

Outcome Measures for Oncology Alternative Payment Models: Practical Considerations and Recommendations

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Several alternative payment models (APMs) are being piloted to address affordability, equity, and quality-of-care challenges in oncology care. Of these arrangements, the Oncology Care Model (OCM), developed by the Center for Medicare and Medicaid Innovation (CMMI), is among the most extensive, covering about 200,000 chemotherapy episodes annually. The OCM relies on multiple quality measures to determine the level of payment for each provider, with the goal of incentivizing higher-quality care in a cost-effective manner. The OCM's payment design is described in [eAppendix A](#) (available at [ajmc.com](#)).

Despite innovations in the payment landscape, limited consensus exists about what constitutes indispensable quality measures in oncology. The absence of such consensus may not only limit the development of better payment models, which increasingly link payment to quality of care, but also result in a lack of agreement on how value should be defined (and demonstrated) in an era of innovative, ever more expensive cancer therapies. In 2016, a roundtable of national experts in cancer care and oncology measurement recommended that policy makers “prioritize and develop effective cross-cutting measures that assess clinical and patient-reported outcomes, including shared decision making, care planning, and symptom control” and highlighted an “overreliance on condition-specific process measures.”¹ Disease-specific quality measures have been developed, but there is a lack of consensus on what quality measures ought to be utilized across multiple cancers, especially when measuring clinical outcomes.² As oncology APMs evolve, there are practical considerations in the design and implementation of outcome-based measures.

The development of new quality measures for oncology has been underway for many years. For example, CMS together with America's Health Insurance Plans (AHIP) and others developed Core Quality Measures in 8 therapeutic areas, including medical oncology, to assess provider performance.³ This initiative included quality indicators focusing on breast cancer, colorectal cancer, prostate cancer, and, more generally, end-of-life care.⁴ It also identified areas for future measure development in oncology (eg, pain control, hospital admission, 5-year cure rates) and highlighted challenges

ABSTRACT

OBJECTIVES: This paper aims to synthesize existing scholarship on quality measures in oncology, with a specific focus on outcome-based quality measures, which are often underutilized. We also present a set of “core outcome measures” that may be considered in future oncology alternative payment models (APMs).

STUDY DESIGN: Our research consists of a focused literature review, content analysis, and quality measure synthesis and categorization.

METHODS: We conducted a focused literature review to generate key evidence on quality measures in oncology. We studied 7 oncology quality assessment frameworks, encompassing 142 quality metrics, and synthesized recommendations using the Center for Medicare and Medicaid Innovation APM toolkit, focusing on outcome measures.

RESULTS: We present 34 outcome-based oncology quality measures for consideration, which are classified into 5 domains: clinical care (eg, hospital and emergency department visits, treatment effectiveness, mortality), safety (eg, infections, hospital adverse events), care coordination (for hospital and hospice care), patient and caregiver experience, and population health and prevention. Both general and indication-specific outcome measures should be considered in oncology APMs, as appropriate. Utilizing outcome-based measures will require addressing multiple challenges, ranging from risk adjustment to data quality assurance.

CONCLUSIONS: Oncology care will benefit from a more rigorous approach to quality assessment. The success of oncology APMs will require a robust set of quality measures that are relevant to patients, providers, and payers.

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TAKEAWAY POINTS

Evidence is scarce on what outcome measures are most suitable and feasible for future oncology payment models. This paper reviews 7 oncology quality assessment frameworks and existing literature on quality measurement in oncology and recommends that:

- ▶ Outcome quality measures in future oncology payment models should include domains for clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention.
- ▶ Future oncology payment models should draw on the core outcome set but should be tailored to unique care delivery needs and context.
- ▶ The inclusion of diverse outcome measures in oncology may help improve care delivery to all patients with cancer.

TABLE 1. Key Advantages of Process- and Outcome-Based Quality Measures⁷

Measures	Process-Based	Outcome-Based
Actionable feedback for quality improvement	✓	
No or limited risk adjustment	✓	
Rapid data collection	✓	
Evidence available to support measure development		✓
Low cost of testing measure validity		✓
Value to patients and nonphysicians		✓
Ease of defining comprehensive measures		✓
Improvement in measure is linked to better care		✓

Source: Rubin et al.⁷

related to data access and measurement as the standard of cancer care progresses, requiring frequent reassessments.⁴ In parallel, the American Society for Radiation Oncology has been working with the American Society of Clinical Oncology (ASCO) to develop measures “for utilization by both organizations in various quality programs and reporting environments.”⁵ However, no comprehensive set of core outcome-based quality measures in oncology has been published.

