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Defining current gaps in quality measures for cancer immunotherapy: consensus report from the Society for Immunotherapy of Cancer (SITC) 2019 Quality Summit

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ABSTRACT

Background Quality measures are important because they can help improve and standardize the delivery of cancer care among healthcare providers and across tumor types. In an environment characterized by a rapidly shifting immunotherapeutic landscape and lack of associated long-term outcome data, defining quality measures for cancer immunotherapy is a high priority yet fraught with many challenges.

Methods Thus, the Society for Immunotherapy of Cancer convened a multistakeholder expert panel to, *first*, identify the current gaps in measures of quality cancer care delivery as it relates to immunotherapy and to, *second*, advance priority concepts surrounding quality measures that could be developed and broadly adopted by the field.

Results After reviewing the existing quality measure landscape employed for immunotherapeutic-based cancer care, the expert panel identified four relevant National Quality Strategy domains (patient safety, person and family-centered care, care coordination and communication, appropriate treatment selection) with significant gaps in immunotherapy-based quality cancer care delivery. Furthermore, these domains offer opportunities for the development of quality measures as they relate to cancer immunotherapy. These four quality measure concepts are presented in this consensus statement.

Conclusions This work represents a first step toward defining and standardizing quality delivery of cancer immunotherapy in order to realize its optimal application and benefit for patients.

BACKGROUND

The estimated national expenditure for cancer care in the USA was $147.3 billion in 2017 compared with an estimated $137.4 billion in 2010. The National Institutes of Health predicts continuous cost increases as more advanced and expensive treatments are developed and become standards of care.[1 2] Furthermore, the Centers for Disease Control and Prevention expects that the number of new cancer cases will increase as the population ages, resulting in a subsequent rise in the overall cost of cancer patient care.[3] As cancer costs increase, policymakers are testing innovative oncology-focused models to meet the National Quality Strategy's (NQS) objective to provide improved, more affordable care for the individual and the community.[4] The Health Care Payment Learning and Action Network found that, between 2015 and 2017, healthcare payments tied to alternative payment models (APM) increased from 23% to 34%.[5] Specifically for cancer care, multiple commercial payers have implemented oncology-based APMs, including bundled (or episode-based) payments, cancer- focused accountable care organizations (ACO), and oncology medical homes.[6] Under this evolving care delivery and payment landscape, it is important that appropriate treatments are delivered to the patient populations that would benefit the most.

Quality measures are important tools for monitoring and improving healthcare delivery because they can unify various healthcare organizations in providing standardized cancer care as well as set national benchmarks for assessing healthcare systems, through certification programs or recognition purposes. Furthermore, patient-reported quality measures are a means for assessing key elements of personalized treatment, an evolving priority in cancer care. Quality measures also may be used to highlight opportunities for improvement in performance and outcomes among individual providers, to inform public reporting about the

cost-to-benefit ratio, or value, of care among competing plans or providers. Correspondingly, measures are used to support 'value-based' payment models that reward healthcare providers for delivering high-quality care and reducing cost. The availability of meaningful quality measures allows these value-based payment programs to better assess the quality of healthcare delivery in the context of costs, and to protect against possible unintended consequences where quality may be compromised to reduce spending by program participants. Given the unprecedented growth rate in the development of novel cancer immunotherapies and their associated costs, gaps in immunotherapy-related quality measures represent an unmet and high-priority need.

