OXFORD

JNCI J Natl Cancer Inst (2020) 112(6): djz234

doi: 10.1093/jnci/djz234

Commentary

Evolution of Cancer Care Delivery Research in the NCI Community Oncology Research Program

Ann M. Geiger, MPH, PhD,[1,*] Ann M. O'Mara, PhD, RN, FAAN,[1] Worta J. McCaskill-Stevens, MD,[2] Brenda Adjei, MPA, EdD,[1] Priyanga Tuovenin, MA,[1] Kathleen M. Castro, RN, MS, AOCN[1]

[1]Division of Cancer Control and Population Sciences, National Cancer Institute, Rockville, MD and [2]Division of Cancer Prevention, National Cancer Institute, Rockville, MD

[*]**Correspondence to:** Ann M. Geiger, MPH, PhD, Division of Cancer Control and Population Sciences, National Cancer Institute, 9609 Medical Center Dr., Rockville, MD 20852 (e-mail: NCINCORPCCDR@mail.nih.gov).

Abstract

Research seeking to improve patient engagement with decision-making, use of evidence-based guidelines, and coordination of multi-specialty care has made important contributions to the decades-long effort to improve cancer care. The National Cancer Institute expanded support for these efforts by including cancer care delivery research in the 2014 formation of the National Cancer Institute Community Oncology Research Program (NCORP). Cancer care delivery research is a multidisciplinary effort to generate evidence-based practice change that improves clinical outcomes and patient well-being. NCORP scientists and community-based clinicians and organizations rapidly embraced the addition of this type of research into the network, resulting in a robust portfolio of observational studies and intervention studies within the first 5 years of funding. This commentary describes the initial considerations in conducting this type of research in a network previously focused on cancer prevention, control, and treatment studies; characterizes the protocols developed to date; and outlines future directions for cancer care delivery research in the second round of NCORP funding.

The challenge of providing high-quality cancer care in the context of increasing treatment complexity, an aging population with a high prevalence of comorbidities, and a rapidly changing health-care delivery environment has been recognized for at least two decades. In 1999 (1) and again in 2013 (2), the Institute of Medicine (now National Academy of Medicine) identified key challenges to the delivery of high-quality cancer care in the United States, including inadequate patient engagement in decision-making, insufficient use of evidence-based guidelines, lack of care coordination, inconsistent measurement and clinical application of patient-reported outcomes, and unsustainable patient and societal costs of care. The American Society of Clinical Oncology and National Comprehensive Cancer Network have both highlighted reimbursement pressures as a practice-level barrier to high-quality care (3,4). Those two groups, plus professional groups such as the Oncology Nursing Society and patient advocacy groups including the National Coalition for Cancer Survivorship, feature improvement to cancer care delivery in their activities (5,6).

The National Cancer Institute (NCI) has for many years supported research aimed at identifying, understanding, and intervening on these care delivery challenges. Although community practice participation in such studies was limited, they were actively and successfully participating in cancer prevention, control, and treatment studies in the NCI Community Clinical Oncology Program (7) and engaging in quality improvement activities in the NCI's Community Cancer Centers Program (8). Thus, recognizing the need to include community-based practice settings to increase generalizability and a venue in which to test delivery system-based interventions, in 2014 the NCI included cancer care delivery research as part of the new NCI Community Oncology Research Program (NCORP).

The original goal of cancer care delivery research in NCORP was articulated by Kent et al. as "evidence-based practice change" in topics of importance to patients and clinicians in diverse practice settings (9). The requests for NCORP applications issued in 2013 operationalized this goal by broadly defining cancer care delivery research as

> a multidisciplinary field of scientific investigation that studies how complex, multi-level forces including social factors, financing systems, organizational structures and processes, health technologies, provider and individual behaviors affect cancer outcomes, access to cancer care, the quality and cost of cancer care and ultimately the

Received: October 3, 2019; **Revised:** November 27, 2019; **Accepted:** December 11, 2019

> health and well-being of cancer patients and survivors. Its focus includes individuals, families, organizations, institutions, providers, communities, populations, and their interactions.