Research on healthcare quality measures typically differentiates between 2 key categories: process-based measures, which focus on proper reporting and procedure execution, and outcome-based measures, which involve clinical outcomes and patient-reported experience of care. This paper aims to synthesize existing scholarship on quality measures in oncology, with a specific focus on outcome-based quality measures, which are underutilized given their perceived benefits. We also present a set of “core outcome measures” that may be considered in future oncology APMs. Our study does not aim to provide a definitive list but, rather, to present a diverse set of outcome measures most commonly included in quality initiatives and payment models in oncology.

METHODS

Our research consists of a focused literature review, content analysis, and measure categorization, similar to Macefield et al.⁶ First, our focused literature review summarizes key evidence related to quality

measures in oncology, with an emphasis on classification, their unique advantages and disadvantages, and the challenges related to implementation in clinical practice. Second, our descriptive analysis of the most commonly used quality measures in oncology draws on a convenience sample of existing payment models and other quality assessment frameworks. Our sample includes 7 oncology quality assessment programs, frameworks, and payment models (also referenced as “oncology quality assessment frameworks”), which encompass 142 quality measures: the OCM by CMMI, the Quality Oncology Practice Initiative by ASCO, the Prospective Payment System–Exempt Cancer Hospital Quality Reporting Program by CMS, the Core Quality Measures Collaborative Core Sets by CMS and AHIP, the Oncology Medical Home program by the Community Oncology Alliance, the Osteoporosis Quality Improvement Registry by the National Osteoporosis Foundation and National Bone Health Alliance, and the Oncology Qualified Clinical Data Registry by the Oncology Nursing Society.

In this paper, we categorize these measures into process- versus outcome-based and analyze their frequency. Given our primary focus on

outcome-based quality measures, we decided to expand our literature review to include the evidence base for each of the key outcome measure categories identified. These sources were identified by snowballing from quality measure summaries by CMS and reviewing other relevant literature. In addition, we review and summarize published reports on the impact of emerging oncology APMs on clinical outcomes and spending. We conclude with a synthesis of existing evidence on key outcome-based measures and their appropriateness in future oncology APMs. Finally, we discuss directions for customization and further validation of oncology core outcome measures.

RESULTS

Advantages of Process- and Outcome-Based Measures

Previous scholarship finds that both process- and outcome-based quality measures have advantages and disadvantages (for one such classification, see Table 1).⁸⁻¹⁰ For example, it is generally easier to generate actionable feedback based on process-based measures and there is mostly no or limited need for risk adjustment (unlike the case for quality measures such as mortality, for which complex case mix, indication, and disease stage adjustments are often required).⁷ In addition, data collection for process measures is generally faster, can draw on smaller sample sizes, and does not require advanced statistical analysis to yield practical results.⁷

On the other hand, outcome measures are generally based on clinical end points with proven significance in the quality of care. They are more understandable by patients and nonclinicians and are easier to define comprehensively (eg, hospice admissions for at least 3 days prior to death).⁷ Relatedly, an improvement in process measures may be a useful step in care coordination but may not always have an observable effect on improvement in clinical outcomes, especially when included for billing purposes only.¹¹ Given these realities, the Agency for Healthcare Research and Quality regards outcome-based measures as the “gold standard” in quality measurement.¹² Expert groups such as the Healthcare Association of New York State suggest that “regulators and payers should focus on overall performance (outcome measures), and defer the operations and use of process measures for internal quality improvement by healthcare providers.”¹³

Process-based measures dominate the OCM and other oncology quality assessment frameworks, yet outcome-based measures have an important role to play. Outcome-based measures are directly connected to real-world outcomes, ranging from hospital admissions to mortality and patient-reported outcomes (PROs), reflecting what patients and providers care about most.

Outcome Measures in Existing Oncology Quality Frameworks

Of the 142 quality measures from 7 oncology quality assessment frameworks that we reviewed, 80.3% (n = 114) were process-based measures and 19.7% (n = 28) were outcome-based measures. An earlier analysis of the National Quality Measures Clearinghouse found an even lower proportion of outcome-based measures (7.1%) based on a total of 1958 quality indicators from a wide range of therapeutic areas.¹¹ Of those nearly 2000 indicators, only 1.6% were patient-reported outcome measures (PROMs).¹¹

We condensed the 28 outcome-based measures into 23 unique outcome measures by merging identical or near-identical measures and grouping them into 5 categories: (1) admissions and hospital visits (including emergency department [ED] visits), (2) hospice care, (3) mortality, (4) PROs, and (5) adverse events (AEs) (Table 2).