Stakeholders are increasingly focused on incorporating more meaningful measures to determine quality of care as reimbursement for cancer treatment shifts from fee-for-service to value-based models. Policymakers are seeking to overcome cancer care quality measurement challenges and fill gaps in long-term clinical outcomes and patient-centered measures.[7] The Centers for Medicare and Medicaid Services (CMS) Quality Measure Development Plan identified oncology as a priority for measure development and noted significant gaps in oncology clinical outcomes, patient-reported outcomes, medication safety, team-based care, effective use of new technology, shared decision-making, and overuse.[8] Cancer immunotherapies have created a new treatment paradigm unique from traditional cytotoxic and targeted treatments, characterized by more durable response rates, distinct side effects, and unique response kinetics, shifting the conversation to a broader consideration of value in cancer treatment.[1] Clinical practice is also evolving, with an increased focus on the use of biomarkers to guide personalized decision-making in therapy selection, new models for response and toxicity monitoring, and emerging standards for management of immune-related adverse events (irAE), resulting in the need for improved coordination and education among multidisciplinary teams.[9] In the absence of long-term outcome data, clinical decision-making around when to stop treatment and how best to sequence or combine immunotherapeutics have largely been empirical. Innovative cancer immunotherapies also impact cost and, therefore, discussions around value have suffered from a lack of quality measures associated with clinical outcomes given the rapidly shifting landscape.[10] While traditional oncology quality measures have focused on surgery, radiation, cytotoxic and/or targeted therapy, and corresponding supportive care, the diagnostic and treatment pathways for immunotherapy lack such quality measures. This gap presents urgent challenges for benchmarking and decreasing widespread variability in the delivery of immuno-oncology care, including biomarker testing,[11] prescribing,[12] treatment evaluation, and monitoring and management of irAEs.[13] To identify measure concepts that can be used to bridge gaps in value-based models, the Society for Immunotherapy of Cancer (SITC) analyzed the cancer quality measure landscape, identified, and prioritized cancer immunotherapy quality measure concepts that are urgent areas for development.

METHODS

Cancer immunotherapy-specific guidelines[14] to identify consensus-based recommendations to define opportunities for measurement were reviewed. Quality measure databases (eg, National Quality Forum (NQF) Quality Positioning System, Merit-Based Incentive Payment System (MIPS), Qualified Clinical Data Registries) and program measure sets (eg, CMS value-based payment programs, Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program, Medicare ACO programs, Oncology Care Model (OCM), American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative (QOPI), SITC, the Oncology Nursing Society (ONS), and the American College of Surgeons Commission on Cancer (CoC)) were scanned to identify available cancer immunotherapy quality measures with the assistance of Discern Health, a consulting firm with quality measurement and value-based payment expertise. Based on the guideline review and measure scan, gaps in available measures and program measure sets were identified. A literature review was also conducted to find studies that identify gaps and variation in the delivery of cancer immunotherapy to inform priorities for quality measure development.

Following this comprehensive review of the published data, SITC convened a 1 day multistakeholder expert panel representing multidisciplinary fields within academia, professional associations, industry, patient advocacy, purchasers/employers, and quality organizations to review the findings of the landscape scan, prioritize opportunities for quality measurement, and define quality measure concepts for development. The expert panel prioritized quality gaps through a dot voting exercise, with individual gap areas identified for four NQS domains (patient safety, person and family-centered care, care coordination and communication, and effective prevention and treatment). Expert panelists were assigned to one of four breakout groups that each considered a different quality domain. The breakout group members collaboratively discussed quality measure concepts based on the highest priority gap area for their assigned domain. Following breakout group reports, the full expert panel discussed the consensus-based identified measure concepts and considered opportunities and challenges for measure development. The panel agreed to focus the discussion exclusively on immune checkpoint blockade as this treatment impacts the largest number of patients with cancer treated with immunotherapy.

CONSENSUS RECOMMENDATIONS

Identification of gaps in quality measures within cancer immunotherapy

The first step was to assess the landscape of currently available quality data related to cancer immunotherapy through peer-reviewed literature, professional organizations, and other established quality networks. Through a review of SITC, National Comprehensive Cancer Network (NCCN), ASCO clinical guidelines, among others, measurement opportunities were identified across the cancer care trajectory for patients receiving cancer immunotherapy. This included considerations related to treatment decision-making at the time of initial cancer diagnosis through active treatment, recognition and management of irAEs, and initial care outcomes as well as long-term survivorship issues. The panel recognized that only a few quality measures exist that are directly related to the use of cancer immunotherapy. 'Direct' measures include those specifically assessing the use of cancer immunotherapy in clinical care. 'Indirect' measures include those assessing clinical care for general cancer populations that are inclusive of patients treated with immunotherapy.

