing 7.4 million lives [30].

2.3. Reducing per capita cost

Addressing the cost of cancer has been a particular challenge, given the complexity of treatment decisions, a care-delivery culture that promotes overutilization, and the rapid development of new and costly technologies and drugs. Central to the discussion is how best to pay providers and do so in a way that ensures high-quality, value-based care. Commercial and government payers have explored various approaches. An early effort launched in 2010 tied reimbursement to quality indicators from the American Society of Clinical Oncology Quality Oncology Practice Initiative [31]. Other payers have targeted disease sites for incentive programs, such as early intervention for palliative care for lung cancer [32] and the use of cancer clinical pathways, with a goal of reducing variation in care to control costs [33].

In 2016, the Centers for Medicare and Medicaid Services (CMS) launched an effort, focused on medical oncology practices, to develop and evaluate alternative payment models for cancer treatment with outpatient chemotherapy, hormonal therapy and/or immunotherapy. The model is testing whether additional funding for enhanced services and financial incentives improves quality and efficiency of care provided [34]. One early outcome of this initiative is the introduction of financial penalties for patients admitted to the hospital with specific symptoms following chemotherapy treatment [35]. For radiation therapy, a high-cost service where there have been patterns of overtreatment, a new five-year CMS pilot to begin in 2020 but delayed due to COVID-19, will shift reimbursements from fee for service to episode-based payments [36].

Reducing the cost of cancer care will require partnerships between payers and providers and access to data on cost, quality, patient-reported outcomes, and clinical outcomes. Partnerships and investments in prevention and screening programs ultimately will reduce the cost of cancer care and should be a priority for payment, with more support needed for these programs and for related research.

3. Practice implications: the role of management

> "Never allow a crisis to go to waste. It's an opportunity to do the things you once thought were impossible." *Rahm Emanuel* [37]

COVID-19 is such a crisis – one that has disrupted well-established patient care and work force patterns throughout the country. In the post-COVID era, "business as usual" is not an acceptable option. Management, in collaboration with clinical leadership, has the opportunity to assess, refine, and in some cases, replace the prevailing infrastructure and care practices to ensure increased access to evidence-based managerial interventions and to improve the quality of the care experience, reduce per capita cost and improve the health of the population. With a focus on multi-levels of intervention and an emphasis on balance and integration, the Triple Aim offers a synergistic strategy to improve cancer care in the community and meet the challenges of a changing health system.

Cancer's complexity, coupled with the impact of professional, political and economic forces in health care, makes managerial decisions daunting at best. In collaboration with clinical leadership, management can take proactive steps to make an impact on access, quality and value, while balancing financial performance. Management and organizations already know they must adapt rapidly to changing priorities, and they have capacity to do so. The pandemic also has reminded us of the need to plan for uncertainty and for management to have flexibility as a competence and to lead their organizations with the related skills [38].

3.1. Building and using databases

The existing array of cancer databases to assess practice patterns and end-point markers provides benchmarks as providers and organizations rebuild and redesign the delivery system and cancer care delivery process in the post-COVID era. Redesign efforts should include the integration of financial and quality data across the continuum of care. The American College of Surgeons' Commission on Cancer [39] provides reliable data that span cancer specialties and hospital and physician performance and include measures for 12 cancer disease sites. The American Society of Clinical Oncology [40] has developed a quality benchmarking and certification program for oncology practices, and through its CancerLinQ big data initiative, is providing real-world data for use by its participating physicians. These measures benchmark quality and other data across comparable oncology practices, providing organizational learning to advance access and provide quality cancer care. The link between cost and quality has not been well developed. The CMS Oncology Care Model has included cost information, but given its focus on medical oncology practices, it does not reflect the total cost of care. More attention is needed on approaches to link cost and quality.

Databases provide evidence for clinical, managerial and policy decisions that also may challenge well-established clinical and hospital procedures. Some of these, while revenue-generating for the institution, are of low value or are harmful for the patient, such as overutilization of mammography, and present management and clinical leadership with the challenge of de-implementing or rescinding such practices [41]. This is achieved when the use of evidence-based guidelines is given priority over economic benefit. That requires management's collaboration with clinical leadership.

