

U.S. Health Reform—Monitoring and Impact

Shared Decisions in Cancer Care: Is Medicare Providing a Model?

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With support from the Robert Wood Johnson Foundation (RWJF), the Urban Institute is undertaking a comprehensive monitoring and tracking project to examine the implementation and effects of health reform. The project began in May 2011 and will take place over several years. The Urban Institute will document changes to the implementation of national health reform to help states, researchers and policymakers learn from the process as it unfolds. Reports that have been prepared as part of this ongoing project can be found at www.rwjf.org and www.healthpolicycenter.org.

SUMMARY

Medicare's Oncology Care Model (OCM) is designed to incentivize providers to reduce unnecessary spending, improve care, and involve patients more closely in decisions about the use of chemotherapy. The model includes a 13-point care plan recommended by the Institute of Medicine (IOM) that represents a significant step toward making patients partners in their own care; in particular, it aims the volume of OCM episodes by reducing overly aggressive use of chemotherapy

and underuse of hospice services among patients who are close to death. However, IOM recommendations since 1999 and recent medical literature suggest that a formal shared decision-making process (SDM) remains vitally important. This paper discusses the rationale for and barriers to adopting a more formal SDM. We recommend that SDM be added to the OCM in at least a subset of cancers and/or oncology practices before the demonstration program ends in 2021.

INTRODUCTION

The diagnosis of cancer is at once terrifying and all too common. Each year, more than 1.6 million Americans are told they have the disease,¹ and it is already the leading cause of death among those ages 60 to 79. As the U.S. population ages, cancer diagnoses are projected to increase 45 percent by 2030.²

The health care system response has taken four main approaches: (1) improve prevention; (2) increase screening; (3) intensify research, as in the federal "Cancer Moonshot" initiative; and (4) ensure better use of currently available therapies.

This fourth area, largely out of the public spotlight, is the focus of the Oncology Care Model (OCM) developed by the Innovation Center of the Centers for Medicare & Medicaid Services (CMS). The OCM, launched July 1, 2016, as a five-year experimental program, is part of a broader movement to improve care delivery by changing incentives to "pay for value." It changes how oncology practices are paid for providing chemotherapy, with the goal of reducing costs and improving

quality. With total medical expenditures for cancer expected to reach at least \$158 billion (in 2010 dollars) by 2020, the financial stakes are high. So, too, are the emotional ones.

The overly aggressive use of chemotherapy and underuse of hospice services among patients who are close to death is well documented.³ In particular, the use of chemotherapy in late-stage cancer can raise serious questions of clinical effectiveness and patient autonomy. It is often difficult to tell whether chemotherapy is truly what the patients would want if they were fully informed about alternatives.

One health policy activist, referring to his late wife's long battle with peritoneal cancer, wrote of the "wretchedness of life that becomes worn to the nub by the adverse effects" of chemotherapy. He added:

Our physician referred to each new round of therapy as the "gold standard," meaning the approach that scientific

evidence shows works the best ... What we did not appreciate then was how little evidence there is that ... gold standard treatments produce outcomes that actually matter to patients and families.⁴

This policy paper examines the OCM approach to chemotherapy within the context of “outcomes that actually matter to patients and families.” We focus on shared decision-making (SDM), which is not currently required by the OCM. This paper builds on our 2015 research report, *The Road to Making Patient-Centered Care Real: Potholes and Policy Vehicles*, which described federal policy efforts to make patient-centeredness an integral aspect of care delivery.⁵

The OCM is an influential initiative, involving more than 3,200 voluntary participants in 195 oncology practices nationwide and affecting an estimated 155,000 Medicare beneficiaries.⁶ Its impact will extend beyond Medicare: 16 private health insurers have agreed to pattern their own payment models after it.⁷ In addition, other alternative payment models under CMS consideration are modeled on the OCM. This report includes a short description of the OCM and examines cost, quality, and shared decision-making in cancer; explores the factors keeping SDM out of the OCM; and discusses the policy implications. It is based on a review of the medical and policy literature and interviews with key stakeholders including researchers, physicians, federal officials, and patients.

THE ONCOLOGY CARE MODEL

The OCM is triggered by an initial order for chemotherapy. It does not rely upon pure, episode-based payment (i.e., paying a fixed, predetermined amount). Instead, it pays participating oncologists based upon their usual fee schedule for each traditional Medicare beneficiary and then adds a substantial monthly capitation payment in order to cover an enhanced set of management and support services. Participants can receive additional payments if total spending shows savings relative to a risk-adjusted, practice-specific target amount based on historical spending.