Professional society quality programs, including the ASCO QOPI and the American College of Surgeons CoC, have developed and implemented quality measures related directly to the use of cancer immunotherapy that primarily assess suitable prescribing methods for certain therapies, ordering of appropriate testing of specific biomarkers, and utilization of certification programs, such as ASCO QOPI.[15–17] Importantly, professional society quality programs have not yet incorporated clinical outcome measures. In Medicare value-based payment and reporting programs, the quality measures are predominantly indirect measures and focus on achievement of general outcomes (eg, 30-day unplanned readmissions) (table 1). There is a lack of similar quality measures for novel cancer immunotherapies such as immune checkpoint inhibitors or chimeric antigen receptor (CAR)-T therapies. In addition, there are other key cancer programs, such as the OCM and the PPS-Exempt Cancer Hospital Quality Reporting program, which do not incorporate any cancer immunotherapy quality measures or standards.

Table 1 Examples of cancer immunotherapy-related measures

Direct quality measure examples	Indirect quality measure examples
► Assessment for and management of immune-related adverse events during cancer treatment with checkpoint inhibitors (ICPi)[49]	► Patient-reported health-related quality of life (HRQOL) during treatment for advanced cancer[50] ► 30-day unplanned readmissions for patients with cancer[51 52] ► Patient-reported experience of care (Cancer CAHPS)[53] ► Risk-adjusted proportion of patients with all-cause hospital admissions within the 6-month episode[54] ► Goal setting and attainment for cancer survivors[55]

CAHPS, Consumer Assessment of Healthcare Providers and Systems.

Outcome measures for the assessment and implementation of evidence-based interventions (ASCO/NCCN) for adverse events (AE) related to immune checkpoint inhibitors have been developed by the ONS and Premier.[18] ONS and Premier collaborated to offer outcome quality measures that assess patient experience, quality of life, and early identification of symptoms and include the use of evidence-based interventions related to cancer immunotherapy. These two measures were released through MIPS reporting as well as for practice or institutional quality improvement purposes in 2019. Despite the availability of these measures, there are still gaps in outcome and evidence-based management of symptoms that capture patient experience and quality of life.[18] Table 2 provides examples of available quality measures in professional society sets that relate directly or indirectly to cancer immunotherapy, which were also considered by the panel. The NQF, Center for Medicare and Medicaid Innovation (CMMI), and Core Quality Measures Collaborative (CQMC) (The CQMC is a broad-based coalition of health leaders convened by America's Health Insurance Plans, the CMS, and the NQF. CQMC collaborates to recommend core sets of measures by clinical area to assess quality of care. More information can be found here: http://www.qualityforum.org/cqmc/) have separately identified measure gaps for general cancer populations.[14 19–22]

High-priority gaps in this population include:

- Survival rates.
- Access to hospice.
- Five-year cure rate.
- Quality of life/patient-reported outcomes.
- Shared decision-making.
- Overuse/underuse.
- Medication reconciliation.
- Clinical trial access.
- Functional status.
- Mortality rates.
- Goal setting.
- Post-treatment complication rates.

The gaps identified by NQF, CMMI, and CQMC above are cross-cutting and apply broadly to cancer care. ASCO, Cancer Support Community, the Community Oncology Alliance, and the Patient Advocate Foundation explored opportunities to advance cancer quality in the era of innovative treatments and prioritized survival and shared decision-making, among others listed below, as areas for future measure development[23]:

- Survival.
- Shared decision-making.
- Social, emotional and spiritual health.

