

The Oncology Care Model: Perspectives From the Centers for Medicare & Medicaid Services and Participating Oncology Practices in Academia and the Community

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OVERVIEW

Cancer care delivery in the United States is often fragmented and inefficient, imposing substantial burdens on patients. Costs of cancer care are rising more rapidly than other specialties, with substantial regional differences in quality and cost. The Centers for Medicare & Medicaid Services (CMS) Innovation Center (CMMIS) recently launched the Oncology Care Model (OCM), which uses payment incentives and practice redesign requirements toward the goal of improving quality while controlling costs. As of March 2017, 190 practices were participating, with approximately 3,200 oncologists providing care for approximately 150,000 unique beneficiaries per year (approximately 20% of the Medicare Fee-for-Service population receiving chemotherapy for cancer). This article provides an overview of the program from the CMS perspective, as well as perspectives from two practices implementing OCM: an academic health system (Yale Cancer Center) and a community practice (Hematology Oncology Associates of Central New York). Requirements of OCM, as well as implementation successes, challenges, financial implications, impact on quality, and future visions, are provided from each perspective.

Oncology is a complex and expensive medical specialty with costs rising faster than other medical specialties. The care is often fragmented and inefficient, imposing substantial burdens upon patients. Importantly, data show major differences in the cost of care in different regions of the United States without appreciable differences in outcome,¹ thus identifying opportunities for improvement. For these reasons, the CMMI recognized oncology as an important specialty for a patient-focused model emphasizing care coordination and enhanced services and worked to create the OCM.²

As of March 2017, 190 practices are participating in OCM, with approximately 3,200 oncologists included in the model, providing care for an estimated 150,000 unique beneficiaries (and 190,000 episodes) per year, or approximately 20% of the Medicare Fee-for-Service (FFS) population receiving chemotherapy for the treatment of cancer. The goal of OCM is to use payment incentives and required practice redesign activities to transform oncology care in the United States so that it becomes universally high quality, high value, and patient focused. In addition to usual fee-for-service payments, OCM provides a \$160 per beneficiary per month (Monthly Enhanced Oncology Services [MEOS]) payment to practices to support enhanced services for Medicare bene-

ficiaries receiving chemotherapy. A retrospective analysis is done on each 6-month episode of care to generate a performance-based payment (PBP) for practices that successfully reduce expenditures while providing high-quality care.

In addition to the payment methodology that incentivizes high-value care, there are six required practice redesign activities intended to move practices toward coordinated, patient-focused care: (1) access to a provider on a 24/7 basis with access to the patient's clinical record, (2) use of data for clinical quality improvement, (3) use of certified electronic health record (EHR) technology, (4) treatment of patients according to national guidelines, (5) provision of care navigation services, and (6) documentation of a care plan incorporating the 13 elements of the Institute of Medicine (IOM) care plan cited in the 2013 consensus report on cancer care.³

PERSPECTIVE FROM CMS

CMS appreciates the difficult work that practices throughout the country are undertaking to transform cancer care. Although even early objective analysis of the program's impact to date is still several months away, we are gratified by the anecdotal reports of improvements in patient-centered care. These include improved care attributed to the man-

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dated use of the IOM care plan and the creation of interdisciplinary teams formed to coordinate patient care. Our communications with participating practices often focus on the changes these practices have made to their care processes to improve quality and patient focus. In the design of OCM, such as the payment incentives and through the inclusion of other payers, our goal has always been whole-practice transformation, so we have been pleased to hear many practices report that their enhanced and newly coordinated services are offered to all of their patients, not just Medicare FFS beneficiaries.

OCM is a model test intended to transform and improve the way oncology care is delivered in the United States. The model must work across diverse geographic regions, business models, and practice types. It must function within the existing frameworks of CMS claims and ICD-10 while providing complex care to patients with a diverse array of diseases and comorbidities. Given these challenges, the model is not static; it has already adapted to address early lessons learned, and it will evolve over time as problems are identified and solutions developed.

