The Oncology Clinical Pathways Congress, the official meeting of the Journal of Clinical Pathways, was held October 11-13 in Boston, MA. Attendees, including clinical oncologists, life-science company representatives, and healthcare quality specialists convened to discuss the development of clinical pathways and how to align this work with improving patient outcomes. While the agenda featured a wide array of topics, from ovarian cancer therapies to value-based care and physician burden, several key themes emerged throughout the conference: the need for multi-disciplinary buy-in for institutions and patients to fully reap the benefits of clinical pathways implementation, the importance of patient-centered care, and the increased role that technology is playing in health care.

Clinical Pathways:

The goal of clinical pathways is to standardize care, reduce variation in treatment, and ensure evidence-based decision-making. Clinical pathways increase accountability among care teams for outcomes, quality, and costs, and are increasingly appearing in payment reform models. The 2017 ASCO Trends Report demonstrates that between 2014-2016, there was a 42% increase in practices reporting compliance with a pathway program, and of the oncology practices participating in the pathway, 46% were required by health plans to comply with one or more pathways. The benefits of clinical pathways are becoming widely known through the demonstration of positive results – in an analysis of the Dana-Farber Cancer Institute Clinical Pathway, for instance, it was determined that pre- and post-implementation of pathways resulted in a 12-month cost-of-care savings of $15,000 for patients living with stage IV non-small cell lung cancer.

Despite the benefits, there are many challenges to rolling out clinical pathways, including keeping content up to date, time- and cost-intensive resources, EHR integration, and perhaps most poignantly, provider participation. Indeed, presenters of the "Clinical Pathways Beyond Treatment Decision Support" session stressed that simply *having* the pathway and expecting changes in care delivery to be made was not enough. Rather, it is essential to foster internal partnerships with departments such as IT and pharmacy and encourage hospital leadership to champion the use of pathways, while allowing a supportive, incentivizing, and user-friendly environment for providers to utilizing pathways in treatment decision-making.

Patient-focused Care:

Clinical pathways are an effective way to standardize care delivery across an institution, however by design, they offer very narrow options for treatment decision-making, with the goal of achieving up to 90% of pathway concurrence in certain cases. [i] While pathways can assist the clinician by demonstrating evidence-based treatment options, pathways are also subjected to offering narrow cost and treatment benefit considerations, and do not take into account the needs of the patients themselves, said a presenter from the Patient Advocate Foundation (PAF). Patients retain less than half of the information delivered to them during their first oncology consult, [ii] and when large amounts of information are presented, even less information is likely to be recalled by patients. Lack of treatment and self-management comprehension can lead to low medication adherence, disease progression, and poor quality of life, and care teams should strengthen care coordination efforts to supplement the clinical pathway-driven treatment guidance.

Managed care organizations and oncologists say that the tension between standardization and personalization is one of the greatest challenges facing cancer care. Oncologists are shifting their approach and thinking more about patient issues, such as treatment costs, quality of life, socioeconomic factors, and transportation when it comes to patient care. In a soon-to-be published PAF survey, researchers discovered that the existence of three components were likely to shape a positive patient experience: respect, listening, and personal connection. The project surveyed over 1,300 low-income patients across various cancer sites who stated overwhelmingly that they wish to make final treatment decisions *with* their provider, and that if given the choice, 96% would choose highly-personalized over standardized care. Such highly-personalized care is not always an option in many cases, emphasizing the need for care teams to educate patients on the significance of clinical pathways, as well as addressing the individual barriers to care when standardizing pathways. Furthermore, presenters stressed the need to address survivorship and end of life issues in the developing of pathways and demonstrated the ability of pathways to hold care teams accountable for presenting patients and caregivers with information and resources related to palliative and hospice care.

