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The Global Perspective on Value in Cancer Care

n June 1, 2014, the penultimate day of the 50th Annual Meeting of the American Society of Clini-

cal Oncology (ASCO), the discussion on value in cancer care was rekindled, but this time on a global scale. The session, "ASCO/European CanCer Organisation (ECCO) Joint Session: Value and Cancer Care," saw participation from physicians and economists from around the world, with individual perspectives on defining value and the programs being developed to ad- Elisabeth De Vries, MD, PhD dress the issue. Regula-

tory approval does not guarantee patient access to efficient therapies. So where lies the problem?

The first talk was "ESMO-EONS: Value and the Exchange Between Physicians, Nurses, and Patients" by Elisabeth De Vries, MD, PhD, University Medical Center Groningen, Netherlands, a member of the Magnitude of Clinical Benefit Scale task force.

De Vries began with an overview on cancer drug use in Europe, and discussed how the cancer drug development process is influenced by the European Society for Medical Oncology (ESMO).

Similar to what has been demonstrated in the United States, the 5-year relative cancer survival rate in Europe increased between 1999 and 2007. However, the cost of treatment is only burgeoning.

So what is the relevance of the cost of cancer drugs? Using imatinib as an example, De Vries presented a pricing plot that showed that the drug costs the most in the United States, but costs substantially less in Europe and other countries elsewhere around the globe.

She went on to state that there are differences in access to relevantly new anticancer drugs in Europe-differences in price, differences in healthcare costs, and differences in time to access following approval by the European Medicines Agency (EMA). These disparities are associated with various issues, one of which is the cost of the drug and reimbursement.

Among European nations, a 1.8-fold difference in the cost of trastuzumab has been identified. Additionally, a difference in time to availability after EMA approval has been observed. The bottom line: the lack of timely access to anticancer drugs can result in major disparities in cancer outcomes.

With the hope of standardizing policies and easing patient access to novel treatments, ESMO is developing the Magnitude of Clinical Benefit

Scale. How will the scale be used? EMA-approved drugs will be scaled by the task force, and drugs with the highest value will then be promoted.

Various factors that contribute to the scale include quality of life (QOL), overall survival (OS), progression-free survival (PFS), prognosis of condition, toxicity, hazard ratio, long-term survival, and rate of response.

These factors will be used to determine the magnitude of clinical benefit. "We did not factor costs into the equation due to the heterogeneity that exists across Europe," clarified De Vries. "We believe the ESMO scale will be constantly evolving with the availability of increasing efficacy and toxicity data as the treatment is used by the wider population."

The scales, she noted, are distinct for curative versus palliative settings. PFS, for example, can never qualify for a grade 4 score as a primary end point, but could be a secondary end point to be considered concurrent with OS, toxicity, and QOL.

The major heterogeneity in drug price and access across Europe can result in

inequality in optimal care. The ESMO scale grades drugs to determine the ideal drugs that should be immediately accessible to patients across Europe.1 The task force plans to develop and further mature this grading scale by collaborating with sister societies to generate as much data as possible to improve patient access.

Next on the panel was Richard Sullivan, MD, Richard Sullivan, MD, PhD PhD, Kings Health Part-

ners Integrated Cancer Centre, London, England, who discussed "Cancer Care in Cost-Restrained Healthcare Systems." Sullivan, who is also a part of the team that is developing the ESMO scale, conducts a research program whose focus extends from the sociopolitical policy of global cancer (OncoPolicy) to the development of public health systems in highrisk conflict areas focusing on DR Congo, Afghanistan, and Libya. In OncoPolicy, he

recently led the first major Lancet Oncology Commission that examined the affordability of cancer in high-income countries.2

"All healthcare systems are struggling to deliver affordable and equitable cancer care," said Sullivan. Cancer care operates as a complex adaptive system, and unlike other normal systems:

- it is non-linear, dynamic, and can even appear chaotic;
- · individuals who comprise the system behave according to social and structural norms rather than the needs of the system;
- goals and behaviors are often in conflict; and
- there is no single point of control.

"Our global economic systems have become 'addicted' to the returns generated by cancer care and treatment," pointed out Sullivan. Income equality is worsening globally, and we need to gain a better handle on value and equitability. Research has shown that three-fifths of the global population has less than 5% of global wealth. How can that provide equitable cancer care?

Additionally, the cancer research portfolio is extremely narrow when it comes to drug discovery and fundamental biology. The sheer volumes and pace of outputs is outstripping the ability of policy makers. "It's harder to make cost-

> effective and rational decisions to provide or make available efficient therapy to the population as a whole," said Sullivan.

Cancer care systems are framed by behaviors and cultures that are not coterminous with affordability and equity. Patients can have very high expectations from their cancer treatment. Therefore, "How we frame

the debate becomes as important as the content of the debate," proclaimed Sullivan.

Identifying sites for fiscal controls and sustainability mechanisms is an uphill battle, and recognizing problem areas to adapt cost-effectiveness is very hard. This is even more difficult in developing nations like India, where 67% of out-ofpocket expenditure with financial hardship and 21% catastrophic expenditure has been documented with cancer care, according to Sullivan.

Most of our societies are reaching limits on affordability or what we are willing to pay. How do we then get value-based pricing?

Balancing costs and benefits with toxicity of new technologies needs consideration. New, extremely efficient drugs (such as the developing immunooncology molecules) could be the stepping stone in this setting.

"Value-based pricing without universality or universal healthcare does not work," concluded Sullivan. "Reform can never stop, as exogenous factors emerge and societal demands and values change."

The final presentation in the session, by Lowell E. Schnipper, MD, Beth Israel Deaconess Medical Center, discussed "American Perspective on Globally Defining Value in Cancer Care."

The United States spends a lot more on healthcare than a lot of European nations, and the data are spotty.

"Why do we emphasize value?" asked Schnipper.

Drug price is a part of the high cost of cancer care, but not the only problem by any means. Outside the United States. clinical aspects are used for assessment first, and then the results are applied for price negotiation.

He reiterated that the physician has an active role to play in value determination and cost regulation, and ASCO is making efforts to help define value in cancer care with the long-term goal of integrating these suggestions in the clinic.

His final thoughts were that the value model must also be adaptable for early disease settings, which is ongoing.

The closing remarks were provided by Clifford Hudis, MD, Memorial Sloan Kettering, and the immediate past president of ASCO. "We are entirely dependent on industry for both innovation and cash flow. But we want to develop a dialogue and generate communication when it comes to drug costs." **EBO**

References

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