Table 2 Examples of cancer immunotherapy-related measures in professional society sets

Direct quality measure examples	Indirect quality measure examples
► PET or PET-CT ordered by the practice between 0 and 12 months after treatment with curative intent for patients with colon cancer (lower score is better)[56] ► Hepatitis B virus infection test (HBsAg) and hepatitis B core antibody (anti-HBc) test within 3 months prior to initiation of obinutuzumab, ofatumumab, or rituximab for patients with non-Hodgkin's lymphoma[57]	► Staging documented within 1 month of first office visit[58] ► Molecular testing for patients with stage IV non-small cell lung cancer (NSCLC) with adenocarcinoma histology[38 43 59 60] ► At least 10 regional lymph nodes are removed and pathologically examined for AJCC stage IA, IB, IIA, and IIB resected NSCLC[61]

AJCC, American Joint Committee on Cancer; PET, positron emission tomography.

- Genomic sequencing informing biomarker-based treatment selection.
- Accuracy of diagnosis and comprehensive treatment.
- Screening/management for depression.

Efforts are underway to close gaps in cross-cutting cancer clinical outcome measures. Of note, the NQF Incubator is exploring measure development and testing for lung cancer and melanoma survival measures and a lung cancer patient-reported outcome performance measure.[24]

Based on the output of SITC's gap analysis process, gaps in measures were also identified in relation to the care model:

- First, second, or third-line cancer immunotherapy prescribing, including biomarker testing.
- Pretreatment evaluation and assessment of longer term clinical outcomes (eg, response duration, treatment-free survival/remission, survival).
- Monitoring and management of irAEs.

Gaps impacting cancer immunotherapy care delivery were also identified through a review of the literature:

- *Knowledge and adoption of immunotherapy*: There is significant variability in the adoption of immunotherapy by oncology practices.[25] Along with the variation in implementation and use of cancer immunotherapy, there is a gap in knowledge and understanding of immunotherapy treatments among oncology providers. In 2017, a survey conducted by the Association of Community Cancer Centers reported that only 24% of respondents reported deep familiarity with checkpoint inhibitors, 32% with monoclonal antibody therapy, and 17% with combination treatment regimens.[26] Furthermore, data on CAR-T cell therapies and oncolytic viruses are lacking.
- *Identifying pseudoprogression or hyperprogression of tumors*: Quality issues related to the accuracy in identifying tumor 'pseudo'-progression or 'hyper'-progression related to immunotherapy were identified. These only occur in a subset of cancer immunotherapy patients but can have implications for decisions to continue or discontinue therapy and have subsequent effects on the long-term health outcomes for a patient.[27 28] These unusual patterns of response also add complexity to defining when to continue or discontinue therapy.
- *Communication and coordination of care*: Quality issues in cancer immunotherapy relate to the monitoring and management of clinical care. A 2017 study concluded that only 37% of healthcare professionals notify the primary cancer team of their decision to treat the patient with immunotherapy 80%–100% of the time, and most healthcare professionals notify the primary cancer team less than 60% of the time.[29]
- *Monitoring and management of AEs*: Only 49% of healthcare professionals are comfortable with recognizing and managing irAEs.[29] The issues related to the early recognition and management of irAEs expose a gap and need for education.[30 31]
- *Use of patient-reported outcome measures (PROM)*: The routine use of PROMs is recognized in the literature as an important strategy to evaluate treatment-related toxicities, evaluate functional declines and/or improvements associated with irAE management.[32]

PRIORITIZING QUALITY MEASURE CONCEPTS

Through this analysis, quality measure gaps were organized into relevant NQS quality domains and these quality domains were presented to the expert panel stakeholders for prioritization through a dot voting exercise. Four relevant NQS domains (patient safety, person and family-centered care, care coordination and communication, and effective cancer prevention and treatment) with significant gaps in immunotherapy-based quality cancer care delivery were prioritized (see figure 1). Expert panelists in four breakout groups, representing each of the relevant NQS quality domains, discussed quality concepts that could be quantified to be able to assess improvement and, thus, considered a high priority to focus efforts on quality measure development in order to bridge a gap in their assigned quality domain. Each group was asked to identify one or two quantifiable and high-priority quality measures. The following represents the quality measures, by domain, that were proposed by the panel:

Patient safety

Proposed quality measure: timely and appropriate management of immune-related colitis in patients with cancer treated with immune checkpoint inhibitors

The group recognized the many types of irAEs can occur with cancer immunotherapy, and agreed the field would benefit from gathering further data and generating benchmarks for individual AEs, such as immune-related dermatitis, colitis, pneumonitis, hypophysitis, hepatitis, and others. Thus, the patient safety breakout group considered the recognition and management of AEs, with an emphasis on identification and management that can lead to improved outcomes, as an important quality measure concept since most existing measures are pure process measures. The group recognized that there are published data supporting the hypothesis that timely management of care and/or rapid specialist

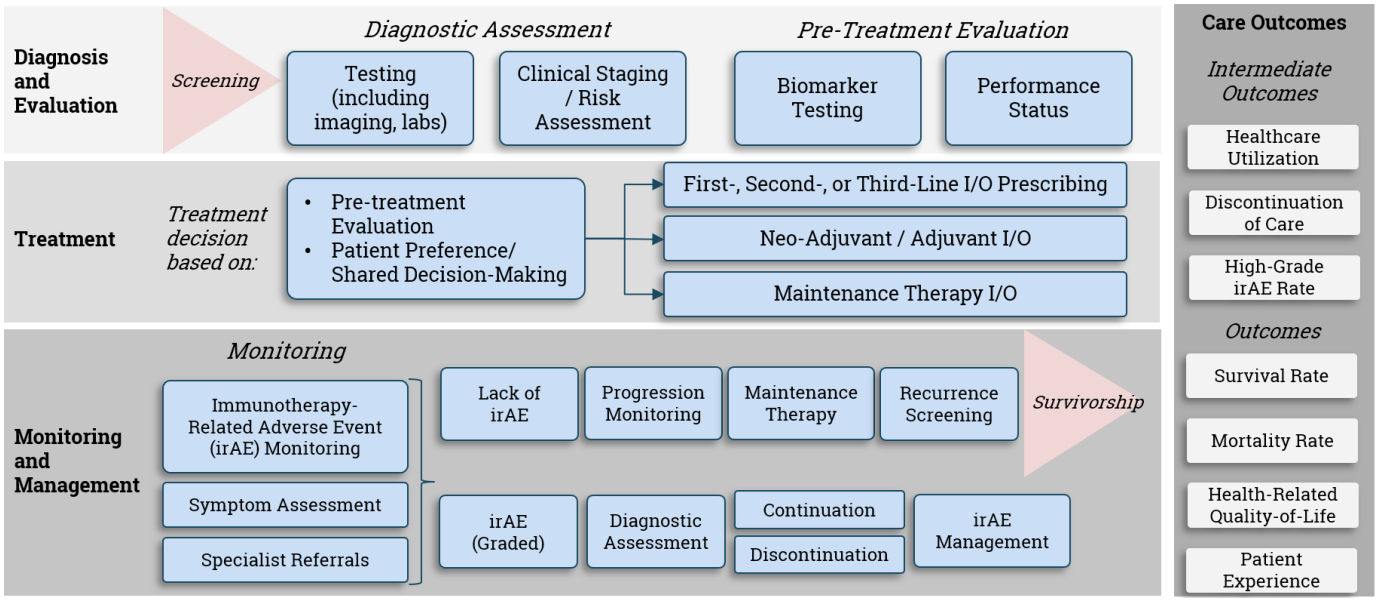

Figure 1 Cancer immunotherapy care model. The Discern/Society for Immunotherapy of Cancer (SITC) quality task force identified four key areas of focus for immunotherapy quality gap analysis: diagnosis and evaluation; treatment; monitoring and management; and care outcomes. The panel considered specific aspects of immunotherapy care extending from initial cancer diagnosis through active treatment, recognition and management of adverse events, preliminary care outcomes and long-term survivorship issues. I/O, immuno-oncology.

referral for immune-related colitis results in beneficial outcomes for patients.[33] As such, the group selected diarrhea (ie, immune-related colitis) for rapid diagnosis and treatment. Colitis is a common, potentially serious, and well-characterized AE during immunotherapy that can be easily identified and monitored, and which likely could result in improved clinical outcomes if mismanagement that results in serious morbidity and mortality is avoided.

