

Clinical, practice, and policy trends: a round-up and review of the 2016 oncology landscape

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We end this year with yet another encouraging list from the US Food and Drug Administration (FDA) of new drugs or expanded uses for some previously approved drugs for patients with life-threatening cancers. As clinicians focused on delivering quality, cost-effective care to our patients, that is exciting, but the overarching issues of dosing specificity, increasingly specific gene mutation testing, and complex therapy sequencing requirements explain another major trend of 2016: the increasing adoption of standardized pathways. In addition, given the continued explosion in drug pricing and the expanding use of high-cost drugs in more common diseases and in more lines of therapy, payers and providers are working to incorporate expanded decision support tools such as pathways to guide and optimally monitor therapies for patients.

The state affiliate council of the American Society of Clinical Oncology (ASCO) raised concerns in 2014 from practicing oncologists who said their time was increasingly being diverted away from patient care toward a focus on pathway care and compliance. That could be in the form of either practice-wide adopted pathways or from multiple payer-chosen pathway programs imposed on practices for their members. Thus patients with the same tumor stage and features required different pathway choices, data entry, vendors, and authorization processes. In addition, clinicians have voiced growing frustrations over data entry with more complex electronic medical record documentation to facilitate compliance and outcome analytics in the cumbersome shift to value-based methods of practice. In response, ASCO appointed a pathways task force to devise recommendations for streamlining the development and use of oncology pathways and processes so that clinicians could fully focus on the delivery of evidence-based, high-value, cost-effective care. As the ASCO board of directors' liaison and a member of the pathway task force, I wanted to share that



the criteria for a high-quality oncology pathway program focus on three key areas: development, implementation and use, and analytics. The pathway criteria are:¹

- **Expert driven** – Do practicing oncology providers play a central role in the pathway development?
- **Reflects stakeholder input** – Is there a way for stakeholders to provide input during the development process?
- **Transparent** – Is there a clear, consistent process and methodology for pathway development, and is relevant information disclosed to stakeholders and the general public?
- **Evidence-based** – Is the pathway based on the best available scientific evidence?
- **Patient-focused** – Does the pathway include evidence-based options to account for differences in patient characteristics and/or preferences?
- **Clinically driven** – Is there an established methodology for prioritizing efficacy, safety and cost? Are stakeholder assessment and analysis used to revise the pathway?
- **Up-to-date** – Is the pathway updated in a timely way as relevant new information becomes available?
- **Comprehensive** – Does the pathway address the full spectrum of cancer care? If the pathway is not comprehensive, does it clearly describe the phase and elements of care it is intended to address?
- **Promotes participation in clinical trials** – Are available clinical trials options incorporated in the pathway?
- **Clear and achievable expected outcomes** – Is informa-

tion provided on the specific cancer type that the pathway is intended to cover, and on what constitutes on-pathway versus off-pathway treatment and goal adherence rates?

- **Integrated, cost-effective technology and decision support** – Does the pathway comply with federal mandates for meaningful use of electronic health records, and does it offer – or plan to offer – resources that can be integrated into commonly used electronic health records?
- **Efficient processes for communication and adjudication** – Does the pathway provide references that may support pathway variation, inform the provider in real time of pathway compliance, and offer a mechanism for choosing an off-pathway recommendation?
- **Efficient and public reporting of performance metrics** – Does the pathway offer providers and the public with reports on provider performance over time and compared with other groups of providers, and do such reports reflect valid occasions when the provider has gone off-pathway?
- **Outcomes-driven results** – Does the pathway have analytics in place to enable a movement over time from adherence-driven compliance to outcome-driven results?
- **Promotes research and continuous quality improvement** – Does the pathway demonstrate a commitment to research aimed at assessing and improving the impact of pathways on the patient and provider experience, clinical outcomes, and value?

