Quality Measurement of Personalized Medicine

Tensions Between Personalization and Standardization

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Introduction

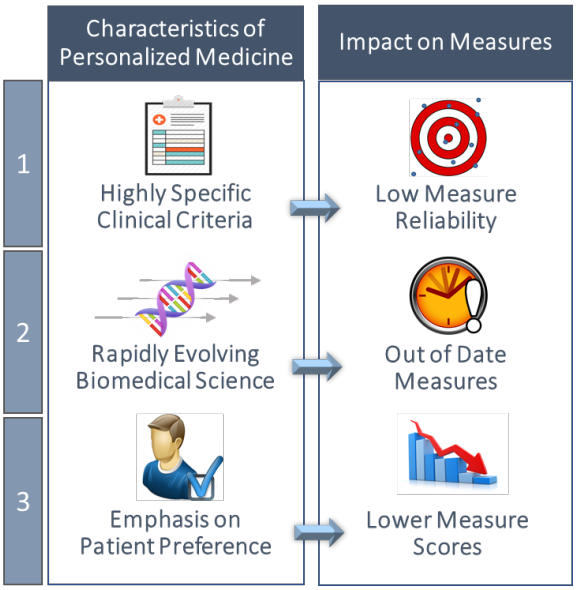
Personalized medicine, sometimes referred to as precision medicine, is an evolving field that uses genetic testing and an individual's medical history, circumstances, and preferences to develop targeted treatments.[1] The application of personalized medicines is perhaps most advanced in oncology, where targeted therapies such as trastuzumab have been available for nearly two decades, and new immunotherapies and gene therapies such as Chimeric Antigen Receptor (CAR) T-cell therapy are now available. A recent analysis found that more than 7 in 10 oncology drugs in development were personalized medicines.[2] In addition, the Food and Drug Administration (FDA) recently implemented policy changes to accelerate the development and approval of genomic tests that can guide treatment, and Medicare announced new coverage for such technologies.[3,4]

The evolution of personalized medicine coincides with the movement in the United States toward value-based care and emphasis on measuring the quality of care. Quality measures are being used by Medicare, Medicaid, and private insurers to hold providers accountable for the quality and costs of care they provide. Personalized medicine has the potential to improve value by enabling nuanced tailoring of treatment and helping ensure patients receive and remain adherent to the right treatment at the right time. As personalized medicine becomes more common, it is necessary to critically assess whether the existing approaches to quality measurement and the infrastructure for collecting quality data will adequately and appropriately capture the quality of personalized medicine.

Tensions Between Personalized Medicine and Quality Measurement

There are three fundamental tensions between personalized medicine and the traditional approach to quality measurement that detract from the goals of value-based care. First, quality measures typically assess whether a standard of care has been met for a broad patient population, while personalized medicine focuses on approaches to care that are tailored to individuals and subgroups of patients meeting specific clinical criteria. As the clinical criteria becomes more specific, the number of applicable patients meeting measure inclusion criteria decreases, affecting measure reliability at the provider-level. Second, the speed with which new diagnostics and

Figure 1. Tensions between Personalized Medicine and Quality Measurement



targeted therapies are developed and utilized presents challenges for ensuring that clinical guidelines and quality measures derived from guidelines keep up with the science. Third, personalized medicine places greater emphasis on patient preferences for care, but standardized quality measures do not always account for preferences. When measures do not address patient preferences, providers' performance on measures may decline if they respect patient wishes, which in turn may result in penalties in quality measurement and value-based payment programs.

Goals of this Issue Brief

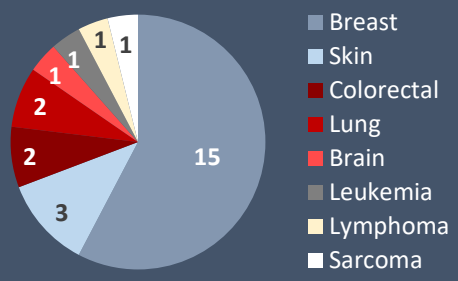
In this issue brief, we explore the tensions between personalized medicine and standardized measurement. We also recommend new approaches to quality measurement that align with the patient-centered objectives of personalized medicine, while ensuring that providers are not held accountable for factors beyond their control. To better understand the impact of the tensions on patients and providers, we conducted a scan of existing oncology quality measures and analyzed their relevance to personalized medicine. We also conducted a series of stakeholder interviews to validate our findings and inform the recommendations.