3.2. Cancer as an organizational strategy

The effective delivery of cancer care requires an integrated management and clinical partnership and structure to support patient-centered, high-quality, evidence-based and high-value care along the care continuum. Cancer care is more than a clinical program; it has to be an organizational program as it involves multiple technical steps and interfaces among providers and departments that affect care outcomes [42,43]. COVID-19, and the prospect of future pandemics, adds to the challenge with the urgency of cancer treatment, the need to maintain the health of clinical staff and protect the safety and well-being of patients and their families, while meeting public health requirements.

Clinical operations staff and their management are the front line of the organization and are essential to improving cancer care and the care experience. These managers and staff serve as the operational bridge that translates the organization's core values, and they are essential for the achievement of institutional objectives. Executive management provides the structural framework and critical support to these frontline managers and to cancer specialty physicians (employed and private practice) to break down silos and bridge the clinical program and essential organizational functions needed to support cancer care, such as diagnostic imaging, pharmacy, research support for clinical trials,

revenue cycle and managed care contracting, information technology, palliative care and home care for symptom management, and outreach for screening. Such a bridge requires alignment of incentives and an infrastructure that facilitates communication, engaging and empowering staff so that all recognize that their individual contributions are part of a larger health care effort. This effort involves the full care continuum and its relationship to the larger organizational field.

The findings of a national survey of hospitals and their use of quality improvement studies offer potential to improve the care process, as measured by standard indicators of hospital performance [44]. Such approaches are receiving recognition as an important component of quality cancer care along the care continuum, including survivorship planning [45]; reducing infusion wait time [46]; participation in interdisciplinary conferences [47]; and improving tobacco cessation in a clinic setting [48].

COVID-19 accelerated the need for improved coordination across organizations and providers, with many expanding on or introducing strategies such as daily huddles and accelerating IT and data initiatives to meet changing priorities. Meeting the demands of the COVID-19 pandemic has required that many clinical and nonclinical personnel perform their functions in uncommon ways, often remote from patients and one another and linked only through technology. Health care is a human, interpersonal enterprise, not a commercial transaction that can be conducted easily through electronic communications. As health care organizations work to meet new and changing COVID-19 guidelines by adapting care delivery models and expanding the use of telehealth, the provision of patient-centered care is increasingly stressful, especially as patients continue to face the realities and uncertainty of a cancer diagnosis. Scheduling delays in treatment regimens and the less personal way these delays are conveyed to patients – as well as the logistical challenges of maintaining continuity of care – are challenging under the best conditions, much less during a pandemic. Ensuring patient-centered care in a post-COVID era remains a managerial challenge, but the pandemic already has presented opportunities for innovation that could easily be adopted for some approaches to care delivery.

While challenging, the health care system and its infrastructure are a platform for evaluating various approaches as natural experiments. Perhaps most opportune is the NCI NCORP national network of participating medical providers and hospital and health systems that already are engaged in cancer care delivery research, with ready capacity to conduct care delivery studies. Several issues related to COVID-19 should be studied to determine their impact on outcomes and the patient experience. These include options for managing the care of patients who are unable or unwilling to come to a cancer center for an in-person provider visit; systems for monitoring oral chemotherapy or hormonal medication compliance for a metastatic breast cancer patient when telehealth is not effective; and ways to offer clinical trials to patients or monitor their clinical trial progress so the studies can continue. The NCORP already has launched some COVID-19 related studies [49], and it is uniquely positioned to contribute to the development of new evidence-based practices, as its scientists can design studies rapidly to assess interventions and evaluate outcomes related to these and other issues.

3.3. *Leveraging the organizational field*

COVID-19 has demonstrated that executive management must recognize that many challenges are external to the organization for which managers are responsible and plan accordingly. The expanding role of organizational alliances, reassessment of "just-in-time management" and supply chains is an attempt to extend the boundaries to more effectively manage care across the care delivery environment.