The pressure to facilitate delivery of ever more expensive, complex, sequenced, and integrally managed cancer diagnostics and therapies to achieve the best health outcomes for a diverse and aging population has also fueled the continued consolidation of community practices into larger networks, with many now partnered with large academic centers or regional hospitals. The expense of infrastructure for sophisticated electronic medical records and team-based documentation and care to ensure delivery of personalized cancer therapies can benefit from economies of scale in larger organizations.

We are still in the early phase of piloting the tools, teams, and processes to achieve reportable clinical and financial outcomes across the spectrum of patients that oncologists and hematologists care for. As the oncology workforce burn-out rate has reached unsustainable levels, we will need to figure out what data should be collected, by whom, and at which points along the care continuum and then address the “best outcomes” scenarios. It is already clear from early pilots that we need to figure out regional and systemic approaches to providing 24-7

access for patients to have emergent and urgent symptom management to prevent costly and avoidable emergency department visits and hospitalizations. We have identified the growing educational needs of patients, care givers, and families to optimize compliance with complex therapy regimens as well as improving disease knowledge to help patients maintain realistic expectations for their health outcomes across their lifespan.

An array of approvals from the FDA

New approvals

- **Delfitelio** (defibrotide sodium, Jazz) in March, for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, also known as sinusoidal obstructive syndrome, with renal or pulmonary dysfunction following hematopoietic stem cell transplant.
- **Venotoclax** (Venclexta, AbbVie and Genentech) in April, for patients with chronic lymphocytic leukemia with 17p deletion as detected by an FDA-approved test, who have received at least one prior therapy.
- **Cabozantinib** (Cabometyx, Exelixis), also in April, for the treatment of advanced renal cell carcinoma in patients who have received previous anti-angiogenic therapy.
- **Atezolizumab** (Tecentriq, Genentech) in May, accelerated approval for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression with or after platinum-containing chemotherapy or who have disease progression within 12 months or neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. In October, atezolizumab was also approved for the treatment of patients with metastatic non-small-cell lung cancer (NSCLC) whose disease progressed during or following platinum-containing chemotherapy. Patients with epidermal growth factor receptor (EGFR) or ALK genomic tumor aberrations should have disease progression on an FDA-approved therapy for those aberrations before receiving atezolizumab.
- **Olaratumab** (Lartruvo; Eli Lilly) in October, accelerated approval for the treatment of patients with soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery and with a histologic subtype for which an anthracycline-containing regimen is appropriate.
- **Daratumumab** (Darzalex, Janssen) in November, in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for patients with multiple myeloma who have received at least one prior therapy.
- **Nivolumab** (Opdivo, Bristol-Myers Squibb), for patients with recurrent or metastatic squamous cell carcinoma of

the head and neck with disease progression on or after a platinum-based therapy.

Extended approvals

- **Ofatumumab** (Arzerra injection, Novartis) in January, for extended treatment of patients who are in complete or partial response after at least 2 lines of therapy for recurrent or progressive chronic lymphocytic lymphoma.
- **Erbulin** (Havalen, Eisai) in January, for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.
- **Palbociclib** (Ibrance, Pfizer) in February, in combination with fulvestrant for the treatment of women with hormone receptor-positive, human EGFR-2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- **Obinutuzumab** (Gyzyva, Genentech) in February, approval for use in combination with bendamustine followed by obinutuzumab monotherapy for the treatment of patients with follicular lymphoma who relapsed after, or who are refractory to, a rituximab-containing regimen.
- **Everolimus** (Afinitor, Novartis) in February, approval in February for use in adult patients with progressive, well-differentiated, non-functional, neuroendocrine tumors of gastrointestinal or lung origin with unresectable locally advanced or metastatic disease.
- **Crizotinib** (Xalkori, Pfizer) got approval in March for the treatment of patients with metastatic, NSCLC whose tumors are ROS1 positive.
- **Lenvatinib** (Lenvima, Eisai) in May, approval in combination with everolimus for the treatment of advanced renal cell carcinoma after one previous anti-angiogenic therapy.
- **Nivolumab**, also in May, approval for the treatment of patients with classic Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin.
- **Pembrolizumab** (Keytruda; Merck, Sharp & Dohme) in August, accelerated expanded approval for treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy. In addition, in October pembrolizumab got extended approval for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test.