Early Lessons

Tracking OCM beneficiaries. To be eligible for MEOS payments for a 6-month episode of care, OCM beneficiaries must have a qualifying cancer diagnosis and a qualifying chemotherapy trigger. These beneficiaries must receive the enhanced services described above, including the initial completion of the IOM care plan, with an update to the care plan during subsequent episodes if applicable. These payments and care requirements direct practices to track beneficiaries with specific diagnoses receiving specific therapies, including the dates those therapies were received. This has

required practices to put in place processes that track these data to identify when claims for MEOS payments should be filed, as well as to ensure that enhanced services have been provided to OCM beneficiaries (and that these activities have been documented).

Particular attention has focused on tracking episodes for OCM beneficiaries (with Part D coverage) receiving only oral chemotherapy. The episode commences on the fill date of the chemotherapy (in association with a Part B cancer service in the previous 2 months). CMS cannot provide real-time Part D data to practices, though these data are available to practices on a several-month time lag as part of their quarterly feedback reports. To date, some practices with patients who do not fill their prescriptions in house have contacted pharmacies to obtain the fill dates of oral chemotherapy drugs for their OCM patients, though this is a manual process. We continue to work on identifying best practices and possible solutions to this challenge.

IOM care plan. One of the practice redesign activities requires practices to document a care plan that includes the 13 elements recommended by the IOM consensus committee. These elements were identified as the foundations necessary to provide comprehensive, high-quality care to the oncology patient and promote shared decision making. There has been much discussion about one of the elements—patients' out-of-pocket costs for cancer treatment—specifically how to estimate these costs. Although not traditionally an aspect of health care, increasing concerns about financial toxicity, especially in oncology, have made this an important issue. Practices are working diligently to understand not only the costs they generate specific to chemotherapy, but also costs generated from other aspects of oncology care such as radiation therapy, imaging, and laboratory diagnostics.

Adoption of EHR standards. OCM requires the entry of anatomic staging and other clinically relevant data into its data registry (e.g., molecular mutations that enable the use of targeted therapies). These data will inform the creation of subsequent payment bundles that are narrower and more clinically focused. Collection of quality measurement data is necessary for the calculation of PBPs and for practice quality improvement. The ultimate goal for reporting data to OCM is that required data elements will be seamlessly exported from practice EHRs to the OCM data registry with minimal provider burden.

CMS surveyed the EHR landscape and identified heterogeneity in capabilities, data capture fields, and electronic export standards. Several EHR vendors stated they were waiting for OCM to release such standards before building their EHRs to those specifications. CMS therefore identified the Health Level Seven (HL-7) standard for export, referred to as "Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers," to support submission of staging and clinical data. Additionally, we aligned our quality measures with nationally validated measures and existing registry reporting programs wherever possible. Given

KEY POINTS

- The OCM was recently launched by the CMS Innovation Center.
- OCM uses payment incentives and practice redesign requirements toward the goal of improving quality while controlling costs.
- As of March 2017, 190 practices are participating, with approximately 3,200 oncologists providing care for about 150,000 unique beneficiaries per year (approximately 20% of the Medicaid Fee-for-Service population receiving chemotherapy for cancer).
- Key requirements for practices in OCM are to: (1) provide patients with 24/7 access to a clinician with real-time access to health records; (2) use of electronic health records certified by the Office of the National Coordinator for Health Information Technology; (3) use data for continuous quality improvement; (4) provide core functions of patient navigation; (5) document a care plan that contains the 13 components in the Institute of Medicine Care Management Plan; and (6) treat patients with therapies consistent with nationally recognized clinical practice guidelines.

the spectrum of both practice and EHR capabilities, and the variety of existing registries, there have been some early difficulties. Accordingly, CMS decided to reduce practice reporting requirements in the first year of the model to allow time for continued practice process improvement and for EHR capabilities to further align with OCM requirements. Work continues with the data registry contractor and EHR vendors to make the data registry more user friendly and to improve the automated data export process.

Bladder and prostate cancer care. Target prices for broad cancer bundles inherently include low-cost patients for whom the cost of treatment is lower than the target price and high-cost patients for whom the cost of treatment is higher than the target price. In OCM, the target price is based on the average costs of all patients in each bundle in the historical baseline period adjusted by each practice's baseline experience. In a practice that treats a random distribution of all cancer stages and molecular subtypes, this methodology is appropriate. When separate practices consistently treat patients of different stages, then this methodology may not be appropriate.