Diarrhea is one of the four AEs (diarrhea, rash, fatigue, pruritus), which the ONS and Premier included in their CMS-approved quality measure 'Assessment for and Management of Immune-Related Adverse Events During Cancer Treatment with Checkpoint Inhibitors'. ONS currently has a grading system in place for diarrhea but it does not include the length of time of the management and/or treatment, which highlight gaps and needed areas of clarification within existing guidelines. Panelists discussed key considerations for the measure concept but generally agreed that standardized and validated grading systems are lacking. A goal of the proposed measure concept would be to reflect an evidence and guideline-based definition of timeliness. The panelists also indicated the potential utility of patient self-reporting for immunotherapy AEs to reflect overall daily health and management.[34]

Person and family-centered care

Proposed quality measure: goal-concordant care: patient-reported establishment of care goals and assessment that goals were met

The 'Patient-Reported Establishment of Care Goals and Assessment That Goals Were Met' measure concept was recommended to assess an essential element of patient experience of care, through recognizing individual patient goals and engagement in the shared decision-making process. For example, developing goal-concordant care of a patient experiencing an AE related to immune checkpoint inhibitors could be included in goal setting and attainment measures. The intention of this measure is to first evaluate the communication of initial immunotherapy treatment options and associated side effects and subsequent goal-concordant care between the patient and the physician prior to treatment initiation as well as throughout the care trajectory. A second intention is to measure whether patient care goals were acknowledged and considered. Differing perspectives on shared decision-making include issues of informed consent, types of patient expectations, quality of life, and symptom management, and panelists aimed to create a measure concept which can be continuously reassessed to account for varying priorities throughout the duration of care. The measure concept would require a patient survey covering three concepts:

1. Did your clinician discuss your expectations/preferences up front and set goals with you?
2. Was there continuous shared decision-making based on response to treatment, evolution of scientific and clinical knowledge, and others?
3. Were the defined goals respected and considered throughout the process?

Significant limitations exist for establishing this type of quality measure. First, while measuring goal-concordant care is a quality measure for seriously ill patient populations,[35] targeted goal-setting quality measures have not been developed for use in pretreatment cancer populations. Second, data collection may be challenging. Patient

self-reporting would be a gold standard occurring either at the point of care (eg, electronic tablets in the waiting room) or independently (ie, mailed or phone survey at the patient's home). While some care-planning quality measures in this area focus on electronic health record (EHR) documentation by clinicians, panelists determined that a clinician-facing EHR structured data element (ie, 'checkbox') documenting the occurrence of shared decision-making conversations would be insufficient since there is often a discrepancy between what the patient and the physician consider to be shared decision-making and unaudited attestation measures lack sufficient validity.[36] Finally, the unique issues of this patient population add additional measurement challenges. Appropriate timing of the measurement window for the collection of patient self-reported data may also be challenging, as treatment decisions are made quickly based on diagnostic information and second-line and higher treatment options may happen over several weeks or even months. Also, as with any patient-facing assessment, patient burden to answer these questions should always be considered. Given these administrative and timing challenges, panelists discussed the potential utility of piloting this measure concept as a feasibility study in a cancer immunotherapy clinical trial ahead of real-world deployment. Another approach would be to use a validated cancer-focused patient experience of care measure to benchmark communication and shared decision-making at the provider level. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey was developed to provide a standardized measure of patient experience of care during cancer treatments.[37 38] CAHPS Cancer Care was developed to be valid and reliable for cancer treatment modalities, including immunotherapy, and clinic type (eg, cancer center, community clinic, and so on). CAHPS Cancer Care includes quality measures on general clinician–patient communication and shared decision-making.[39] The CAHPS' shared decision quality measure includes questions such as: 'Doctor asked patient what cancer treatment choice was best for him/her' (three response options: (1) yes, definitely; (2) yes somewhat; (3) no), the communication measure asks cancer patient agreement (5-point Likert scale: never to always): 'Cancer care team showed respect for what patient had to say.' While deployed as a retrospective cross-sectional survey, it is independent from patient care and could allow for benchmarking and quality improvement efforts.