How is Personalized Medicine in Oncology Currently Measured?

Results of our Measure Scan

We reviewed measure databases to assess how personalized medicine in oncology is currently being measured. In our measure scan, we identified 14 existing measures of genetic and/or biomarker testing and 12 measures focused on targeted cancer treatment based on an individual's genetic factors. Each of these testing and treatment measures focused on a single type of cancer, with the majority (15) focused on breast cancer. Only skin, colorectal, and lung cancer also have multiple testing and treatment measures. Figure 1 shows the breakdown of testing and treatment measures by cancer type. Additionally, we identified 15 measures of person-centered care relevant to personalized medicine in cancer care. These measures focus on care planning, patient experience, and shared decision-making.

Figure 1. Existing Measures of Personalized Medicine by Cancer Type



Of the 41 measures we identified, 15 are used to assess provider performance in Centers for Medicare & Medicaid Services (CMS) programs, including the Merit-Based Incentive Payment System (MIPS), Medicare Shared Savings Program (MSSP), and the Oncology Care Model (OCM).

The complete results of the scan, as well as a description of the methods of the scan, are provided in Appendix 1. A full list of the measures in use in CMS programs is provided in Appendix 2.

Tension 1: Highly Specific Clinical Criteria → Low Measure Reliability

Small numbers of patients meeting a measure definition is a challenge for provider-level measurement that will only become more difficult to address as therapies become more individualized. When only a small number of patients meets clinically-specific measure denominators and/or numerators, the reliability of a measure may be low. If a measure is focused on provision of a therapy for a narrow group of patients, and a given community oncologist only sees a handful of patients in that narrow group in a given year, the measure result will be highly variable and may be driven more by chance than performance. This issue is particularly noteworthy given the increasing focus of research and development on treatments for rare cancers and subpopulations within more common cancers.

Size of the patient population and the ability for measures to achieve reliability are key factors in measure development and determining what measures are used in quality measurement and value-based payment programs. The National Quality Forum (NQF) requires reliability testing for all measures submitted for endorsement, and the testing results are central to the endorsement process. Moreover, while CMS sometimes selects non-endorsed measures for its quality and payment programs, the agency still considers measure reliability when choosing non-endorsed measures. Existing oncology measures are focused on breast and colorectal cancers, which are cancers with relatively high prevalence where precision diagnostics and treatments are well established.[5] Issues of small numbers, and the resulting low measure reliability, likely explain why there are few measures for rarer cancers or for non-rare cancers that have smaller, clinically-specific subpopulations.

In addition, the testing and treatment measures we identified were primarily used in the Merit-Based Incentive Payment System (MIPS) program, which is the largest payment program for clinicians participating in Medicare. In MIPS, clinicians report a minimum of six measures of their choice from a set of over 270 measures to avoid negative payment adjustments.[6] A typical community oncologist is unlikely to have enough cases to meet the case minimum for reporting some of the available oncology measures. The implication of this scenario is that even measures in use for the most common cancers may have limited utility in the current value-based payment structures due to small numbers.

Tension 2: Rapidly Evolving Biomedical Science → Out of Date Measures

The testing and treatment measures identified in the measure scan were all specific to individual tests and therapies for individual cancers. As biomedical science rapidly evolves, and new testing and treatment options become available, there is a significant risk that these measures will not evolve

quickly enough to stay up to date. This raises the prospect of measures promoting use of less effective tests or therapies.

Measures are generally derived from clinical guideline recommendations, and processes are in place to ensure that measures keep up with evolving guidelines. All NQF-endorsed measures must go through an annual update to verify that their specifications are up to date, as well as a three-year maintenance review to re-evaluate the measure against NQF's criteria. Additionally, NQF-endorsed measures are subject to ad hoc review, which can be requested by any third party. The NQF maintenance process helps to ensure that measures remain up to date and in alignment with guidelines.[7]

However, guidelines themselves do not always keep up with the availability of new technologies and changing clinical practice. The American Society of Clinical Oncology (ASCO) has stated that their guidelines are sometimes out of date and is attempting to streamline the guideline review process to respond more rapidly to changes.[11] Even with streamlined review processes, guidelines may never fully keep up with the development and release of new therapies.