CMS noted that, in general, urologists cared for a greater proportion of patients with low-risk bladder and prostate cancer, whereas medical oncologists cared for a greater proportion of high-risk patients. To ensure equity in the model, CMS created separate target prices for high- and low-risk bladder and prostate cancer for episodes beginning after July 1, 2017. CMS identified drugs typically used in the treatment of these different stages of cancer to generate separate target prices.

Future Directions

In the first year of OCM, participating practices have invested considerable energy and resources implementing the model, and CMS has made adaptations where necessary to respond to identified problems. We view the model test as an opportunity to learn about how care and health outcomes can be improved for Medicare beneficiaries with cancer who receive chemotherapy in diverse practice environments.

As noted above, one of the limitations of OCM, as currently designed, are its broad clinical bundles, because anatomic staging and relevant molecular markers are not a part of existing Medicare FFS claims data. By collecting detailed staging and molecular information in the data registry, we plan to link these data with claims to design more clinically refined payment bundles for different stages and molecular subtypes of cancer where meaningful cost and outcome variations exist. Part of this process will involve remaining current in clinical oncology so that molecular mutations with new targeted therapies are incorporated into the data registry as quickly as possible.

OCM also has a robust learning and diffusion component incorporated into the model. Among other activities, such as OCM's online collaboration platform, our webinars will highlight practices that develop successful approaches to practice transformation so that others may benefit from this

innovative work. In addition, CMS has launched a palliative care affinity group, and future affinity groups will focus on topics such as using data for quality improvement to allow practices with specific interests or needs to learn from one another.

CMS looks forward to engaging with OCM practices and other stakeholders during the remaining 4 years of OCM to ensure that this is a successful model test that will improve the quality of cancer care in the United States.

ACADEMIC HEALTH SYSTEM OCM PARTICIPANT PERSPECTIVE (YALE CANCER CENTER)

Smilow Cancer Hospital at Yale New Haven Hospital is the clinical facility of the Yale Cancer Center. Today, we deliver care to one in four patients with cancer in the state of Connecticut. We have 10 community medical oncology and hematology practices and an academic main campus where care is delivered in multispecialty disease teams. We serve as the largest academic referral center in the state and care for the largest proportion of uninsured and underinsured patients.

Rationale for Joining OCM

The transition toward value-based care presents different challenges for a large health system compared with ambulatory oncology practices. Although reducing hospitalizations and emergency department visits represent an opportunity for savings for payers and society at large, for a health system, this savings represents a loss of revenue. For the Smilow Cancer Hospital, OCM served as a catalyst to move toward value-based payment. OCM's MEOS payments would fund clinical infrastructure that would improve oncology care, and the potential for PBPs would offset potential losses in revenue.⁴

In a best-case scenario, OCM would allow us to transform how we care for patients through implementation of new programs in care management, oncology urgent care, implementation of clinical pathways, and expansion of palliative care into the ambulatory setting, while allowing us to earn PBPs for reduced cost and higher-quality care. In a worst-case scenario, OCM would allow us to build this essential clinical infrastructure and gain experience with value-based payment, even if we did not achieve savings or PBPs. With either scenario, Smilow Cancer Hospital leadership believed OCM would enhance the quality of care while providing early experience with an alternative payment model.

Finally, as a National Cancer Institute–designated comprehensive cancer center, our mission is to improve outcomes for patients with cancer; to that end, we must participate in, learn from, and help inform new, value-oriented models for cancer care delivery. Academic centers must have a voice in national conversation that will ultimately redefine quality cancer care and inform the restructuring of our national payment system. OCM gave us this opportunity.

Steps to Prepare for and Implement OCM

Our clinical transformation and cost-saving strategy is focused on keeping patients out of the hospital by providing care management while patients are home, expanding access to urgent visits and symptom management services, and integrating palliative care earlier in the disease process. In many ways, this has meant creating the clinical infrastructure to function as an oncology medical home.