Admissions and hospital visits. Admissions and hospital visits, after risk adjustment, are important indicators of the appropriateness and timeliness of care. Up to 50% of ED visits are related to complications from chemotherapy, which can potentially indicate suboptimal management of the disease and care coordination (ranging from information sharing among providers to education about end-of-life care).¹⁴

The significant variation observed in admission rates and hospital/ED visits between different providers, even when controlling for other factors, has spurred research related to avoidable hospitalizations and appropriateness of care, especially in late-stage cancer care.¹⁵ In 2016, for example, CMS announced the inclusion of inpatient admissions and ED visits for patients receiving outpatient chemotherapy in its Hospital Outpatient Quality Reporting Program.¹⁶ Including hospital visits in payment models aims to “encourage reporting facilities

TABLE 2. Outcome Measures Identified in Oncology APMs

Category	Unique Outcome Measures
Admissions and hospital visits	<ul style="list-style-type: none"> • Admission to ICU in last 30 days of life • Admissions and ED visits • All-cause ED visits • All-cause hospital admissions • ED visits in last 30 days of life • Hospitalization in last 30 days of life • Unscheduled readmissions within 30 days
Hospice care	<ul style="list-style-type: none"> • Hospice admission for ≥3 days • Hospice admission for <3 days • Hospice enrollment • Hospice enrollment or palliative services • Length of hospice care
Mortality	<ul style="list-style-type: none"> • Death outside of a hospice • Deaths in acute care setting • Died after ≥3 days in hospice • Died in extended care facility (with hospice/palliative care)
Patient-reported outcomes	<ul style="list-style-type: none"> • Fatigue • Patient-reported experience
Adverse events	<ul style="list-style-type: none"> • Inpatient hospital-onset <i>Clostridium difficile</i> infections • Inpatient hospital-onset methicillin-resistant <i>Staphylococcus aureus</i> bacteremia • Healthcare-associated, catheter-associated urinary tract infections • Surgical site infections • Central line-associated bloodstream infections

APM indicates alternative payment model; ED, emergency department; ICU, intensive care unit.

Source: Authors’ analysis of a convenience sample of quality assessment frameworks in oncology.

to take steps to prevent and improve management of side effects and complications from treatment.”¹⁷

Hospice care. Although it offers patients, caregivers, and the healthcare system advantages relative to hospital settings, hospice care is generally underutilized. Quality measures related to hospice care may improve the quality of life of patients with late-stage cancer, reduce spending, and reduce burden among providers and caretakers.

Allowing patients with cancer to receive palliative care in a hospice setting is traditionally associated with improvements in quality of life, as well as system efficiencies. Yet, up to 66% of patients with cancer are not enrolled in hospice in the last 30 days of life, and less than 29% are enrolled for at least 2 months (considered appropriate care), based on an international review of 78 studies published between 1998 and 2011.¹⁸ One factor explaining the suboptimal transition to palliative care may be doctors’ tendency to overestimate survival prospects of a patient.¹⁹ Hospice-related measures aim to reduce wasteful spending on care that is unlikely to improve clinical outcomes and to provide patients with a higher quality of life. Specific provisions may be needed for palliative

chemotherapy and other treatments that can extend the length of life while in palliative care.

Although outcome-based measures in this domain tend to focus on hospice settings alone, recent discussions suggest that palliative care may improve patient quality of life if initiated earlier in the cancer treatment course.^{20,21} In 2012, the National Quality Forum endorsed 14 measures related to end-of-life care, of which several are outcome-based, including “comfortable dying” and bereaved family survey measures.²² Finally, patient- and caregiver-reported outcomes may have a more prominent role to play, as end-of-life care should reflect patient and caregiver preferences.²³

Mortality. Mortality is a common outcome indicator used in both clinical practice and clinical trials, and it may be reported in different ways (eg, patient mortality over a specific period, overall survival, progression-free survival, by the setting of a patient’s death). Additionally, the setting of death (in a hospital vs at home or in a hospice) may play an important role in patients’ quality of life^{18,24} and is sometimes used as part of mortality-related quality measures.

PROs. Ranging from pain to social function evaluation, PROs are increasingly used to evaluate appropriateness of care given their ability to reflect patient needs and preferences, which may vary significantly. The FDA issued a PRO-specific guidance in 2009,²⁵ defining PROs as “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else,” and stating that in general, “findings measured by a well-defined and reliable PRO instrument in appropriately designed investigations can be used to support a claim in medical product labeling if the claim is consistent with the instrument’s documented measurement capability.”²⁵

PROs are relevant in both early and late disease stages, complementing other measures that address outcomes in a hospital setting. In 2016, a multistakeholder roundtable on improving oncology measurement recommended that PROs be collected “before, during, and after treatment.”²⁶ Although more evidence is needed, PROMs have been studied for use during an initial consultation and during shared decision making regarding patient care, aside from tracking treatment progress and patient satisfaction.²⁷ A 2013 report on PROs by the National Quality Forum indicates that several guiding principles for selecting PROMs should be followed: psychometric soundness, person-centricity, meaningfulness, amenability to change, and implementability.²⁸ Progress in drawing on electronic PROs may catalyze the ability of plans to systematically and reliably collect patient- and caregiver-reported outcomes, especially if they impose minimal burden on staff and patients.²⁹

Nonetheless, the use of PROs has been associated with multiple challenges, including representativeness, inclusion of PROs in medication labels, necessity for both standardized and customizable PROs, and operational and organizational barriers to collecting and analyzing them.³⁰ In addition, PRO collection is often resource-intensive, the validity of disease-specific PROs may be limited, and many PROs lack predictive value.³⁰ Despite these challenges, PROs can be useful tools to obtain insight into patient needs and

preferences in order to make better patient-level, as well as policy, decisions and to support further research and development.