An oncology practice’s share of savings depends upon its adherence to five quality measures related to three common types of cancer: breast, colon, and prostate.⁸ In addition, CMS would calculate a target price for each chemotherapy episode based on baseline, current Medicare expenditures and compare that target price to the performance year actual expenditures in services included in the episodes for the practice. Baseline episode expenditures include all Medicare Part A and Part B expenditures, and certain Part D expenditures, with exclusions for indirect medical education, disproportionate share hospital expenditures, and a few other items. How the practices perform on the total spending for episodes would determine whether it achieved savings. There are two possible risk arrangements: a one-sided, upside-only arrangement, in which CMS takes a 4 percent discount before calculating savings; and a two-sided, upside/downside arrangement with a lower, 2.75

percent discount. CMS would implement a maximum savings percentage on savings a practice could achieve and a risk stop-loss in the two-sided model, both set at 20 percent of the target amount. The two-sided risk option would be available starting in third OCM model performance year.

Oncology costs vary considerably for traditional Medicare beneficiaries with advanced cancer, though these costs have no clear link to survival.⁹ The performance-based component is meant to encourage more prudent interventions and greater care coordination, reducing preventable hospitalizations.

In its 2016 launch announcement, CMS called the OCM a “patient-centered care model,” noting that its enhanced services requirement addresses aspects of patient-centeredness that have often been lacking.¹⁰ These include coordination of appointments with providers inside and outside the oncology practice, 24/7 patient access to needed care, receipt of test results in advance of the patient visit, and access to resources such as pain management or emotional support.

Participating practices must also discuss treatment goals with patients as part of a 13-point care planning process for clinicians recommended by the Institute of Medicine (IOM) in a 2013 report (Table 1). However, CMS does not require shared decision-making as a formal process beyond simple disclosure or discussions.¹¹

SHARED DECISION-MAKING IN CANCER POLICY

Some 600,000 Americans die each year from cancer; it is second only to heart disease as a leading cause of death in the United States.¹² The lethality of cancer has long drawn attention to patterns of doctor disclosure. A 1961 study found that 90 percent of physicians preferred not to disclose a cancer diagnosis at all. The same study found that nearly an identical percentage of patients felt they *should* be told.¹³ By 1979, doctors' attitudes about disclosure had undergone a complete reversal, with 97 percent of physicians indicating a preference for telling the patient.¹⁴

Policy reports have repeatedly sought to rectify this doctor-patient disconnect. A 1999 IOM report explicitly called SDM in oncology as important as technical competence, stating that eliciting patient preferences for treatment is “central to high quality cancer care.”¹⁵ SDM also was recommended by the IOM in 2001, in a palliative care report emphasizing the need for SDM throughout the care continuum.¹⁶ A 2007 IOM report on whole patient care in cancer highlighted decision support for older patients and those of lower socioeconomic status,¹⁷ while a National Cancer Institute monograph that same year again emphasized SDM for all.¹⁸

The 2013 report by the IOM Committee on Improving the Quality of Medical Care—a touchstone in the development of

the OCM—named “engaged patients” as its first priority and devoted an entire chapter to “patient-centered communication and shared decision-making.” The report noted that clinicians seek patients’ treatment preferences only about half the time—though most doctors believe they do so routinely—and it directly addressed the special challenges of oncology:

1. cancer care is extremely complex and patients’ treatment choices have serious implications for their health outcomes and quality of life;
2. the evidence supporting many decisions in cancer care is limited or incomplete; and
3. trade-offs in the risks and benefits of cancer treatment choices may be weighed differently by individual patients

However, the report stated, “clinicians [still] need to elicit patient needs, values, and preferences in these circumstances.”¹⁹

When CMS invited oncology practices to participate in the OCM in early 2015, it explicitly required “*shared decision-making* with beneficiaries to inform their recommendation about whether a beneficiary should receive chemotherapy treatment” (emphasis added).²⁰ But when the program began in mid-2016, that mandate was missing. The need, however, seems clear.

CHEMOTHERAPY APPROPRIATENESS AND COMMUNICATION

Episode-related payment in the OCM remains tied to the number of qualifying episodes, raising the potential for inappropriate increases in service volume. The appropriateness of any particular episode, in turn, involves both clinical criteria and patient preferences—that is, whether a well-informed patient truly wants the procedure or treatment.