Care coordination

Proposed quality measure: effective care coordination between clinicians and patients with cancer including primary care physicians and pathologists to ensure timely delivery of treatment

Expert panelists identified 'Effective Care Coordination Between Clinicians and Cancer Patients Including Primary Care Physicians and Pathologists' as an important measure to address gaps in care coordination between the primary cancer team and other healthcare providers sharing a mutual patient, as well as between the provider and the patient. Panelists emphasized the need for an ongoing exchange of information between clinicians (oncologists and subspecialists involved in managing patient-related toxicities) and assessing the coordination in educating primary care providers and patients on awareness for the risk of irAEs. Pathologists were also specifically identified as essential members in care coordination for patients considering immunotherapy, as a lack of coordination and miscommunication about tissue samples, biomarker testing, and other tests can negatively impact patients' treatment plans.[37 40–42]

Communication between healthcare providers should be streamlined and documented in patient records and electronic medical record tools to acknowledge the exchange of information and plan of care in the event of an AE. Panelists emphasized the need to determine how measures could be implemented and documented in a community hospital compared with larger academic institutions, as community or rural settings may be more prone to fragmentation. Optimal care requires close integration among primary care providers, surgeons, medical oncologists, subspecialists engaged in managing potential AEs, surgical and molecular pathologists, radiologists' teams, and other members of the cancer care team to interact as part of a multidisciplinary approach to deliver care to the whole patient, especially when immunotherapy is being considered.[43 44]

Effective prevention and treatment

Proposed quality measures: (1) concordance with nationally recognized cancer immunotherapy guidelines/participation in a certificate program; (2) biomarker testing and appropriate cancer immunotherapy prescribing

Panelists acknowledged challenges defining a measure concept to address the prioritized gap of prescribing appropriate and timely first-line, second-line, or subsequent/maintenance cancer immunotherapy. In line with CMS' goals to shift toward cross-cutting quality measures, an ideal measure denominator would include all patients with cancer treated with immunotherapy. However, evidence and standard of care differs across tumor types and among different immunotherapy drug classes. Panelists recommended both broad and narrow quality measure development.

The broad measure concept, 'Concordance with Nationally Recognized Cancer Immunotherapy Guidelines/Participation in a Certificate Program', focuses on following nationally recognized cancer immunotherapy guidelines and could be applied across all types of cancer where immunotherapy is indicated. For example, a certificate program that recognizes providers and/or organizations with experience in immunotherapy administration could serve as a proxy for demonstrating competency, with institutions and payer organizations recognizing either this certification or a threshold of certificate holders in their provider settings. An MIPS improvement activity[45] recognizing immunotherapy prescribing certification could also be developed as a surrogate to

quality measurement. The CMMI OCM includes a similar requirement for participants and specifies that participating practices and providers provide 'treatment with therapies consistent with nationally recognized clinical guidelines'.[46] Some panelists viewed this concept as a 'checkbox' measure and indicated policymakers are moving away from unaudited attestation measures but others embraced this as more informative than current meaningful use requirements for providers to confirm in the medical record that national guidelines have been used in clinical decision-making. For example, panelists envisioned demonstration of individual provider certification or the number of certified providers within a healthcare delivery system as an easily reported measure. It will be important to establish whether certification is associated with improved patient outcomes.