The requests went on to specify expected activities such as creation of a data infrastructure, secondary analyses to better understand patterns of cancer care, observational studies of alternative care models, and interventional studies of approaches to improve care delivery practices (10–12).

The purpose of this commentary is to articulate how the initial conceptualization of cancer care delivery research in NCORP has evolved in response to the interests and capacity of individuals and organizations involved in the network. We have three objectives: describe the initiation of NCORP cancer care delivery research, characterize the study types and topics that emerged during this growth period, and outline the future direction of cancer care delivery research in NCORP.

Initiation of NCORP Cancer Care Delivery Research

Funding began in 2014, with the first year focused on understanding how NCORP could best contribute to cancer care delivery research and building capacity to plan and conduct studies. To fulfill their role in supporting study development and providing research infrastructure, the Research Bases (13) formed committees with a focus on care delivery science, identified scientific experts to develop studies, and adapted their operational processes to accommodate protocols, including randomization of and data collection from nonpatient study participants such as clinicians and organizations. Preparing to conduct research activities led the 34 Community Sites and 12 Minority/Underserved Community Sites (14) to identify champions for cancer care delivery research and to establish relationships with stakeholders across their organization who traditionally had limited engagement with research. Research Bases and Sites worked together to identify study topics that would be germane to cancer care in the community and feasible within the network.

Cancer care delivery research protocols began to be submitted in the second year of funding, with four studies open and accruing participants by the end of year three (Table 1). An additional four studies opened in funding year 4, nine in year 5, and one in the first month of year 6. The first three open studies are expected to close within the first half of year 6. Approximately 6000 patients and 400 clinicians and staff have participated in studies so far. Several hundred practices have exhibited a strong interest in cancer care delivery research by providing organizational information. These accomplishments have demonstrated the capacity of NCORP for cancer care delivery research.

NCORP Cancer Care Delivery Research Topics and Study Designs

The 18 cancer care delivery studies open in NCORP as of October 1, 2019, encompass a diverse set of topical areas, study designs, patient populations, and outcomes (Table 1). The most frequent scientific gaps being addressed, defined using National Library of Medicine Medical Subject Headings, are understanding or improving guideline adherence (n = 5) and health service accessibility (n = 4). Studies randomizing practices account for eight of the studies, with individually randomized designs used for an additional two studies. The patient populations include children, adolescents, young adults, and adults with hematological malignancies and both early- and late-stage breast, colorectal, lung, prostate, and other solid tumors; 11 studies include more than one cancer type as an eligibility criterion. The diversity of patient populations means that the studies are being conducted in medical, radiation, and surgical oncology as well as urology settings. Patient outcomes of interest include knowledge of treatment options, smoking abstinence, rates of neutropenia, and financial hardship.

The first three protocols to open highlight the potential for the results of NCORP cancer care delivery studies to change practice. A protocol prospectively assessing financial hardship in patients with metastatic colorectal cancer (NCT02728804) will lay a foundation for systematic efforts to address this growing challenge for patients. Another protocol seeks to increase guideline-based prescribing of colony stimulating factor to prevent neutropenia through use of automated recommendations integrated into electronic medical records (NCT02728596). Although many automated recommendations have been incorporated into electronic medical records, the effectiveness of this approach has rarely been tested. Finally, a protocol testing the use of decision aids (NCT03103321) is intended to provide insight into strategies that might reduce racial and ethnic disparities in cancer treatment.

The heterogeneity of topics, designs, populations, and outcomes is consistent with the breadth of potential research outlined by Kent et al. (9). Those authors recognized guideline adherence and accessibility of care as potential areas of focus. Although interventional research was a goal, having one-half of the initial protocols designed as randomized studies was unexpected and likely reflects the NCORP network's expertise in and decades of experience with studies. Trials randomly assigning by practices rather than individuals addresses the need to understand and intervene on clinician and organization contributions to delivery challenges. This design also facilitates the characterization of clinical settings for the purposes of understanding generalizability at the practice level. The diverse mix of patient populations and outcomes illustrates the recognition that cancer care delivery research concepts are applicable across all age groups, cancer types, and cancer care specialties. Overall, the rapid development of a diverse portfolio demonstrates the potential for NCORP-based research to have a high impact on improving cancer care delivery.