New reimbursement models for cancer span across providers and call for organizational alliances and some co-investment, or risk-sharing. This requires participation by clinical leaders and support from executive managers, as such partnerships involve decisions on the fair allocation of resources and associated benefit. Within these partnerships, executive management must have a strategy that frames innovative developmental and inter-organization programs in ways that are meaningful and relevant to other organizations in the relevant organizational field. As these arrangements fall outside the formal boundaries of organizations' command and control approaches, unique tactics are needed. Successful alliances often begin by pursuing "small wins," a phrase used by Karl Weick to describe initial interactions that provide the basis for developing a dialogue, attracting supporters and changing the underlying premise influencing past relationships. For cancer patients, especially now and in the post-COVID era, it is critical to reduce hospitalizations, length of stay, and emergency department visits. Managing the care of patients and their symptoms at home is not within the usual scope of hospital staff. Neither is such care a mandate of certified home care organizations, but home care organizations have the staff expertise to conduct home visits and work as an extension of the medical practice, provided there is a sustainable financial model. Solving patient care problems across organizational boundaries and along the care continuum requires management's commitment to sharing investment for mutual benefit and finding ways to create health care teams of the future that span organizational boundaries enabled by real time and digital communications technology.

4. Conclusion

Moving forward, continuing advances in science and clinical application within a changing health care system will present unrelenting challenges to the provision of high-quality health and cancer care in the community. The onslaught of the COVID-19 pandemic on a global scale – and the likelihood that these challenges will define the future of health care in the U.S. and other high-income countries – reminds us that management is responsible for ensuring that the health system and its supportive infrastructure are available and accessible to meet the infectious disease and cancer needs of the population while managing a financially sustainable operation. This involves difficult management decisions, made in close collaboration with the clinical leadership within the hospital or health system; a rethinking of care processes, differentiating between what is useful and not by implementing evidenced-based care improvement interventions and de-implementing inappropriate or excessive interventions, with the goal of minimizing patient harm, maximizing efficient use of resources, and improving population health [50].

Though the challenges are significant, there are signs that, at least within the cancer care microcosm, managers and clinical leaders are in dialogue and collaborating to meet this responsibility:

- The public sector and the NIH/NCI have played an important role in many clinical practice advances that are now taken for granted. In a public-private partnership with community hospitals, the NCI provided the infrastructure and served as a catalyst for advances along the continuum of care in the community setting [43]. More than ever, these efforts are needed to meet the challenges of an advancing science, clinical application, changing disease patterns, and a complex and evolving health care system.
- Extensive collaboration is the cornerstone to improving cancer care within a community setting. In 2019, the U.S. National Academies of Sciences, Engineering and Medicine (NASEM) issued a report calling for coordination of cancer control efforts across various federal agencies so that relevant issues, such as quality, scientific advances, safety, and cost and payment, could be addressed in an integrated way across the sectors involved in the delivery of care [51]. These efforts may represent the prototype for improved collaboration in the management of both acute and chronic disease as well as for unanticipated events such as a pandemic.
- Programs such as the NCORP aim to conduct cancer care delivery system research across a national network of community oncologists

and health care organizations and systems. This network offers the capacity to collaborate with the clinical community to develop evidence-based interventions across the full continuum of care. Such interventions include evaluation to improve care processes, assess alternative reimbursement models, and study new care delivery models as changes in science and the health system accelerate. Finding ways to expedite the timeframe for the study of these urgent issues is important if we are to leverage the value of these programs.

- Hospitals are strengthening their cancer service lines with improved alignment with cancer specialty physicians and organizational support to ensure patient- centered care. COVID-19 has accelerated efforts to develop home-based programs to manage symptoms through home care partnerships and expanded use of digital monitoring technology. Some providers have introduced home chemotherapy infusion, despite the financial impact under some current payment models, and many have launched aggressive efforts to address the delays in cancer screening due to COVID-19. Others are addressing work process redesign through strategies such as LEAN Six Sigma [52]. In the future, cancer programs will be faced with increasing competition from the commercial sector, including technology companies, cost pressures and consumerism, which will require management flexibility, innovation, and rapid decision-making.

The building blocks for multilevel approaches and the objectives of the Triple Aim are in place, and new paths within the public and private sectors are being forged to improve cancer care in the community, with implications for the larger health system. Success is contingent upon the development of a shared vision, a supportive learning environment and building trust between management and clinical leadership. As suggested by John Schaar, a political scientist and futurist:

> *The future is not someplace we are going, but one we are creating. The paths are not to be found but made. And the activity of making them changes both the maker and the destination* [53].