AEs. Quality measures based on reporting of AEs aim to lower the number of avoidable incidents, potentially shortening hospitalization length and reducing costs as well as mortality. Initial guidance on the reporting of AEs in oncology trials was published by the Consolidated Standards of Reporting Trials in 2003, and AEs related to oncology care are now understood better.³¹ However, AEs in clinical settings are thought to be significantly underreported, partly driven by voluntary reporting and the use of instruments that may be prone to lower sensitivity.³² Improvements in documentation and electronic reporting are expected to improve the reliability of data about AEs observed in clinical practice (most hospitals do not use electronic health records [EHRs] to “directly measure [or record] patient harm”).³³

If implemented broadly, the magnitude of potential improvements may be significant: Studies have shown that AEs can extend the length of hospitalizations, increase costs of care, and increase mortality up to 2-fold.³⁴

DISCUSSION

Evidence From Early Quality Initiatives in Oncology

Although no comprehensive evaluation of OCM has taken place, limited evidence suggests that previous quality initiatives with outcome-based components have improved care while reducing costs. For instance, during a 2-year pilot in Texas involving 221 oncology patients (Innovent Oncology program by McKesson Specialty Health, Texas Oncology, and Aetna), savings of more than \$500,000 were achieved.^{35,36} The program has also been shown to improve adherence to clinical pathways and clinical outcomes: Pathway adherence has increased from 63% to 76%; reductions in ED visits, hospital admissions, and hospital days of 48%, 34%, and 44%, respectively, were observed; and average inpatient days decreased from 2.1 to 1.2 days.^{32,33} Innovent Oncology based its value-based reimbursement on 3 pillars: (1) Level I Pathways Program (aiming to increase the use of evidence-based treatment guidelines), (2) clinical benchmarking (based on a number of quality indicators), and (3) contract negotiation services.³⁷ Among the quality measures included have been gastrointestinal toxicities, infection, thromboembolic events, pain, and depression.²³

Similarly, an oncology pilot by UnitedHealthcare that drew on episode payments for more than 800 patients with breast, colon, and lung cancer in 5 oncology practices achieved net savings of more than \$33 million (a 34% reduction of the predicted total medical cost).³⁸ Some of the key quality measures used by this pilot included ED and hospitalization rates, admissions for cancer symptoms, febrile neutropenia occurrence rate, admissions for treatment-related symptoms, days from last chemotherapy to death, and hospice days for patients who died.³⁸

However, a lack of a counterfactual (via a matched control group, for example) undermines a direct causal link between quality

TABLE 3. Proposed Outcome-Based Quality Measures in Oncology

	Hospital and ED Visits	Treatment Effectiveness	Mortality
Clinical care	<ul style="list-style-type: none"> All-cause ED visits All-cause hospital admissions Unscheduled readmissions within 30 days Hospice enrollment or palliative services 	<ul style="list-style-type: none"> Response rate Progression-free survival Overall survival 	<ul style="list-style-type: none"> Deaths in acute care setting Death outside of a hospice Died after ≥3 days in hospice Died in extended care facility (with hospice/palliative care)
	Infections	Hospital Adverse Events	
Safety	<ul style="list-style-type: none"> Inpatient hospital-onset <i>Clostridium difficile</i> infections Inpatient hospital-onset methicillin-resistant <i>Staphylococcus aureus</i> bacteremia Healthcare-associated, catheter-associated urinary tract infections Surgical site infections Central line-associated bloodstream infections 	<ul style="list-style-type: none"> Patient safety indicators <ul style="list-style-type: none"> Pressure ulcer rate Retained surgical item or unretrieved device fragment count Iatrogenic pneumothorax rate In-hospital fall with hip fracture rate Perioperative hemorrhage or hematoma rate Postoperative acute kidney injury requiring dialysis Postoperative respiratory failure rate Perioperative pulmonary embolism or deep vein thrombosis rate Postoperative sepsis rate Postoperative wound dehiscence rate Unrecognized abdominopelvic accidental puncture/laceration rate Transfusion reaction count 	
	Hospital Care	Hospice Care	
Care coordination	<ul style="list-style-type: none"> ED visits in last 30 days of life Hospitalization in last 30 days of life Admission to ICU in last 30 days of life 	<ul style="list-style-type: none"> Hospice admission for ≥3 days Hospice admission for <3 days Mortality after ≥3 days in hospice Percentage of deaths at home or in hospice versus in hospital Length of hospice care 	
	Patient-Reported Outcomes	Caregiver-Reported Outcomes	
Patient and caregiver experience	<ul style="list-style-type: none"> Symptomatic adverse events Physical function Disease-related symptoms 	<ul style="list-style-type: none"> Caregiver burden Caregiver need Quality of life 	
Population health and prevention	<ul style="list-style-type: none"> Stage of cancer diagnosis Median time to diagnosis resolution Time from diagnosis to the initiation of treatment 		

ED indicates emergency department; ICU, intensive care unit.

measurement and observed outcomes in these pilots, and more comprehensive evaluations are still needed.