Clinical Illustration: Leukemia

Quality measurement in leukemia is a telling case of the impact of small numbers and measures not keeping up with evolving science. MIPS includes a measure of cytogenetic testing for myelodysplastic syndrome (MDS) and acute leukemias. Cytogenetic testing is recommended for both MDS and acute leukemia to guide treatment and determine prognosis, but the conditions are different, and the test results are used in different ways.[8] The conditions were likely grouped together in this measure to avoid issues of small numbers. However, grouping in this way is not ideal, as it makes the measure results less meaningful and interpretable by patients and providers. Moreover, even after grouping the two conditions, few oncologists are likely to have enough patients to be able to report this measure in MIPS.

At the same time, there are no measures for chronic myeloid leukemia (CML), which has an even lower incidence. Fewer than 9,000 individuals are diagnosed with CML in a given year.[9] CML patients with the Philadelphia chromosome—about 95 percent—respond favorably to tyrosine kinase inhibitors, which have been available for 15 years. However, there are no measures for genetic testing or tailored treatment of these patients, likely due to small numbers.

Additionally, a new targeted therapy for chronic lymphoblastic leukemia (CLL) patients with 17p deletion was approved by the Food and Drug Administration (FDA) in April 2016. However, CLL is not included in the existing genetic testing measure for patients with leukemia, despite being the most common type of leukemia.[10] This example illustrates that the risk of measures becoming out of date is significant, and it is worth considering measurement approaches that are less tied to individual tests and therapies.

Perhaps most concerning, it may take several years for new measures to be developed or existing measures to be updated to reflect new therapies, even when the new therapy is recommended in clinical guidelines. The measure development process takes at least two years, and sometimes longer. The lengthy development process raises the prospect of a measure promoting the use of a certain test or targeted therapy when a newer and more effective test or therapy is available.

Tension 3: Emphasis on Patient Preferences → Low Measure Scores

Engaging patients to understand their care preferences and applying that understanding to clinical decision-making is a fundamental tenet of both value-based health care and personalized medicine.[12,13] We analyzed the measures identified in the scan to determine whether they account for patient preferences. Seven of 10 testing and treatment measures, and all the patient-centered care measures, were found to consider patient preferences in some way. The three measures that did not include consideration of preferences were treatment measures focused on patients receiving, or being spared, a targeted therapy based on a mutation status. The complete results of this analysis are shown in the measures table in Appendix 2.

When application of patient preferences is not included in a testing or treatment measure, and a patient's preferences do not align with the measure, the provider's performance on the measure will be worse. For measures that are included in value-based payment programs, there may be adverse financial consequences for respecting a patient's wishes. Measures could better incorporate patient

Clinical Illustration: Breast Cancer

Personalized medicines for patients with the HER2 mutation in breast cancer have been available for more than 20 years. As shown in the measure scan, HER2 mutation and targeted therapies are the focus of several quality measures. One of these measures, "HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies" illustrates the need for additional incorporation of patient preferences into measures. In 2005, a study generated promising evidence that some patients with low HER2, who would be classified as negative, might benefit from trastuzumab.[14] A new study was released in December 2017 showing no benefit for patients with low HER2, but for 12 years it seemed possible that a benefit existed. This measure is included in MIPS and was included in the Physician Quality Reporting System (PQRS), the measurement program that preceded MIPS.

This example demonstrates how evidence in personalized medicine is always evolving, but patients and their providers must make decisions with the best available information. The trastuzumab measure would have penalized a clinician for following patient preferences based on currently available evidence.

preferences by allowing providers to exclude from measure calculations patients whose preferences are at odds with measure recommendations, or focusing measures instead on the provider recommending a certain test or treatment. These two approaches would achieve balance between promoting evidence based-care while preventing adverse financial consequences to the provider for addressing patient preferences.

Recommendations

We developed a set of recommendations for improving quality measurement of personalized medicine based on the findings of our quality measure scan and analysis and common themes from our key informant interviews, which are summarized in Appendix 3. The recommendations specifically address issues of narrow clinically-specific patient populations resulting in low measurement reliability, measures not keeping up with new technologies and evolving science, and lack of attention to patient preferences in guiding clinical decisions. The recommendations attempt to address the tension between traditional standardized measurement, which treats variation in care as a negative outcome, and personalized medicine, which is about desirable variation in care to address differences in patient characteristics and preferences.