Technology in Health Care:

During the conference, presenters frequently touched on both the increasing need for technology in health care to improve patient access, and the capacity of technology to improve health care on multiple fronts. Artificial intelligence and machine learning can reduce error, predict outcomes by treatment option, as well as support clinicians through the advent of imaging and algorithmic diagnoses. Presenters discussing "The Role of Technology in Oncology Clinical Pathways" emphasized that the healthcare system is lagging behind changemakers in the private sector who not only see opportunities for innovation but have the resources to provide tailored care and address patient access issues. For instance, Amazon Care provides on-site clinics for its employees, and Google has plans to utilize clinical data from various sources with behavioral data it already routinely collects on users to develop high-impact health interventions. These behemoth companies, say the presenters, understand the customer far deeper that payers, and are already accustomed to providing services that make consumers' lives easier.

Recent technological innovations also have the capacity to streamline care delivery, such as the Butterfly iQ portable ultrasound machine (which plugs into an iPhone or iPad), or phone applications for telemedicine that eliminate the logistical burden on patient and provider for face-to-face meetings. Such technology can be used to drive the much-needed shift from a diagnostic retrospective view, to a real-time predictive, prospective use of data, which presenters say would be the most important impact technology could have on oncology care.

Related to the need for real-time data, attendees learned about Project GENIE (Genomics Evidence Neoplasia Information Exchange), an international "pan-cancer" registry from the American Association of Cancer Research (AACR), with sponsored research funds from life-science companies such as Merck, Novartis, and Janssen. Project GENIE contains real-world data built through data-sharing of clinical-grade genomic data, with clinical outcomes from tens of thousands of cancer patients at participating institutions and can be used to inform precision medicine, inform treatment pathways, and power real-time clinical decision support.

<u>Session Highlight:</u> Biosimilars and Oncology Clinical Pathways: Perfect Together, Gary Lyman, MD, MPH, FASCO, FRCP, Senior Lead, Healthcare Quality and Policy, Hutchinson Institute for Cancer Outcomes Research, Seattle, WA

In addition to overarching themes on clinical pathways implementation, patient-focused care, and technological innovation, one particular session stood out, as it pertains directly to the raising cost of cancer care. During the session, Dr. Lyman highlighted that cancer drugs continue to drive overall healthcare spending, and that globally, was a major contributor to the increase in spending from $46 billion in 2002 to $221 billion in 2017. [iii] As median household income has stayed relatively flat from 1975-2014, the median monthly cost of new cancer drugs has grown. Incorporating biosimilars into the workplace via oncology clinical pathways, says Dr. Lyman, could be an instrumental way to address the exponential growth in global cancer care spending.

Biosimilars have no clinically-meaningful differences with the reference product in terms of safety and potency and are more cost-effective treatment options that could promote greater competition in the pharmaceutical industry. In addition to a lower-cost market price, biosimilars have a lighter research burden, requiring fewer intensive studies such as clinical trials, and instead utilizing pharmacokinetic pharmacodynamic modeling methodologies, for example. The FDA evaluates biosimilar candidates on a totality of evidence, including analytical studies, animal studies, clinical and immunogenicity assessments to determine if further research is needed to eliminate residual uncertainty with the reference product.

Some of the major challenges to the use of biosimilars include variability and drift –significant differences in drug products that are caused by production in different sites– and changes in manufacturing processes after initial approval. To manage these challenges, manufacturers need to be aware of clinically significant issues that could arise from process changes in manufacturing, and there is a need for increased pharmacovigilance to ensure products retain the correct molecular composition.

With a number of biologic product patents expiring before 2020, there is significant opportunity for the development and promotion of biosimilars in cancer care. There are currently 23 biosimilars that have been approved by the FDA, however, providers remain skeptical of their efficacy and impact on reimbursement, and have had the experience that payer-designated formularies require biologic failure *before* switching to a biosimilar. A strengthened effort to educate providers and patients on the benefits of biosimilars, and payers on the incorporation of biosimilars in clinical pathways could result in major advantages in terms of cost and enhancing patient access to high-quality care.

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