Unfortunately, inadequate communication about prognosis and treatment choices is commonplace in advanced cancer,²¹⁻²³ as in the following examples:

- Important conversations about prognosis in advanced cancer frequently don’t occur or take place late in the course of illness with someone other than an oncologist.²⁴

- Many patients receiving chemotherapy for end-stage cancers do not understand it is unlikely to be curative.²⁵⁻²⁶
- Just one in six patients with metastatic cancers could accurately articulate their prognosis, though most had received chemotherapy.²⁷ Cancer patients who don’t recognize that their illness is terminal are more likely to prefer and receive aggressive care at the end of life and are less likely to receive hospice services and palliative care.²⁸
- One-third of respondents to a 2016 survey of cancer patients said they weren’t getting the information about treatment options they needed in order to make an informed decision.²⁹

In 2012, an American Society of Clinical Oncology expert panel concluded that chemotherapy use among patients for whom it had no evidence of clinical value was the most widespread, wasteful, and unnecessary practice in oncology.³⁰

Not all patients prefer to participate in medical decisions.³¹ However, shared decision-making provides a structured approach to facilitate difficult but necessary discussions. It can improve care quality, appropriateness, and value without creating anxiety or diminishing hope, according to studies reviewed in the 2013 IOM report. Thus, SDM could guard

against chemotherapy overuse or underuse, which can be affected by both physician preference³² and patient preference.

Formal SDM also may address social disparities, an ongoing CMS concern. Black and Hispanic patients tend to receive less information from their doctors about the reasons for treatment recommendations.³³ Perhaps as a consequence, black patients with advanced cancer are more likely to make inaccurate estimates of how much longer they have to live than white patients.³⁴

PUTTING SHARED DECISION-MAKING INTO POLICY PRACTICE

Stakeholders we interviewed agreed that OCM adoption of the 13-point care planning procedure could lead to better information sharing, particularly near the end of life. Similarly, they agreed that the OCM promotes patient services that often have been neglected, such as navigational help and emotional support.

Less clear is whether the OCM adequately promotes working *with* patients to elicit “values, preferences, and expressed needs.”³⁵

CMS can examine the decision to initiate chemotherapy, although first use of chemotherapy generally does not raise the same concerns about patient misunderstanding as late-stage use. Agency officials also plan to monitor, through claims data and audits, the time elapsed between referral to hospice and a patient’s death. This communication measure will indicate whether an oncologist shows a pattern of delaying referral for palliative care while instituting or continuing chemotherapy.

Although these activities could complement a requirement for shared decision-making, CMS officials do not recommend a standard SDM process or validated instruments to measure its use. CMS asks about the use of SDM in its patient experience

of care survey, but answers will not be scored for payment purposes because according to CMS, field tests showed it wasn’t adequately reliable.

Though CMS emphasizes that SDM can be challenging to implement in cancer treatment, the 2013 IOM report provides examples of success. Benjamin Moulton, senior vice president of policy and advocacy for the Informed Medical Decisions Foundation, said, “Patients have the right to know the limits of scientific knowledge, how sick they’ll get [from chemotherapy] and what the benefits are” (interview, October 6, 2016).³⁶ However, Dr. Patricia Ganz, a University of California, Los Angeles, oncologist and health policy researcher, praised the OCM for its adoption of the IOM 13-point care plan and said it made significant strides toward SDM in many areas (interview, November 22, 2016).³⁷

Both practitioners and patients may require SDM training³⁸ because, as one 1999 study put it, “physicians have no natural place for [it] in their usual medical interview script.”³⁹ Still, one literature review noted, “Unless we explicitly build patient-centered metrics and flexibility into policy and remuneration models, this facet of quality care may become diluted as we strive to achieve high-value cancer care.”⁴⁰

POLICY CONTEXT

The absence of a formal shared decision-making requirement in the OCM highlights the continued challenge of closing the gap between desirable and doable in value-based care. Can we implement and measure shared decision-making in cancer, or is it still impractical?

Value-based care means obtaining better outcomes at lower cost. Research shows that patients involved in shared decision-making in cancer are more likely to think about treatment risks and benefits fully and to be more satisfied with the clinical encounter. In addition, some evidence suggests that more informed and involved patients have better psychosocial, and in some cases physical, outcomes.⁴¹ But no definitive evidence confirms that making patients partners pays off financially by leading to more conservative treatment decisions.⁴² Promoting SDM as a counterweight to overtreatment and rising costs is expecting too much.⁴³

These findings underscore an important distinction between moral values, which concern patient autonomy and peace of mind, and economic value, which concerns dollars and cents. The OCM accounts for a number of measures of the patient experience of care, including an end-of-life care plan; nonetheless, CMS focuses primarily on conventional cost and clinical indicators in the OCM.