Recommendation 1: Continue to develop measures that promote use of appropriate genetic testing, including broader measures that apply across cancers

Measures that encourage appropriate genetic testing are relatively common and are needed to help promote patient access to personalized therapies. However, due to small numbers issues, it would be beneficial to move away from test-specific measures toward broader measures of appropriate testing that can be used across multiple cancers. This movement to broader testing measures was supported by multiple key informants we interviewed, including practicing oncologists and quality improvement organizations. A specific opportunity is to develop a measure of appropriate use of next generation sequencing (NGS) technology, which has applications to multiple cancers.

Recommendation 2: Incorporate allowances for patient preferences into all genetic testing and tailored treatment measures

Personalized medicine not only means that therapies are targeted to patients' genetics, but that patient preferences are prioritized in treatment decisions. More genetic testing and tailored treatment

measures should take patient preferences into account. For instance, measures focused on whether a patient received—or was spared—a targeted therapy could, where appropriate, be defined to focus on whether the therapy was "recommended" or "considered," rather than whether the therapy was ultimately received. Existing measures of adjuvant hormonal therapy (NQF #220) and combination chemotherapy (NQF #559) use this approach.

Recommendation 3: Develop and use measures related to patient goal setting and concordance with patient goals

As new therapies continue to become more targeted, the use of therapy-specific measures will become less feasible due to reliability issues. For example, in the current approach, community oncologists may have no viable personalized medicine treatment measures that meet the minimum case threshold for MIPS reporting. In addition, as new treatment options such as immunotherapy and gene therapy become available, existing therapy-specific measures can become out of date or irrelevant. For these reasons, treatment measures that focus on patient-centered treatment, are not specific to individual therapies, and apply across cancer types should be considered.

Patient advocates and practicing oncologists we interviewed expressed interest in the development and use of measures of patient goal attainment. Patients and providers are increasingly working together to set treatment goals and "co-create" a care plan. This type of approach is required in the CMS Oncology Care Model (OCM).[15] However, in that model, there is no formal review to assess whether care ends up being concordant with the plan. A care plan concordance measure would provide a patient-centered approach to assessing quality of treatment. Measures of care plan concordance have been proposed for use in quality and payment programs for the seriously ill, and could be adapted for oncology.[16]

Recommendation 4: Prioritize the development and use of patient-centered outcomes measures, including measures of quality of life and patient experience, that apply across cancers

There is a dearth of measures in use that are cancer-specific and assess quality of life and patient experience. In fact, there are no cancer quality of life measures in use in CMS programs, including the OCM.[17] While there are measures of shared decision-making for patients with cancer in use in CMS programs, they are narrowly focused on interventional oncology. The use of cancer specific patient

experience measures is limited to a Consumer Assessment of Healthcare Providers and Systems (CAHPS)-based measure in the OCM.

Quality of life and patient experience measures should be prioritized. These overarching outcomes are essential for promoting patient-centered cancer care, given that improvement in quality of life is often a primary goal of cancer care. Quality of life measures should also be used to assess the side effects of chemotherapy and other treatments. These measures can be applied across different cancer types, reducing issues of small numbers and measure reliability, and are not subject to becoming out of date as new therapies are developed. An initial step to expanding cancer-specific patient-centered outcome measures would be to include reporting of the CAHPS-based cancer care patient experience measure in MIPS.

Recommendation 5: Leverage improvement activities, including clinical decision support and other quality-related tools and programs beyond measurement, to promote personalized medicine approaches

There will always be limitations to quality measurement. Measures should be considered one tool in a toolbox that includes other ways to ensure high quality, personalized cancer care. Even with changes such as increased use of cross-cutting patient-centered outcome measures, quality measures are not sufficient to ensure that every clinical decision will result in the highest quality care for each patient at an individual level. Other tools are needed to inform decision-making at the point of care. Shared decision-making and goal setting can be encouraged through MIPS Improvement Activities, facility accreditation programs, practice recognition programs such as the Patient-Centered Specialty Practice,[18] and Alternative Payment Models (APMs). Clinicians we interviewed noted that clinical pathways and clinical decision support systems can assist in making evidence-based clinical decisions, but pathways can be inflexible. These tools should not restrict the application of patient preference to decision-making.