Achieving transformation in care delivery requires uniting multiple stakeholders, including the clinical arm of the school of medicine (Yale Medicine), which employs the physicians and is responsible for MEOS billing, and the hospital (Yale New Haven Health), which is funding most of the infrastructure. We created an OCM executive committee to serve as the decision-making and funding body of the program. We then organized our work into six thematic projects:

1. **Patient identification and MEOS billing:** We built a team that included an Epic report writer, lead pharmacist, lead physician, program manager, and billing representative to translate the detailed patient eligibility criteria into ongoing patient eligibility reports. After multiple iterations, this final patient list was translated into EHR flags and then into work queues for care management, financial counseling, and billing.
2. **IOM care plan:** We worked with our Epic team to centralize the 13 IOM care plan elements into one document. We made a deliberate decision not to burden our physicians and advanced practice providers with additional documentation demands. Instead, we required providers to enter patients' stage and treatment goals when ordering chemotherapy (curative vs. noncurative intent). With this documentation in place, our nurse care managers could fill out the care plan.
3. **Open an oncology extended care clinic:** We developed a business plan to build and staff a new extended care clinic that would be open 16 hours a day, 7 days a week. This center should open in Spring 2017.
4. **Launch a care management program:** The goal of this program is to improve contact with patients when they are home and identify and stabilize early symptom exacerbations before they lead to hospitalizations. We have hired four out of a total of eight OCM care managers.
5. **Integrate clinical pathways into practice:** We have committed to use Via Oncology clinical pathways with the goal of reducing unnecessary variation and reducing the use of high-cost drugs in situations where they do not improve efficacy.
6. **Quality and registry reporting:** We partnered with our tumor registrars and data analysts to define registry requirements. We created hard stops in our EHR to ensure that required documentation would be accessible in structured fields. Our tumor registry has begun abstracting in real-time, a radical change to their workflow.

Successes and Challenges

Participation in OCM requires time-intensive resources from across the organization. There is a constant tension between working to meet the reporting requirements and meaningfully transforming care. Although checklists and EHR tools may help in an audit or improve chance of PBPs, they are unlikely to change patterns of care or reduce cost. Although we are behind on completing each component of the IOM care plan for our more than 3,000 eligible patients, we have made real strides in building the infrastructure we believe will ultimately achieve clinical transformation.

Timeline challenges. Due to the complexity of eligibility requirements described below, it took more than 4 months to finalize our initial patient list; initiation of downstream services (financial counseling, IOM care plan completion, care management) and MEOS billing was delayed until this process was complete.

Barriers with patient identification and MEOS. The patient identification process was rigorous and time intensive and required an iterative report build. Because patients taking oral drugs often received multiple refills when first prescribed, we could not rely on a new prescription to trigger enrollment and instead created a candidate list of patients who received oral prescriptions in the last year. Our pharmacists manually checked disparate data systems for Medicare Part D status and prescription fill verification for thousands of patients. This resource and time-consuming process continues today. There is a critical need for CMS to make this information easily accessible to OCM sites.

We had challenges in the MEOS billing and payment process that have delayed revenue earmarked to support new clinical infrastructure. Because our hospital committed to OCM participation, we have moved forward with clinical program building despite the delayed revenue. Achieving resolution of the billing issues has been slow and labor and time intensive. Going forward, it would be helpful if there were real-time problem resolution at the OCM and CMS support lines.

IOM care plan challenges. Epic did not provide us with an out-of-the-box solution for IOM care plan. Our internal discussions have revolved around whether we should meet the program requirements by creating check boxes—such as, “I closed the referral loop,” or “Treatment benefits and harms discussed with the patient”—or whether we should focus on the spirit of the program and use the care plan to facilitate meaningful discussions with patients. We have chosen the latter and believe that, in the long run, this will facilitate better prognostic understanding and influence downstream health care utilization. In the meantime, we are challenged with completing these care plans and sharing them with more than 3,000 patients.

Reporting. Reporting processes are proving to be more time intensive and manual than we had hoped. For example, classifying patients as having “very high-risk” or “high-risk” prostate cancer is challenging because the data does not exist in structured format in either our EHR or in the tumor registry. Initially, CMS reporting timeframes required

that our tumor registrar begin concurrent abstraction, a dramatic change in their workflow. However, in response to concerns from participating sites, CMS has revised reporting requirements, which has been appreciated by our tumor registrars.

Future Impact on Practice

Like other academic health centers with a strong research mission, we are challenged with balancing our role as a destination hospital for patients seeking the latest treatment options while ensuring that we elicit their true preferences, provide realistic expectations for treatment benefit, and support their quality of life.¹ We believe that OCM will serve as the catalyst to shift care from an inpatient to an outpatient setting.