This may be changing. CMS is trying to lay the groundwork for more widespread implementation of SDM, which was endorsed in sections of the Affordable Care Act that have not been targeted for repeal. A 2015 CMS rule authorizing Medicare payment for annual lung cancer screening using low-dose computed tomography for some current and former smokers explicitly mandated a “counseling and shared decision-making visit.”⁴⁴

In addition, the CMS Person and Family Engagement Strategy issued in late 2016 recommended the use of “evidence-based tools and information ... [so that] individuals are better able to participate in bidirectional decision-making.”⁴⁵ A separate report from the independent President’s Cancer Panel also called for web-based tools to support individuals’ “active participation” in decisions about their care.⁴⁶ In the same vein, a roundtable of national experts advocated development of shared decision-making measures that cut across different types of cancer.⁴⁷

Also in late 2016, CMS announced two Beneficiary Engagement and Incentive Models to test different SDM approaches. The Shared Decision Making Model will examine the impact of a four-step shared decision-making process to be integrated into clinical practice by clinicians in accountable care organizations (ACOs). It will test whether SDM improves outcomes and lowers spending and, separately, whether it “results in increased beneficiary satisfaction with care decisions.”

The model will focus on six preference-sensitive conditions, including clinically localized prostate cancer. ACOs will be paid \$50 for each shared decision-making service.⁴⁸ The other SDM model would set up decision support organizations to provide Medicare fee-for-service beneficiaries with educational materials directly. Although this will occur outside the doctor’s office, CMS says it is meant to encourage a closer physician-patient relationship.⁴⁹

Separately, the 2015 Medicare Access and CHIP Reauthorization Act (MACRA) lists “shared decision-making mechanisms” as an area for measure development under the Merit-based Incentive Payment System.

CONCLUSION

The OCM is designed to incentivize providers to reduce unnecessary spending, improve care, and involve the patient more closely in decisions about the use of chemotherapy. OCM adoption of the IOM 13-point care plan is a significant step toward making patients partners in care. However, the medical literature strongly suggests that a formal shared decision-making process remains vitally important.

Given the evidence in the literature, examples of successful implementation, and 18 years’ worth of expert

recommendations, we believe shared decision-making should be added to the OCM before it ends in 2021. The announcement of CMS Beneficiary Engagement and Incentive Models to test different SDM approaches implicitly acknowledges the difference between SDM and a detailed care plan.

Experts disagree over whether SDM is well-understood and measurable enough to be mandated. However, the evidence after nearly two decades of IOM recommendations is certainly

sufficient to support a shared decision-making test in a subset of cancers or in a subset of OCM-participating practices. In the absence of SDM, judgment calls about the appropriateness of chemotherapy may still be dominated by physician judgment.

Statutory language in the ACA, MACRA, and CMS strategy documents commits to power sharing with patients through SDM. The absence of a formal requirement for SDM could lead to inappropriate care in late-stage cancer that proves costly to Medicare and private insurers following the OCM, even if

conclusive evidence of the model's economic impact is not yet available.

A large body of research indicates that many of the 1.7 million Americans diagnosed with cancer every year would greatly value more information-rich conversations with their doctors. Whether or not that desire for greater control over life-and-death decisions saves money for third-party payers, the implementation of shared decision-making shouldn't require a moonshot-level effort.

Table 1: Using patient-centered communication and shared decision-making, the cancer care team should collaborate with patients to develop a cancer care plan. A patient-specific cancer care plan may include the following components:

1.	Patient information (e.g., name, date of birth, medication list, and allergies)
2.	Diagnosis, including specific tissue information, relevant biomarkers, and stage
3.	Prognosis
4.	Treatment goals (curative, life-prolonging, symptom control, palliative care)
5.	Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedule, as well as surgery and radiation therapy (if applicable)
6.	Expected response to treatment
7.	Treatment benefits and harms, including common and rare toxicities and management of toxicities, as well as short-term and late effects of treatment
8.	Information on quality of life and a patient's likely experience with treatment
9.	Delegation of responsibility for specific aspects of a patient's care (e.g., among the cancer care team, primary care/geriatrics care team, or other care teams)
10.	Advance care plans, including advance directives and other legal documents
11.	Estimated total and out-of-pocket costs of cancer treatment
12.	Plan for addressing a patient's psychosocial health needs, including psychological, vocational, disability, legal, or financial concerns and their management

Source: From the 2013 Institute of Medicine report *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis* (Box 3-3).

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