Recommendations for Outcome-Based Measures in Oncology

A synthesis and recommendations for future core outcome sets in oncology are available in **Table 3**. Measures that are generally seen as being closely tied to the quality of care received by oncology patients were classified into 5 quality domains identified by a CMMI APM toolkit³⁹: clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention. When possible, this set of outcome measures should be tailored to unique patient populations, diseases, providers, or other factors in individual payment models. In addition, some measures, such as hospice care—albeit appropriate for patients with more advanced disease—may not be relevant for patients with curable, early-stage

cancer. Future oncology APMs should implement outcome measures relevant to the disease type and stage(s). For a detailed justification and discussion of individual categories and measures, please see **eAppendix B**.

Collecting outcomes data in all 5 domains of cancer care is fraught with challenges that have been documented in multiple studies. For example, to measure and track outcomes properly, programs often require big data that involve multiple sources, such as EHRs, health insurance claims, and patient/caregiver surveys; however, whether data are complete and accessible and can be translated into clinical practice remains a challenging issue.⁴⁰ Many outcome-based measures rely on administrative claims data, which tend to have a long report lag. Some outcomes data, such as hospice care, may be challenging to access, especially when the patient is transferred from one payer to another. Chung and Basch⁴¹ discuss specific challenges related to collecting and using patient-generated health data (including PROs),

ranging from “provider concerns, workflow issues, standardization of patient-generated health data and interoperability of devices/sensors, security and privacy issues” to a “lack of the necessary EHR functionalities and software innovations.” Additionally, statistical challenges related to missing values, highly dimensional data sets, and confounding (bias) require robust statistical approaches that are not yet available in broad clinical practice.⁴² Nonetheless, new approaches are being tested as outcome measures gain support from clinicians, patients, and payers, including a collaborative pilot on establishing a framework to evaluate real-world end points in advanced non–small cell lung cancer led by the Friends of Cancer Research and supported by both public and private stakeholders.⁴³

CONCLUSIONS

As highlighted in this paper, both OCM and other quality initiatives in oncology rely on process- or outcome-based quality measures to determine the quality of care and—in some cases—the level of payment. Given evidence from the literature and an analysis of 7 oncology quality assessment frameworks, we presented a set of outcome-based measures for consideration in future payment models in oncology. Although some measures may be omitted in specific cases, we believe the inclusion of measures related to all 5 domains—clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention—is highly desirable in future oncology APMS. Selective measurement of 1 outcome domain may create perverse incentives for providers to improve performance by underutilizing appropriate care and jeopardize optimal patient outcomes. Where appropriate, indication-specific quality measures should be included to account for quality-of-care complexities associated with individual cancer types and disease stages.

Overcoming hurdles to broader utilization of outcome-based measures in oncology will require a consensus between both payers and providers. These efforts should highlight the benefits of implementing outcome-based measures in oncology APMS (especially relative to the cost of implementation) and solutions to data and evaluation challenges (including risk adjustment and bias control). Future research is also needed to develop best practices for the inclusion and implementation of outcome measures in oncology clinical pathways.⁴⁴ Additional considerations include developing strategies for quality control, dispute resolution, and administrative burden on providers and payers.

Given the steadily increasing costs of oncology care and, in some cases, the availability of multiple high-cost treatment options for patients with cancer, oncology care is in need of a more rigorous approach to quality assessment. The success of emerging oncology APMS will depend on a robust set of quality indicators that are relevant to patients, providers, and payers alike. ■

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eAppendix A. Oncology Care Model’s Payment Design

The Centers for Medicare and Medicaid Innovation launched the Oncology Care Model (OCM) on July 1, 2016, with an objective to improve (1) care coordination, (2) appropriateness of care, and (3) access for beneficiaries undergoing chemotherapy. It consists of a flat per-beneficiary per-month payment, and a performance-based payment, whose level is set based on a practice’s performance in the specific quality measures relative to a matched comparison group. OCM is set to run from July 2016 to June 2021. It applies to both Medicare fee-for-service beneficiaries and patients covered by other payers.