Conclusion

We assessed the current approach to measuring the quality of personalized medicine in oncology and found that only a limited number of relevant measures are in use, and these measures have significant limitations. We found that small numbers issues render cancer condition-specific testing and treatment measures infeasible for use in CMS quality and payment programs for all but a few cancers and may result in providers' payment adjustments being due to chance rather than performance. In addition,

because of a focus on specific genetic tests and targeted treatments for some measures, there is a significant risk that measures will become out of date as biomedical science quickly evolves. Finally, not all testing and treatment measures account for patient preferences, meaning that providers may be penalized for recognizing patient wishes.

Based on these findings and a series of interviews with key informants representing patients, practicing oncologists, academic researchers, and other stakeholders, we identified a set of recommendations for improving the current approach to quality measurement of personalized medicine. Our recommendations include increased development of measures for genetic testing that are not specific to individual tests and cancers, incorporating allowances for patient preferences in all genetic testing and treatment measures, and increased focus on patient-centered outcomes, such as goal concordance, patient experience, and quality of life. These approaches to measurement should be complemented by other quality-related tools, such as improvement activities, accreditation and certification programs, care pathways, and clinical decision support systems, to improve the quality of personalized medicine.

Appendix 1: Measure Scan Methods and Full Results

Measure Scan Methods

The oncology measure search queried the National Quality Forum (NQF) Quality Positioning System (QPS), the Agency for Healthcare Research and Quality's (AHRQ) National Quality Measures Clearinghouse (NQMC), and the Centers for Medicare & Medicaid Services (CMS) Measures Inventory. Oncology was chosen as the focus of this analysis because the specialty has by far the most approved therapies and the most therapies in the development pipeline.

We used a broad set of search terms related to cancer, personalized medicine, and individual genetic biomarkers to ensure that we captured all relevant measures. See Table 1 for a list of the search terms. Any measure that contained one or more of the search terms in its title, measure description, numerator, and/or denominator was captured. We then filtered the resulting measures to remove measures not related to oncology.

Table 1. List of Measure Search Terms

Measure Scan Search Terms		
ALK	Genetic screening	Mutation
Biomarker	Genetic testing	Neoplasm
BRAF	HER2	Oncology
BRCA	KRAS	PD-L1
Cancer	Leukemia	Ph+(BCR-ABL1)
EGFR	Lymphoma	RAS
ErbB2	Malignant	Receptor
Gene amplification	Melanoma	Tumor
Gene overexpression	MOAB	
Genetic counseling	Molecular	

Next, we reviewed the description, numerator, and denominator of each measure to identify testing and treatment measures. We removed those that did not include genetic or mutational testing or a genetic biomarker linked to treatment decision in the numerator or denominator.

To identify person-centered care measures, we reviewed the description, numerator, and denominator to identify measures related to: (1) shared decision-making, (2) goal concordance, (3) patient experience, (4) care planning, and/or (5) patient communication.

After the final measures were identified, we then reviewed the measures to identify their use in Medicare quality measurement and value-based payment programs. Among those that are part of Medicare programs, we analyzed the measures to determine whether they would generate issues of small numbers and low measure reliability or run the risk of becoming out of date. We also reviewed the measure specifications to determine whether the measures include exclusions or other allowances for patient preferences.

Full Measure Scan Results

Genetic/Biomarker Testing and Targeted Treatment Measures

We identified 14 genetic/biomarker testing measures and 12 targeted treatment measures. A majority (15) of these measures focused on breast cancer and specifically on the HER2 gene and estrogen and progesterone receptors. In addition to breast, only skin, colorectal, and lung cancer had multiple measures. Brain cancer, leukemia, lymphoma, and sarcoma had one measure each. Table 2 shows the counts of the testing and treatment measures by cancer type. These results demonstrate that measurement is limited to a narrow set of cancers, with only the most prevalent cancers having multiple measures.

Table 2. Existing Genetic/Biomarker Testing and Targeted Treatment Measures by Cancer Type

Cancer Type	Testing	Treatment	Totals
Breast	6	9	15
Skin	2	1	3
Colorectal	1	1	2
Lung	1	1	2
Brain	1	0	1
Leukemia	1	0	1
Lymphoma	1	0	1
Sarcoma	1	0	1
Totals	14	12	**26**

Person-Centered Care Measures

We identified 15 person-centered care measures, all of which are applicable across different cancers. Of the 15 measures, 5 are focused on care planning and 4 are focused on patient experience, including one

measure derived from the CAHPS® Cancer Care Survey. The results show that there are currently no cancer quality of life measures in use in CMS programs. While there are measures of shared decision-making in use for patients with cancer, the measures are narrowly focused on interventional oncology.

