

VIEWPOINT

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Outcome Measurement in Value-Based Payments

Value in health care, the balance between outcomes that matter to patients and the costs required to achieve them, is being increasingly recognized as a path to health care reform. The Department of Health and Human Services recently announced its intention to tie 50% of traditional fee-for-service payments, made by the Centers for Medicare and Medicaid Services (CMS), to value or quality through alternative payment models (APM), including accountable care organizations (ACOs) and bundled payments, by 2018.¹ The Centers for Medicare and Medicaid Services is also paying special attention to cancer care, since it accounts for nearly \$125 billion in medical spending and data reveals wide variations in the cost of care delivered with no relation to survival.²

As APMs become more commonplace and value becomes the global metric certain challenges arise. To address the numerator of the value equation we must develop, test, endorse, and use meaningful outcomes measures for the services health care systems provide. Currently, there are an overabundance of validated process measures, and a paucity of outcome measures. As policy experts have noted before, a quality measurement approach that is wholly reliant on process measures misses 2 important facts: patients care more about the results of their care than how these outcomes are achieved, and process measures might contribute to but are not surrogates for outcomes, and omit factors such as staffing patterns, interdisciplinary communication, supportive infrastructure, and transitions of care. However, measuring and reporting outcomes that matter to patients has proven to be difficult, and are especially challenging in cancer, as evidenced by the slow pace of measure development and adoption over the past 2 decades.

In 1999, the Institute of Medicine (IOM) published *Ensuring Quality Cancer Care*,³ an influential report that generated much fervor. It described an aspirational cancer care system and issued 10 recommendations to address pervasive gaps in the delivery of quality care. As of 2014, these recommendations remained largely unfulfilled.³ Further evidence comes from the Department of Health and Human Services, which commissioned the National Quality Forum (NQF) in 2010 to identify areas where outcome measures were needed but not yet developed. The resulting gap analysis found that very few outcomes measures for cancer had been endorsed, and those that have were focused primarily on end-of-life care.⁴

To update that analysis, we compared quality measures for colorectal, breast, prostate, and lung cancer, endorsed by the NQF, ASCO's Quality Oncology Practice Initiative (QOPI), and the International Consortium for Health Outcomes Measurement (ICHOM), as well as those that are being tracked by several major APMs including Medicare Shared Savings ACOs, the PPS-Exempt Cancer Hospitals Quality Reporting Program, and the Oncology Care Model (OCM).

As shown in the Table, all of QOPI's measures, and the majority of NQF's measures represent process measures. Moreover, none of the APMs plan to track actual outcome measures. The quality measures that will be used in Medicare's upcoming Merit-Based Incentive Program are yet to be finalized, so they were not included.

In some respects, it is not surprising that identifying and measuring meaningful outcomes in oncology is difficult. Cancer represents a wide spectrum of heterogeneous diseases, and a detailed outcome measure may be applicable to a limited set of patients in any given time period. In addition delivering cancer care is complex owing to its multi-disciplinary nature (though some cancer centers are starting to collocate multiple treatment and palliative disciplines). Furthermore, cancer often does not follow the linear progression of disease morbidity of other chronic diseases, such as heart failure or diabetes, but rather adheres to a winding course that can abruptly shift in acuity. Finally, quality measures that would apply to patients in the adjuvant setting may no longer apply when patients develop treatment-refractory disease and are pursuing comfort care.

But although developing sound outcome measures is hard, it is not impossible. The ICHOM has used global teams of physician leaders, outcomes researchers, and patient advocate groups to propose cancer disease-specific standard outcome measures (Table). Compared with NQF, QOPI, and APM measures, ICHOM places a larger emphasis on PROs, previously highlighted in the NQF's gap analysis. Whereas the ASCO Quality of Care Committee has focused on using PROs to assess pain and chemotherapy-induced nausea and vomiting, ICHOM has gone a step further to assess important PROs specific for each common cancer type, such as sexual dysfunction and incontinence in prostate cancer, to address the heterogeneity of this disease.⁵

Notably, the OCM requires a documented care plan that contains the 13 components of the IOM's care management plan, which include items such as goals of treatment, estimated out-of-pocket costs, defining physician responsibilities (oncologist vs primary care physician), expected effects on quality of life, and posttreatment surveillance plans.⁶ Although care planning is not outcome measurement per se, this care plan represents an opportunity to improve patient engagement and move closer to the value agenda. The inclusion of the care plan in the OCM does represent CMMI's ability to adopt measures not previously vetted by the NQF and CMS in a pilot program that may set the way for more rapidly testing true outcome measures in upcoming CMMI programs. It remains to be seen whether such accelerated adoption of measures that proffers the opportunity to quickly iterate and pivot is ultimately a better strategy than rigorously testing and validating measures in controlled experimental settings.