The flat monthly payment aims to cover “care management services for Medicare beneficiaries in a 6-month OCM Episode of Care triggered by the administration of chemotherapy,” totaling \$160 per beneficiary per month. In contrast, the performance-based payment is an episode-based, risk-adjusted payment calculated based on the participant’s achievement on a range of quality measures, such as a reduction in all-cause hospital admissions or improved adherence to clinical guidelines in some cancer types. OCM draws on both process and outcome-based quality measures, with the former relatively more represented. Outcome-based measures used in OCM range from all-cause hospital admissions to emergency department visits, mortality after more than 3 days in hospice, and patient-reported experience of care.

eAppendix B.

In our paper, we organize a new COS in oncology by 5 quality domains based on the APM Design Toolkit published by CMS's Center for Medicare and Medicaid Innovation (CMMI):¹

- Clinical care
- Safety
- Care coordination
- Patient and caregiver experience
- Population health and prevention

Acknowledging the overlap between clinical care and care coordination domains, we treat “clinical care” as direct clinical outcomes (such as mortality and readmissions) and “care coordination” as outcomes linked to institutional or system-level health care delivery (such as timeliness of hospice care).

Measures we recommend for inclusion in an oncology COS are consistent with principles proposed by CMS, aiming to improve quality in four different ways in different APMs:¹

- make the care experience better reflect the patients' goals and preferences,
- produce better health outcomes,
- reduce in better-coordinated care, and
- reduce health disparities.

Here, we discuss the rationale and utility of all measure categories as well as individual measures identified in our targeted search.

Clinical Care

Clinical care for cancer patient in different stages of their disease is complex, resulting in several challenges in the measurement of its quality. Most notably, each patient's prognosis is related not just to the disease and its stage, but also to other factors, ranging from lifestyle choices and genetics to socioeconomic status and proximity of high-quality care. Given these underlying differences between patients and patient pools, it is important to risk-adjust clinical care metrics.^{2,3}

Based on reported clinical practice experience and data availability, at least three key categories of clinical care quality metrics should be included in a future COS in oncology: hospital visits and admissions, treatment effectiveness, and mortality-related metrics.

First, *hospital visits and admissions* are among the most easily measurable proxies for the quality of care provided to cancer patients. Given their high costs and, sometimes, preventable nature, hospital (including emergency department) visits and unscheduled readmissions (typically within 30 days of previous release) are also of special interest to public and private payers, and have been thought to result from “poor quality of care or inadequate transitional care”.⁴ And while readmissions, for instance, cannot be avoided fully, variation in specific metrics observed between providers (even after risk-adjustment) is typically indicative of poor quality of cancer care.⁵

Measuring *treatment effectiveness* is customarily specific to the therapy received and the disease (including the stage) at hand. The most common measures for treatment effectiveness are 1) response rate, 2) progression-free survival and 3) overall survival. Several working groups convened by the ASCO Cancer Research Committee have concluded that overall survival is a preferable outcome measure for a treatment’s effectiveness, but have also underscored that it poses measurement challenges due to a longer time-frame required and multiple confounding variables present.⁶ Similarly, progression-free survival is often linked with quality of life improvements (such as in painful bone metastatic cancers) and thus is a useful metric, if implemented prudently, but is not validated as surrogate for survival in all settings and suffers from imprecise measurement and potential bias.⁷ Finally, a therapy response rate may be indicative of the appropriateness of care and while not possible to definitively ascertain *ex ante*, it is likely to be correlated with the adherence to clinical guidelines and best practices in oncology care.⁸⁻¹⁰ In sum, measuring a treatment’s effectiveness accompanied by risk-adjustment should be considered in future COS in oncology.

Finally, avoiding patient death is among the key objectives of medical professionals, including oncology specialists. Different measures of mortality are used, including those related to the setting in which a patient dies (with the assumption that dying in hospice or with palliative care is a better outcome than dying in an acute care setting – for both the patient and their caregivers¹⁰⁻¹²) and how much time a patient has spent in a specific setting before death (longer stays in hospice facilities are thought to improve the quality of life of the patient and their caregiver(s) while reducing unnecessary spending).^{13,14}

We summarize the three categories presented above in Figure 1.

Appendix Figure 1. Core Outcome Measures in Clinical Care

	Hospital and ED visits	Treatment Effectiveness	Mortality
<i>Suggested metrics</i>	All-cause ED visits	Response rate	Deaths in acute care setting
	All-cause hospital admissions	Progression-free survival	Death outside of a hospice
	Unscheduled readmissions within 30 days	Overall survival	Died after 3+ days in hospice
	Hospice enrollment		Died in extended care facility (with hospice/palliative care)
	Hospice enrollment or palliative services		

Safety

We distinguish between two types of safety outcome measures: infection-related and other adverse events-related. Collecting data on events such as hospital-onset clostridium difficile infections and central line-associated bloodstream infections is important regardless of the payment model in place, given the need to mitigate their occurrence, and their reporting allows

for a relatively straightforward implementation in future outcome sets. Data on infections listed in Figure 2 are collected from CDC’s National Healthcare Safety Network (NHSN), for example.¹⁵

