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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?

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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

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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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