Financial Feasibility

Under OCM, health systems face revenue loss from reduced inpatient services; our finance team studied the impact that success in the program would have on revenue from Medicare and private payers who would also benefit from the clinical infrastructure we sought to build. Although achieving the 4% reduction in costs required to achieve PBPs would impact the contribution margin, we found the effects would be tolerable over time.⁴

We have not formally modeled how we will fair with PBPs, which depend first on achieving a greater than 4% savings and then on performing well compared with the national average on multiple quality metrics. However, our financial justification for participation in OCM relied entirely on MEOS revenue and modeling of the impact that care transformation would have on our contribution margin. Thus, even without guarantee of PBPs, we felt the program was sustainable.

Impact on Quality

We believe that participation in OCM should improve clinical quality through better care coordination, access to urgent care services, reduction in variability of chemotherapy choice, and earlier integration of palliative care. Furthermore, OCM will ensure ongoing access to total cost of care claims data, which will allow us to provide physicians, disease teams, and community practices with detailed feedback on patterns of care, including hospital admission rates, emergency department utilization, intensive care unit use, chemotherapy near the end of life, and timeliness of hospice.

Participating in OCM has made investments in clinical infrastructure possible that were not feasible before. For 3 years, we attempted to create a workable business model for an oncology extended care clinic. Each time, the model incorporated loss of inpatient revenue and could not be financially justified. Similarly, we wanted to implement clinical pathways to diminish variation in care but had no risk-based contracts, and thus there was no financial incentive to warrant it. In the context of OCM, MEOS revenue could offset these infrastructure costs, and the potential to earn back savings as PBPs could offset some revenue losses.

COMMUNITY PRACTICE OCM PARTICIPANT PERSPECTIVE (HEMATOLOGY ONCOLOGY ASSOCIATES OF CENTRAL NEW YORK)

Hematology Oncology Associates of Central New York is a hematology/oncology practice comprised of 14 medical oncologists, three radiation oncologists, 20 midlevel providers (17 nurse practitioners and three physician assistants), and a total of 280 employees. Our main office is in East Syracuse, New York, with satellite offices in Onondaga Hill-Syracuse and Auburn. The catchment area is approximately one million. There is an infusion center at all three locations, and two sites have radiation oncology. The great majority of chemotherapy is administered in our offices, although we do have admitting privileges at three local hospitals. We have an outpatient pharmacy at our main office to provide and monitor oral oncolytic agents. We actively participate in clinical research and are a main member of the Alliance for Clinical Trials in Oncology, one of the major National Cancer Institute-sponsored cooperative groups.

Rationale for Joining OCM

Ensuring high quality of care for our patients has always been a high priority for our practice. We are Quality Oncology Practice Initiative-certified through ASCO and are one of nine Oncology Medical Homes certified by the American College of Surgeons Commission on Cancer. We have successfully participated in the CMS Meaningful Use program and continue to report quality data through the Physicians Quality Reporting System.

We decided to apply for participation in OCM for many reasons. The bottom line is that we believe that participation will help us provide better care to our patients. Our practice always strives to be progressive and up to date. We truly believe OCM is a better payment model because quality is incorporated rather than just fee-for-service. We also see participation as a way to prepare for the future.

Steps to Prepare for and Implement OCM

We began preparing for OCM in early 2015 when we hired a quality coordinator to help with the Physicians Quality Reporting System; a year later, we hired an incentive coordinator. Our EHR is regularly updated to meet quality reporting. Our chief clinical officer oversees the entire program and reports to our chief executive officer and board of directors, which is comprised of our physician partners. We also have created a quality care committee with representation from multiple departments.

We were fortunate to be accepted in the OCM program initiated in July 2016. As detailed in our application, we have completed the practice transformation plan as required by CMS:

1. Provide and attest to 24/7 patient access to an appropriate clinician who has real-time access to the practice's medical records.
2. Attest to the use of ONC-certified EHRs.
3. Use data for continuous quality improvement.
4. Provide core functions of patient navigation.

5. Document a care plan that contains the 13 components in the IOM Care Management Plan.
6. Treat patients with therapies consistent with nationally recognized clinical guidelines.