Program Use

Nine of the testing and treatment measures are in use across 4 different CMS programs: Hospital Compare (HC), Merit-Based Incentive Payment System Program (MIPS), the Oncology Care Model (OCM), and the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) program. Five of the 15 patient-centered care measures were used in CMS programs, including OCM, MIPS, the Medicare Shared Savings Program (MSSP), and Physician Compare (PC). Most of the measures in use are used in MIPS. A full list of the measures in use in CMS quality and payment programs is provided in Appendix 2.

Appendix 2: Quality Measures of Oncology Personalized Medicine in Use in CMS Quality Measurement and Value-Based Payment Programs

Measure Title	NQF ID	Type	Program Use	Considers Patient Preference or Perspective
Testing and Treatment Measures				
Adjuvant Hormonal Therapy	0220	Process	PCHQR, HC	Assesses whether treatment is "considered"
Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow	0377	Process	MIPS	Exclusion for "patient reasons for not testing"
Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0387	Process	OCM	Exclusion for "patient refusal"
Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage IB - III hormone receptor negative breast cancer.	0559	Process	PCHQR, HC, OCM	Assesses whether treatment is "considered or administered"
Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	1855	Process	MIPS	n/a*
HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies	1857	Process	MIPS	X
Trastuzumab administered to patients with AJCC stage I (T1c) – III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1858	Process	OCM, MIPS	Exclusion for "patient declined"
KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-	1859	Process	MIPS	X

Epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy				
Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies	1860	Process	MIPS	X
Person-Centered Care Measures				
Communication and shared decision-making with patients and families for interventional oncology procedures	n/a (CMS:5408)	Process	MSSP, PC	√
Patient-Reported Assessment of Communication & Shared decision-making for interventional oncology procedures	n/a (CMS:3284)	PRO	MIPS, MSSP	√
Patient-Reported Assessment of the Communicated Procedure Outcomes following an Interventional Oncology Procedure	n/a (CMS:3285)	PRO	MIPS, MSSP	√
Patient-Reported Experience of Care (derived from CAHPS)	n/a (OCM-6)	PRO	OCM	√
Follow up evaluation and communication of procedure outcomes with patients and families following interventional oncology procedure	n/a (CMS:3159)	Process	MSSP, PC	√
Notes: HC= Hospital Compare, MIPS=Merit-Based Incentive Payment System Program, OCM= Oncology Care Model, PCHQR=Prospective Payment System-Exempt Cancer Hospital Quality Reporting * This measure assesses whether a HER2 test meets certain criteria; patient preference is not applicable.				

Appendix 3: Themes from Stakeholder Interviews

We conducted a series of semi-structured interviews with key informants representing the perspectives of patients, practicing oncologists, academic researchers, measure developers, and quality improvement organizations. The key informants were asked a series of common questions followed by additional questions that were tailored based on their background, expertise, and perspective. Some common themes emerged from the interviews and are summarized by category below. These common themes were used to inform the recommendations.

Personalized Medicine is Rapidly Evolving

- New therapies, and information on existing therapies, are being released often, and it is difficult for clinicians to stay current with the evolving science.
- New information is not always immediately understood or actionable and can be open to interpretation. Clinical guidelines are not providing timely clarity.
- Clinicians do not always know which test to order or how to interpret the results of tests. More education is needed so that clinicians can inform patients of their choices.

Patient Preference is Essential

- Eliciting patient preference should be considered a required component of personalized medicine.
- Discussion of patient goals and embedded shared decision-making should occur at all decision points in the patient journey, including screening, diagnosis, treatment, and follow-up.
- Clinical pathways and decision support tools need to be flexible to allow for patient preference.

Measures Need to Focus on What Matters to Patients

- Quality of life, patient goal setting, patient experience, and patient-centered outcomes are top priorities for measures.
- Quality of life should include side effects of chemotherapy.
- Measures to improve access to testing are also needed.

Need to Address the Shortcomings of Measurement

- Gene therapies and immunotherapies are performing remarkably well, but their impact is not being fully raptured by existing measures.

- Existing measures have poor reliability at a provider-level, and providers fear penalties for factors outside their control.
- There are gaps in measures for many cancers, especially those with lower incidence and prevalence.
- Measures are not, and should not be, the only tool for assessing quality.

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