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Declaration of Competing Interest

The authors report no declarations of interest.

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About the Authors

Arnold D. Kaluzny, PhD, is professor emeritus of health policy and management and director emeritus of the Public Health Leadership Program at the University of North Carolina at Chapel Hill Gillings School of Global Public Health. He is also a senior research fellow at the UNC Cecil G. Sheps Center for Health Services Research and a member of the UNC Lineberger Comprehensive Cancer Center.

Kaluzny has served as consultant to a number of private and public research and health service organizations, universities, and various international, federal and state agencies, including Project HOPE, the World Health Organization, the Joint Commission on the Accreditation of Healthcare Organizations, the Department of Veterans Affairs, the Agency for Health Care Policy and Research, the Institute of Medicine of the National Academy of Sciences, and various programs and institutes within the National Institutes of Health (NIH), including the National Cancer Institute (NCI). From 1991 through 1995, he was a member of the Board of Scientific Counselors for the NCI's Division of Cancer Prevention and Control and served as chair from 1993 to 1995. He was an adviser to the NCI National Community Cancer Centers Program (NCCCP) evaluation, and in 2009, received the NIH Director's Award for his contributions as a member of the team that developed and implemented

the NCCCP. In 2013, he received the NIH Award of Merit for vision and leadership that invigorated multi-level research in cancer care.

Kaluzny is author or co-author of numerous articles, and co-author of several books, focused on the organizational factors affecting program implementation and change in a variety of health care organizations. Throughout many of these publications, emphasis was given to cancer care and research and continuous quality improvement initiatives in both organizational and primary care settings. His book, *Managing Disruptive Change in Healthcare: Lessons from a Public-Private Partnership to Advance Cancer Care and Research* (Oxford University Press, 2015), was co-authored with Donna O'Brien. In all these endeavors, a major focus has been to strengthen the science base of policy and practice.

He has been a member of several editorial boards, including the *Health Care Management Review*, *Quality Management and Health Care*, *Health Services Research*, *Medical Care Review* and the *Joint Commission Journal on Quality Improvement*, and has served as an associate editor of *Journal of the National Cancer Institute*.

Kaluzny earned an undergraduate degree in economics and chemistry from the Wisconsin State College at River Falls (now the University of Wisconsin-River Falls), a Master of Healthcare Administration (MHA) degree in hospital administration from the University of Michigan School of Business, and a doctorate in medical care organizations and social psychology from the

University of Michigan at Ann Arbor's Horace K. Rackham School of Graduate Studies.

Donna M. O'Brien, MHA, is president and chief executive officer of Strategic Visions in Healthcare LLC, a New York City-based consulting firm that specializes in health care strategy and clinical program development. She has more than 25 years of health care experience in academic medical centers, multi-institutional health systems, and community hospitals, including as executive vice president of the Catholic Health System of Long Island (a $2 billion regional health system), and at the University of Texas MD Anderson Cancer Center, in Houston, where she was responsible for inpatient hospital operations.

Over the past 20 years, O'Brien has served on the board of directors of three national hospital systems, including the Dallas-based Christus Health, where she was a founding member of the board.

From 2005 to 2014, she served as a special adviser to the Office of the Director of the NCI and senior adviser to the NCI Community Cancer Centers Program. She has co-authored many NCCCP-related publications, including *Managing Disruptive Change in Healthcare* (2015). In 2009, she was presented with the NIH Director's Award for contributions as member of the team that developed and implemented the NCCCP.

O'Brien has served on numerous boards, councils and commissions, including the Governor of New York State's Commission on Healthcare Facilities for the Twenty-First Century, which provided policy recommendations

on restructuring health care in light of the changing environment. She is currently a member of the board of directors of the Washington D.C.-based International Cancer Expert Corps and on the Board of Trustees of the College of the Holy Cross in Massachusetts.

A graduate of the College of the Holy Cross, O'Brien earned a Master of Healthcare Administration (MHA) degree from St. Louis University. She is a fellow in the American College of Healthcare Executives.