Initial Observations on Feasibility

Although a comprehensive assessment of feasibility will not be possible until data from closed protocols begin to be analyzed, several themes have emerged. Patient accrual for studies has been initially slow then accelerates, consistent with what often occurs in cancer prevention, control, and treatment studies. A cancer care delivery research-specific discovery was that clinical and research staff discomfort with health expenditures topics substantially limited accrual. Addressing this with training rapidly increased accrual, and one of these studies will be among the first closed protocols.

Clinicians and staff have demonstrated a willingness to provide data as study participants both in quantitative surveys and less familiar qualitative methodologies such as key informant interviews and focus groups. The major challenge in accruing clinicians and staff is that requests for participation in NCORP studies compete with numerous research and nonresearch

Table 1. Activated Cancer Care Delivery Research protocols in the NCI Community Oncology Research Program as of October 1, 2019

Scientific gap*	Title (ClinicalStudies.gov identifier)	Study design	Patient outcome	Patient population	Funding year activated
Guideline adherence†	A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention (NCT02728596)	Randomized (practice)	Stable rates of febrile neutropenia	Adults with breast, colorectal or non-small cell lung cancer	3
	Improving the Use of Evidence-Based Supportive Care Clinical Practice Guidelines in Pediatric Oncology (NCT02847130)	Observational	Rates of febrile neutropenia; chemotherapy-induced nausea and vomiting; and offering of fertility preservation	Children with any cancer	3
	Documentation and Delivery of Guideline-Consistent Treatment in Adolescent and Young Adults with Acute Lymphoblastic Leukemia (NCT03204916)	Observational	Receipt of care consistent with guidelines	Adolescents and young adults with acute lymphoblastic leukemia	4
	Assessing Effectiveness and Implementation of an electronic health record Tool to Assess Heart Health among Survivors (NCT03935282)	Randomized (practice)	Number of patient-reported discussions with providers about cardiovascular health	Adults with breast, colorectal, endometrial, gynecological, or prostate cancer, or lymphoma	5
	Biomarker Testing in Common Solid Cancers: An Assessment of Current Practices in Precision Oncology in the Community Setting (NCT03804255)	Observational	Appropriate testing of tumor specimens	Adults with breast, colorectal or lung cancer	5
Case management‡	Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy (NCT03860961)	Randomized (practice)	Blood glucose and cholesterol checked per AHA guidelines	Adults with prostate cancer	5
Decision making, shared§	Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men (NCT03103321)	Randomized (practice)	Knowledge of prostate cancer treatment options	Adults with prostate cancer	2
	Increasing Socioeconomically Disadvantaged Patients' Engagement in Breast Cancer Surgery Decision Making Through a Shared Decision-Making Intervention (NCT03766009)	Randomized (practice)	Knowledge of breast cancer treatment options and ability to discuss with medical team	Adults with breast cancer	5
Drug utilization‖	Understanding the Impact of Drug Shortages on Oncology Care (NCT03953027)	Observational	Patient receipt of non-standard care	Adults receiving infusion chemotherapy	5
Health expenditures¶	Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer (NCT02728804)	Observational	Patient report of degree of financial hardship	Adults with metastatic colorectal cancer	2
	Longitudinal Assessment of Financial Burden in Patients with Colon or Rectal Cancer Treated with Curative Intent (NCT03516942)	Observational	Patient report of degree of financial hardship	Adults with early-stage colorectal cancer	4
	Assessing Financial Difficulty in Patients with Blood Cancers (NCT03870633)	Observational	Patient report of degree of financial hardship	Adults with hematological malignancies	5
Health service accessibility#	Implementation of Smoking Cessation Services within NCORP Community Sites with Organized Lung Cancer Screening Programs (NCT03291587)	Randomized (practice)	Smoking abstinence	Adults undergoing lung cancer screening	4
	A Stepped-Care Telehealth Approach to Treat Distress in Rural Cancer Survivors (NCT03060096)	Randomized (individual)	Feasibility of proposed intervention aimed at reducing survivor distress	Adult survivors of non-metastatic breast, colorectal, prostate, uterine, or cervical cancer, or any stage Hodgkin or non-Hodgkin lymphoma	4