Modified use

- **Erlotinib** (Tarceva, Astellas) in October, had its indication restricted for the treatment of NSCLC to limit its use to patients whose tumors have specific EGFR mutations.
- **Nivolumab** in September, had the previously approved dosing updated to include a single, fixed dose every 2 weeks for use in patients with the currently approved indications in renal cell carcinoma, metastatic melanoma, and NSCLC.

And, notably, in June, the FDA approved the **cobas EGFR Mutation Test v2** (Roche) using plasma specimens as a companion diagnostic test for the detection of exon 19 deletions or exon 21 (L858R) substitution mutations in the EGFR gene to identify patients with metastatic NSCLC eligible for treatment with erlotinib.

Change and uncertainty dog health policy

On the policy front, the impending introduction of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)² and the November elections were prominent players. Given the election outcome, in 2017, we should be watching out for Affordable Care Act (ACA) reform, changes to MACRA's Quality Payment Program, and a potential 5-4 conservative bent in the Supreme Court. The transition from volume- to value-based care has loomed over oncologists for a while, and ASCO has worked diligently to assist its members in preparing for and making the transition.

In a final rule posted on October 14, the Centers for Medicare and Medicaid Services exempted some doctors from having to participate when it increased the threshold for inclusion in the new value-based payment program from those billing \$10,000 or treating more than 100 Medicare patients a year to those billing \geq \$30,000 or treating more than 100 Medicare patients per year. That means that physicians and community oncologists who have a small Medicare population will have some leeway in participating in the Quality Payment Program, which was due to start in January 2017. The rest of us, however, will fall into MIPS reporting requirements starting in January of 2017. Participation is essential as it will impact our 2019 Medicare payment adjustment, which can range from a negative to a positive 4%.

President-elect Donald Trump ran on the promise of ACA repeal. Health policy experts differ in how they see ACA reform coming about, with some predicting a quick repeal coupled with an immediate legislative replacement, whereas others envision repeal, even of some key elements, will be over a longer time, to allow crafting of replacement legislation.

Looking ahead for our journal

We've introduced some innovations this year, and we

hope to refine them in 2017. JCSO is now a standalone publication and no longer a component of the Oncology Practice portal. The JCSO website has accordingly been redesigned and upgraded, we initiated an interview series and a weekly e-newsletter blast, and are bolstering our social media presence.

Although the new therapies capture our imagination of one day finding cures for most if not all cancers, our current knowledge informs us that we will need expanded analytics in addition to therapeutic advances if we are to match best therapies, sequences of therapies,

and care models to provide the best health outcomes for our patients. Oncology remains a most humbling and challenging career choice, and the remarkable progress in 2016 and expanding legions of cancer survivors continue to inspire us as we head into 2017.

On behalf of my colleagues, the Editors and the staff of our journal, we wish you, your families and your staffs a joyful holiday season. Together we can look forward to better tools and teams to give you back more time to care for your patients and energize your work in the year to come.

References

1. ASCO releases criteria for high-quality clinical pathways in oncology [news release]. Alexandria, VA: ASCO press center; November 19, 2016. <http://www.asco.org/about-asco/press-center/news-releases/asco-releases-criteria-high-quality-clinical-pathways-oncology>. Accessed December 13, 2016..
2. Bosserman L, Zon R. Deconstructing MACRA: the switch from volume- to value-based payment. <http://www.mdedge.com/jcso/article/114670/patient-survivor-care/deconstructing-macra-switch-volume-value-based-payment?channel=278>. Published September 2016. Accessed November 30, 2016.