Prior to the start date of the OCM program, we had extensive training for our entire staff, including the physicians. Our EHR was updated to include OCM reporting requirements, and the health care providers had to become proficient in incorporating these changes. For example, chemotherapy could no longer be ordered without answering four questions on a dropdown bar that popped up on the screen: prognosis, goals, expected response, and advanced care plan. Pain had to be graded on a scale of 1 to 10, with a treatment plan entered. There is a tab for referral to our survivorship program.

Eligible OCM patients are identified in a number of ways, including review of health records and pharmacy ordering of chemotherapy. There have been initial challenges in identifying patients who were already receiving treatment. Patients receiving oral agents are more difficult to identify, but the EHR is monitored regularly by a dedicated information technology individual.

Once eligible patients are identified and entered into the OCM program, billing and financial services are promptly notified. A dedicated financial services advocate contacts the patient on the telephone and/or in person to explain the program and distribute the required notification from CMS.

Successes and Challenges

Internal monitoring of individual provider performance is performed regularly, and, for the most part, each individual has exceeded 90% compliance. Patients report over 90% satisfaction in monthly surveys.

Our first report to CMS was in February 2017. Five measures were reported, and these are our results from July 1 to December 31, 2016:

1. Prostate cancer (adjuvant hormonal therapy for high-risk or very high-risk disease): None of these patients were seen during the reporting period.
2. Adjuvant chemotherapy is recommended or administered within 4 months of diagnosis to patients under age 80 with stage III colon cancer: 100% compliance (35 patients).
3. Combination chemotherapy is recommended or administered within 4 months of diagnosis for women under age 70 with stage IB-III hormone receptor-negative breast cancer: 100% compliance (27 patients).
4. Trastuzumab administered to patients with stage I (T1c)-III and HER2-positive breast cancer who receive adjuvant chemotherapy: 100% compliance (34 patients).
5. Hormonal therapy for stage I-III estrogen receptor/progesterone receptor-positive breast cancer: 100% compliance (more than 800 patients).

Financial Feasibility

Enrollment in the OCM program has ranged from 311 to 755 patients. Net revenue for the first 6 months of the program

was \$459,958. Expenses are estimated by multiplying the salaries and benefits of the dedicated employees by the percentage of time devoted to OCM activities. Annualized expenses amount to \$616,317. There are many other expenses that are more difficult to quantitate, including the many additional hours of work provided by our clinical staff and those who work in the financial services and information technology departments.

Future Impact on Practice

We will be changing to a new EHR, OncoEMR, and are working with the engineers to insure incorporation of OCM parameters and requirements into the EHR. We feel that the transition from Mosaiq should be fairly straightforward and seamless. This new EHR will be more user friendly and easier to stage new patients and document care plans, meeting the documentation requirements of CMS. We will be adding two new medical oncologists who will be trained in OCM and EHR use. Our quality committee will continue to monitor our programs. We will update and add in-house clinical pathways consistent with national guidelines.

Impact on Quality

To date, we have been very pleased with our participation in OCM. The amount of work to implement the program has been substantial, but doable, largely as a result of assembling a dedicated and competent team of individuals. They are well prepared and have been learning on the job. We believe that our first year has been a success in terms of maintaining and improving quality. The program appears to be financially viable, and although it is difficult to quantitate, we may realize a profit. In terms of the ultimate goals of CMS, we have indeed demonstrated an improvement in record keeping and compliance with the stated requirements of OCM, which should lead to better quality of care for our patients and overall less expenditure of health care dollars, as hospital admissions and emergency department visits will decrease. Alternative payment models appear to be here to stay, and we plan on continuing our participation in OCM and future programs as they become available.

CONCLUSION

OCM provides a path to improving care quality and controlling costs of care in the United States through a partnership between CMS and practices built on the backbone of the current system for reimbursement and care delivery. OCM has prompted practices to enact patient-centered delivery approaches focused on quality that are intended to improve the patient experience with care as well as measurable outcomes. This program is in its initial phase of implementation, and the ongoing experience of CMS and participating practices will provide further insights about feasibility of various aspects of the model, financial feasibility, impact on outcomes, and sustainability. CMS will be monitoring progress of OCM and a host of metrics at participating and comparator sites. Despite initial challenges at sites to implement various aspects of the model, the

aspiration of this program is to provide insights toward future approaches that optimize resources, quality, and patient centeredness in cancer care delivery.

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