(continued)

Table 1. (continued)

Scientific gap*	Title (ClinicalStudies.gov identifier)	Study design	Patient outcome	Patient population	Funding year activated
	Supportive Care Service Availability for Cancer Caregivers in Community Oncology Practices (NCT03746314)	Observational	Assessment of resources to support intervention design	Adults with any cancer	5
	Implementing a Virtual Tobacco Treatment in Community Oncology Practices: “Smoke Free Support Study 2.0 (NCT03808818)	Randomized (individual)	Smoking abstinence	Adults with any cancer	5
Implementation science**	Improving Surgical Care and Outcomes in Older Cancer Patients Through Implementation of an Efficient Pre-Surgical Toolkit (NCT03857620)	Randomized (practice)	Postoperative function	Adults with solid tumors	5
	Implementing Palliative Care: Learning Collaborative versus Technical Assistance (NTC TBD)	Randomized (practice)	Patient receipt of palliative care assessment and education	Adults with solid tumors	6

*Scientific gaps defined using the National Library of Medicine’s Medical Subject Headings (MeSH). NCORP = National Cancer Institute Community Oncology Research Program.

†Conformity in fulfilling or following official, recognized, or institutional requirements, guidelines, recommendations, protocols, pathways, or other standards.

‡Activities that a physician or other health-care professional normally performs to insure the coordination of the medical services required by a patient.

§Process of making a selective intellectual judgment when presented with several complex alternatives consisting of several variables, and usually defining a course of action or an idea.

‖Use of drugs as reported in individual hospital studies, FDA studies, marketing, or consumption, etc. This includes drug stockpiling and patient drug profiles.

¶Amounts spent by individuals, groups, nations, or private or public organizations for total health care and/or its various components. These amounts may or may not be equivalent to the actual costs and may or may not be shared among the patient, insurers, and/or employers.

#Degree to which individuals are inhibited or facilitated in their ability to gain entry to and to receive care and services from the health-care system. Factors influencing this ability include geographic, architectural, transportational, and financial considerations, among others.

**Study of methods to promote adoption and integration of evidence-based practices, interventions, and policies into routine health-care and public health settings.

queries from employers, professional organizations, and others. Another barrier has been that the use of password-protected electronic surveys has hindered participation because clinicians and staff find paper forms more convenient. Finally, protocol approval has sometimes been delayed due to an inadequate recognition that clinicians and staff merit the same human subjects protections as patients.

The collection of data about organizations has been more challenging. Processes such as how to identify and gather information from the most appropriate contacts continue to evolve. Although information specific to the practice participating in NCORP is often readily available, responding to questions about parent organizations can be burdensome and the quality of the data collected is unclear. There are few standardized organizational measures, so very similar information has been collected in slightly different ways across multiple studies.

Direct relevance to community practice and parsimonious data collection appear to be the most important facilitators of cancer care delivery research in NCORP. Studies seeking to maximize generalizability by using pragmatic research and intervention approaches seem to be more easily implemented and completed than protocols designed to maximize internal validity through rigid control of the research setting and detailed data collection. This suggests that effectiveness studies may tend to be a better fit for NCORP cancer care delivery research than efficacy studies.