The narrow measure, 'Biomarker Testing and Appropriate Cancer Immunotherapy Prescribing', focuses on biomarker testing for select populations to assess the timeliness of biomarker testing for patients and whether appropriate accompanying treatment was prescribed. Healthcare providers should be familiar with and adhere to existing practice guidelines regarding biomarker testing for optimal patient care. Biomarker testing that is not timely may make a difference in treatment decisions and/or patient outcomes. Appropriate treatment delivery could be delayed, or ineffective therapies could be prescribed, resulting in poor clinical outcomes and unnecessary healthcare costs.[47] There is an existing evidence base and standard of care for established biomarkers, such as PD-L1 testing, which supports the case for measures focused on biomarker testing in patients with tumors such as non-small cell lung cancer, urothelial carcinoma, and head and neck cancers.[42] Notably, studies have found undertesting for PD-L1 expression prior to immunotherapy prescription.[48] This may be attributed to lack of tissue for staining, inappropriate tissue collection and/or preservation for biomarker testing, lack of concordance in regard to the PD-L1 testing platform based on the immunotherapeutic drug being prescribed, inconsistent thresholds used to determine PD-L1 positivity (tumor cell and/or immune cell), as well as heterogeneity among different tumor types. Appropriate utilization of other biomarkers for immuno-oncology therapies such as microsatellite instability, DNA mismatch repair deficiency, and implementation of next-generation sequencing for the identification of emerging biomarkers, including tumor mutation burden, should be considered. These are new challenges faced by the healthcare team that may contribute to the delay or lack of PD-L1 testing. Such measures would allow for nuanced performance benchmarking.

ACTION STEPS

Quality measure development can fill urgent gaps and advance the measurement of cancer immunotherapy care to enable benchmarking, improvement, and accountability within value- based care and payment models. Future measure development efforts should align with the priorities and issues that result in the appropriate and efficient delivery of healthcare to patients and are validated as impacting patient outcomes. As discussed during the expert panel meeting, patients perceive a greater focus on the physical outcomes and symptoms, such as nausea or fatigue, than quality of life metrics related to cognitive, emotional and economic effects of treatment—the latter of which may be of higher priority to healthcare administrators and payers. To understand the perspective of patients receiving immunotherapy and the issues that are most meaningful to them, immunotherapy patients should be fully integrated into measure development processes. Panelists described the Patient and Caregiver Council at the Michigan Oncology Quality Consortium as a model for successfully engaging patients in measure development. The Council contributes to the selection of all quality measures, including PROMs, in the Consortium's measure development activities and is an essential aspect of the Consortium's governance structure. When pursuing measure development, organizations should ensure that multiple patient representatives are at the table from the outset and during each step of the process to drive the conversation and ensure that what is being measured is truly what is meaningful to patients with cancer.

The rapidly evolving nature of cancer immunotherapy and lack of long-term clinical outcome data presents a challenge when developing new quality measures. Measures are not readily adaptable to quick change in sync with guideline updates. To address this gap in data evolution, the simultaneous development of measures and guidelines should be considered. As new guidelines for cancer immunotherapy emerge, quality measure developers should work on granular measures that parallel the established standard of care.

Cancer immunotherapy is complex and the field is evolving at an unprecedented pace resulting in gaps in defined quality measures designed to confirm efficient and high-quality care delivery. In response to the rapidly developing field, SITC sought to define the unique characteristics of cancer immunotherapy and bridge the current gaps in quality measures in healthcare delivery as it relates to cancer immunotherapy. As a first step toward bridging these gaps, four priority areas (patient safety, person and family-centered care, care coordination and communication, appropriate treatment selection) were defined and specific quality measures were proposed. Defining national quality benchmarks for cancer immunotherapy will help optimize therapeutic benefit for patients with cancer and contain healthcare costs for society.

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