What is needed now is an accelerated path for cancer outcome measures to be tested and endorsed through the NQF-convened collaborations. To their credit, the NQF

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Table. Comparative Table of Quality Measures^a

Quality Measure	Breast Cancer	Colon Cancer	Lung Cancer	Prostate Cancer
NQF	HER2 testing; axilla evaluation in early stage; adjuvant chemotherapy considered if hormone receptor-negative; adjuvant trastuzumab for HER2 positive; radiation after lumpectomy with dose limitations to normal tissue	Adjuvant chemotherapy for stage 3 disease; at least 12 lymph nodes examined during surgical resection; appropriate KRAS testing and epidermal growth factor receptor antibody use	Risk adjusted morbidity and mortality after resection; length of stay >14 days after elective lobectomy; radiation dose limitations to normal tissue	Adjuvant hormonal therapy for high risk disease; appropriate use of bone scans
QOPI	Adjuvant combination chemotherapy if hormone receptor-negative; endocrine therapy appropriately recommended and received; adjuvant Trastuzumab if HER2 positive; bone modifying agents received in bone metastases, with renal testing first; appropriate use of positron emission tomography/computed tomography/bone scans and tumor markers	Adjuvant chemotherapy for stage 3 disease; At least 12 lymph nodes examined during surgical resection; Appropriate KRAS testing and epidermal growth factor receptor antibody use; CEA within 4 months of curative resection; appropriate colonoscopy after curative resection	Appropriate use of adjuvant chemotherapy and radiation; appropriate use of avastin in metastatic setting; appropriate use of epidermal growth factor receptor inhibitor in metastatic setting	NA
PQRS	Image confirmation of pre-surgical appropriate seed implantation; sentinel lymph node dissection in invasive cancer; adjuvant hormonal therapy if hormone receptor-positive; quantitative HER2 evaluation; radiation dose limits to normal tissue	Adjuvant chemotherapy for stage 3 disease	Radiation dose limitations to normal tissue	Adjuvant hormonal therapy for high risk disease; Appropriate use of bone scans
ICHOM ^b	Survival and recurrence-free survival; acute complications of treatment; reoperation due to positive margins; depression; pain; fatigue; body image; arm and breast symptoms; vasomotor symptoms; neuropathy; arthralgia; sexual dysfunction; health-related QOL	Survival and disease control; hospital admission at end of life and place of death; presence of a stoma and stoma functioning; acute complications of treatment; depression; pain; fatigue; gastrointestinal symptoms; neuropathy; sexual dysfunction; health-related QOL	Overall and cause specific survival; Duration of time spent in hospital at end of life, and place of death; time from diagnosis to treatment; acute complications of treatment; performance status; dyspnea, cough; pain; fatigue; health-related QOL	Overall and cause specific survival; disease progression; acute complications of treatment; urinary and bowel symptoms; sexual dysfunction; pain; fatigue and vitality; emotional functioning and well-being; physical functioning
OCM	Timeliness of chemotherapy for hormone receptor-negative cancer; endocrine therapy received for hormone receptor-positive cancer; trastuzumab received for HER2-positive cancer	Timeliness of adjuvant chemotherapy	NA	Adjuvant hormonal therapy for high-risk disease

Abbreviations: CEA, carcinoembryonic antigen; NA, not applicable; QOL, quality of life.

^a Paraphrased summary of quality metrics endorsed or used by the National Quality Forum (NQF), Quality Oncology Practice Initiative (QOPI), Physician Quality Reporting System (PQRS), International Consortium for Health

Outcomes Measurement (ICHOM), Medicare Shared Savings Program (MSSP), and the Oncology Care Model (OCM). Duplicates within each group were combined. Screening, stage and performance status documentation, and genetics counseling requirements were excluded for table simplicity. ^bOutcome instead of process measurement is given for this row.

has introduced a "measure incubator" meant to accelerate measure development where significant gaps exist. Cancer measures, such as the outcome measures developed by ICHOM for the 4 most prevalent cancers in the US—lung, breast, prostate, and colorectal—should be moved into this program. Similarly, other groups are using PROs to better understand what is truly important to patients, which is not always aligned to what physicians perceive. In addition, CMMI should look to include more true outcome measures where they can in new programs that include alternative payment models.

With the 2015 passage of the Medicare Access and CHIP Reauthorization Act (MACRA) and the Merit-Based Incentive Payment Sys-

tem (MIPS) come new opportunities. The Medicare Access and CHIP Reauthorization Act has earmarked roughly \$75 million over 5 years to accelerate physician-level measure development. Importantly, MACRA gives CMS significantly more leeway to adopt nonendorsed measures, including measures that are still under development. In the first MIPS proposed rule, CMS described significant flexibility in measures it would consider, essentially creating a sandbox of sorts to implement preliminarily tested measures and facilitating data collection that could be used to fully test these measures. Value-based reimbursement will work when alternative payment models include meaningful measures of outcomes that are important to patients.

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