The selection of other adverse events monitored in cancer care may draw on patient safety indicators (PSIs) developed by the AHRQ, which includes outcomes such as the number of Stage III or IV pressure ulcers per 1,000 discharges, postoperative sepsis rate, or the number of medical and surgical discharges with a secondary diagnosis of transfusion reaction.¹⁶ In Figure 2, we report PSIs that are relevant to oncology care. The inclusion of hospital adverse events is especially crucial given a steady increase in their frequency following major cancer surgeries, despite being potentially avoidable.¹⁷

eAppendix Figure 2. Core Outcome Measures in Safety

	Infections	Hospital Adverse Events
<i>Suggested Metrics</i>	Inpatient hospital-onset clostridium difficile infections	Patient Safety Indicators <ul style="list-style-type: none"> ○ Pressure Ulcer Rate ○ Retained Surgical Item or Unretrieved Device Fragment Count
	Inpatient hospital-onset methicillin-resistant staphylococcus aureus (MRSA) bacteremia	<ul style="list-style-type: none"> ○ Iatrogenic Pneumothorax Rate ○ In Hospital Fall with Hip Fracture Rate ○ Perioperative Hemorrhage or Hematoma Rate
	Healthcare-associated, catheter-associated urinary tract infections	<ul style="list-style-type: none"> ○ Postoperative Acute Kidney Injury Requiring Dialysis ○ Postoperative Respiratory Failure Rate ○ Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate
	Surgical site infection	<ul style="list-style-type: none"> ○ Postoperative Sepsis Rate ○ Postoperative Wound Dehiscence Rate ○ Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate
	Central line-associated bloodstream infections	<ul style="list-style-type: none"> ○ Transfusion Reaction Count

Care Coordination

Care coordination is especially challenging in cancer patients due to the complex nature of the disease and its management, often involving multiple specialties and clinical settings.¹⁸ Given that over 40 different definitions of care coordination exist, AHRQ has developed the following definition based on a comprehensive review of them¹⁹:

Care coordination is the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient’s care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources

needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care.

With respect to oncology care, the key objective is to ensure appropriate and timely care is delivered in the most suitable setting, including end-of-life care. In 2013, the Committee on Improving the Quality of Cancer Care recommended that “CMS and other payers design, implement, and evaluate innovative payment models that incentivize the cancer care team to provide cancer patients with timely referral to hospice care for end-of-life care”.²⁰ This is particularly important given the evidence that end-of-life hospice care is associated with “improved quality of life, reductions in symptom distress, better outcomes for family caregivers, and patient and family satisfaction with care.”²⁰

Multiple studies and outcome sets for care coordination exist, including those related to patient and cost outcomes measures as well as those related to care delivery processes.¹⁹ With respect to specific outcome measures in oncology care, we differentiate broadly between hospital and hospice care. Among hospital-related metrics we recommend for consideration are hospitalizations, emergency department visits and admissions to ICU in the last 30 days of life. While in some cases, these are not avoidable, there is evidence that higher event rates do not correspond with high-quality, patient-centered care.^{21,22} For hospice-related metrics, we include admissions under/over 3 days in length (hospice enrollment in the last three days of life is considered poor quality of care because that limits the benefit patients may gain from hospice services²³), hospice mortality (terminally-ill hospice patients live on average longer than non-hospice patients²⁴), the ratio of deaths at home/in hospice relative to in hospital, and the length of hospice care (if clinically appropriate, this provides benefits to the patient²⁵ and their caregivers^{26,27} alike). Proposed measures are summarized in Figure 3.

eAppendix Figure 3. Core Outcome Measures in Care Coordination

	Hospital Care	Hospice Care
<i>Suggested Metrics</i>	ED visits in last 30 days of life	Hospice admission for over 3 days Hospice admission for under 3 days
	Hospitalization in last 30 days of life	Mortality after more than 3 days in hospice
	Admission to ICU in last 30 days of life	Percentage of deaths at home or in hospice, versus in hospital Length of hospice care

Patient and Caregiver Experience

It has been argued that patient-reported experience offers “important additional information to assess the benefits and risks of cancer therapies,” including in cases where longer survival may be traded off for a lower quality of life.²⁸ Patient-reported outcomes (PROs) can be categorized in several ways, such as 1) symptomatic adverse events, 2) physical function, and 3) disease-related symptoms, all of which contribute to the health-related quality of life (HRQOL).²⁸ The assessment of *symptomatic adverse events* (sometimes termed “treatment side effects”) may be based on the National Cancer Institute’s Patient-Reported Outcomes version of

the Common Terminology Criteria for Adverse Events (PRO-CTCAE)²⁹ – an item library of symptomatic toxicities, ranging from difficulty in swallowing to pain and swelling at injection site.³⁰ *Physical function* refers to the ability to perform activities of daily living and as such is included in most patient-reported HRQOL measures.²⁸ For instance, the Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function measures have been validated in cancer patients and shown to be “valid and reliable in multiple race-ethnicity and age groups”.³¹ Finally, *disease-related symptoms* include patient-reported outcomes such as pain, fatigue, dyspnea and cough, with some of these measures overlapping with symptomatic adverse events (in measures such as anorexia).²⁸ Given the lack of symptoms in early cancer stages, some of the disease-related symptoms can be measured on a time-to-event basis while others, where relevant, could be assessed using a symptom palliation endpoint.²⁸