Future Direction of NCORP Cancer Care Delivery Research

The robust growth of the cancer care delivery research study portfolio over 5 years provided a strong justification for continued support of this work. Planning for a second cycle of NCORP also provided an opportunity to refine the scope of this effort in the context of a better understanding of NCORP capacity. Thus, the requests for applications for the second cycle of NCORP funding used a narrower definition of cancer care delivery research: “a multidisciplinary science that seeks to improve clinical outcomes and patient well-being by intervening on patient, clinician, and organizational factors that influence cancer care delivery.”

This definition combines the original emphasis on multidisciplinary science and clinician and practice contributors to patient outcomes with an increased focus on interventional studies that have been shown to fit well with the capacity and interests of the network. The requests for NCORP applications also included a revised description of the most desirable types of studies, which are those that identify modifiable factors in cancer care delivery, particularly at the clinician and practice level; use pragmatic trial designs to assess the effectiveness in community settings of interventions with proven efficacy; and assess implementation facilitators and barriers (15–17).

Cancer care delivery research in the first funding cycle of NCORP has grown rapidly and in a manner consistent with many of the original expectations defined by Kent et al. (9). This includes a diverse set of topics and sophisticated methods to collect data and intervene on clinician- and practice-level barriers to the delivery of high-quality cancer care. Infeasibility of building the data aggregation infrastructure and conducting secondary data analyses as initially envisioned may well have accelerated progress in adapting the cancer control, prevention, and treatment trial capacity of NCORP Sites to interventions aimed at improving care. Research Bases and Sites have stretched beyond traditional trial designs to use effectiveness-implementation hybrid designs (18) and pursue pragmatic studies (19), studies that will hopefully facilitate timely, widespread adoption of approaches shown to be efficacious in NCORP studies.

Despite success in the first funding cycle, there remain unanswered questions about the cancer care delivery research capacity of NCORP. Although patient accrual has been strong and is approximately 60% complete for protocols open on October 1, 2019, accrual of clinicians, administrators, and organizations has been slower. Addressing the full array of care delivery issues a cancer patient or survivor might face is challenging given the need to involve primary care and specialties outside the oncology service line. Barriers to establishing the necessary collaborations include physician shortages, particularly for primary care; high-volume clinical workflows into which it is difficult to integrate unfamiliar research activities; and regulatory requirements. Similarly, policy research on topics such as reimbursement strategies requires access to insurers and policymakers that is beyond the scope of what can realistically be accomplished by research teams in community oncology practice settings.

Achieving the highest possible impact of cancer care delivery research in NCORP requires a robust portfolio of research aimed at reducing disparities in care delivery experienced by underserved groups such as racial and ethnic minorities (10) and rural populations. Concerns about disparities are widespread, meriting mention in the aforementioned National Academy of Medicine reports (1,2). The original conceptualization of cancer care delivery (9) research suggested NCORP could be an invaluable venue for such work, and both requests for NCORP applications identified this as a central goal of the network (10–12,15–17). Of the 18 protocols opened thus far, five include aims seeking to address disparities. Expanding this work will require additional efforts, such as increased collaboration between disparities and cancer care delivery activities within the Research Bases and NCI-sponsored efforts such as the current NCORP disparities working group that includes investigators and clinical representatives from Research Bases, Community Sites, and Minority/Underserved Community Sites.

The long-term value of the NCORP cancer care delivery research portfolio generated in the first funding cycle will likely depend on two things. First is the relevance of the studies and research questions to patients, clinicians, and organizations. Of particular importance is the extent to which results from cancer care delivery research can address the needs of underserved populations and the clinicians and organizations who provide care for those populations. Second is the extent to which interventions have the potential for widespread adoption and long-term sustainability. Developing relevant questions and sustainable interventions in the second funding cycle will require increased engagement of community-based clinicians, staff, and organizations. Facilitating widespread adoption of interventions will benefit from increased incorporation of implementation science concepts and methods into NCORP studies. The evolution of cancer care delivery research from uncertainty to a diverse portfolio in just 5 years suggests NCORP is well positioned to pursue these activities and thus generate the evidence needed to make meaningful and lasting improvements in cancer care delivery.

Notes

The observations and conclusions in this commentary are those of the authors and do not represent the official position of the National Cancer Institute, National Institutes of Health, or other federal agencies.

The authors report no financial or other conflicts of interest directly relevant to this work.

The authors wish to acknowledge the numerous individuals at the NCI Community Oncology Research Program Research Bases, Community Sites, and Minority/Underserved Community Sites, and the National Cancer Institute who have contributed to the success of cancer care delivery research.

References

1. Hewitt M, Simone JV, eds. *Ensuring Quality Cancer Care*. Washington, DC: National Academies Press; 1999.
2. Levit LA, Balogh EP, Nass SJ, Ganz PA. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: National Academies Press; 2013.
3. Kirkwood MK, Hanley A, Bruinooge SS, et al. The state of oncology practice in America, 2018: results of the ASCO practice census survey. *J Oncol Pract*. 2018;14(7):e412–e420.
4. Winckworth-Prejsnar K, McCanney J, Schatz AA, et al. Policy challenges and opportunities to address changing paradigms in cancer care delivery. *J Natl Compr Canc Netw*. 2019;17(5):424–431.
5. Oncology Nursing Society. *Legislative and Regulatory Health Policy Agenda*, 116th Congress, 1st Session. https://www.ons.org/sites/default/files/2019-02/ONSHPAgenda%20116th%20Congress_BOD%20approved.pdf. Accessed December 11, 2019.
6. National Coalition for Cancer Survivorship. *Our mission*. https://www.canceradvocacy.org/about-us/our-mission/. Accessed December 11, 2019.
7. Minasian LM, Carpenter WR, Weiner BJ, et al. Translating research into evidence-based practice: the National Cancer Institute Community Clinical Oncology Program. *Cancer*. 2010;116(19):4440–4449.
8. Clauser SB, Johnson MR, O'Brien DM, et al. Improving clinical research and cancer care delivery in community settings: evaluating the NCI Community Cancer Centers Program. *Implement Sci*. 2009;4:63.
9. Kent EE, Mitchell SA, Castro KM, et al. Cancer care delivery research: building the evidence base to support practice change in community oncology. *J Clin Oncol*. 2015;33(24):2705–2711.
10. Department of Health and Human Services. *NCI Community Oncology Research Program (NCORP) research bases (UM1)*. https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-13-012.html. Accessed December 11, 2019.
11. Department of Health and Human Services: NCI Community Oncology Research Program (NCORP). *Community Sites (UM1)*. https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-13-013.html. Accessed December 11, 2019.
12. Department of Health and Human Services. *NCI Community Oncology Research Program (NCORP) Minority/Underserved Community Sites (UM1)*. https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-13-014.html. Accessed December 11, 2019.
13. National Cancer Institute Community Oncology Research Program. *List of research bases*. https://ncorp.cancer.gov/findasite/research-bases.php. Accessed December 11, 2019.
14. National Cancer Institute Community Oncology Research Program. *NCORP sites*. https://ncorp.cancer.gov/findasite/. Accessed December 11, 2019.
15. Department of Health and Human Services. *NCI Community Oncology Research Program (NCORP) research bases (UG1 clinical trial required)*. https://grants.nih.gov/grants/guide/rfa-files/rfa-ca-18-015.html. Accessed December 11, 2019.
16. Department of Health and Human Services. *NCI Community Oncology Research Program (NCORP) Community Sites (UG1 Clinical Trial Required)*. https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-016.html. Accessed December 11, 2019.
17. Department of Health and Human Services. *NCI Community Oncology Research Program (NCORP) Minority/Underserved Community Sites (UG1 Clinical Trial Required)*. https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-18-017.html. Accessed December 11, 2019.
18. Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3):217–226.
19. Loudon K, Treweek S, Sullivan F, et al. The PRECIS-2 tool: designing studies that are fit for purpose. *BMJ*. 2015;350:h2147.