What distinguishes PROs from clinical metrics is a lack of interpretation of the former by a physician and their breadth – ranging from pain intensity to a broader quality of life assessment – and PROs are increasingly used in clinical practice, where they sometimes are “of better quality than clinician-reported data”.³² However, PROs should not replace data “gathered by clinicians directly or indirectly using medical tests,” but rather complement existing data with information not readily available from laboratory tests or physician’s examination, including lifestyle choices.³² A successful example of the use of PROs is PRO-CTCAE (Common Terminology Criteria for Adverse Events) which “enables patients to self-report toxicities and adverse events at least as reliably as clinician-based reporting.”³² Of special importance in the area of PROs are mental health-related metrics, including measures of anxiety and depression, mood and spiritual well-being.

Similarly to patient-reported outcomes, outcomes reported by informal caregivers or family members are of importance in the assessment of cancer care quality. In clinical practice, however, caregiver-reported outcomes are more nascent in literature and their validation has been more limited, with some exceptions.³³ For example, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Hospice Survey includes measures related to communication, timeliness of care, treatment with respect, emotional and religious support and training, and data from this survey have been reported to the CMS by eligible hospices monthly since 2015.³⁴

Different types of measures have been proposed for caregiver-reported outcomes, mainly falling into one of these three categories: caregiver burden, caregiver need, and quality of life.³³ For example, the Caregiver Quality of Life Index–Cancer (CQOLC) focuses on the latter, consisting of 35 items which are evaluated on a five-point Likert-type scale, ranging from alteration in daily routine to spirituality, and has been shown to possess “adequate validity, test-retest reliability and internal consistency” in a study of cancer caregivers.³⁵ However, there appears to be no comprehensive instrument measuring a full breadth of cancer caregiver-related outcomes.³³ Aside from measuring the direct impact of a cancer diagnosis on a caregiver (who may or may not be related to the patient), there is a close relationship between the well-being of the patient and the caregiver.³⁶ As such, it is important to support future research that would lead to the development of reliable metrics for caregiver-reported outcomes.³⁷ Proposed measures in this category are shown in Figure 4.

eAppendix Figure 4. Core Outcome Measures in Patient and Caregiver Experience

	Patient-reported outcomes	Caregiver-reported outcomes
Suggested Metrics	Patient-reported outcomes	Caregiver-reported outcomes
	○ Symptomatic adverse events	○ Caregiver burden
	○ Physical function	○ Caregiver need
	○ Disease-related symptoms	○ Quality of life

Population Health and Prevention

The domain of *population health and prevention* is less commonly included in oncology payment deliberations. Given the role of providers in reducing the burden of cancer in the population, we pay special attention to their role in early detection, although prevention and population health remains an important priority (such as in preventing cancers caused by tobacco use, viruses, or sun exposure).³⁸

Prompt and effective screening for malignancies in cases such as cervical, colorectal, breast, prostate and skin cancers improves patients’ survival prospects and quality of life, and its use has been linked to the reductions of cancer incidence and mortality in the United States.³⁸ The use of proper and early screening often falls under process-based quality metrics – here, we identify key outcome-based measures that could be considered in future COS in oncology.³⁸

The first one, stage of cancer diagnosis, is used by a study that has shown minority patients face challenges in accessing screening and prevention programs, leading to, on average, higher disease stage at presentation, while the availability of affordable cancer screening may lead to improvements in early-stage cancer detection and result in better clinical outcomes.³⁹ Similarly, ensuring the shortest-possible time between screening and diagnosis, and between diagnosis and the initiation of treatment is another challenge which could be overcome by including relevant measures in financial incentives, also given that vulnerable patient populations often face longer wait times and worse clinical outcomes due to suboptimal timeliness of care.⁴⁰ Large variation in both metrics has been reported in breast and cervical cancers, among others.⁴¹

An overview of the suggested outcome measures related to population health and prevention is presented in Figure 5.

eAppendix Figure 5. Core Outcome Measures in Population Health and Prevention

	Population Health and Prevention
Suggested Metrics	Stage of cancer diagnosis
	Median time to diagnosis resolution
	Time from diagnosis to the initiation of treatment

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