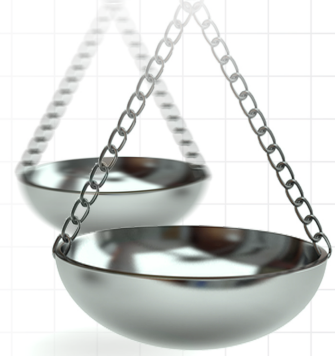
Commentary



Journal of Comparative Effectiveness Research

Musings on value frameworks in cancer

"With increasing budget constraints and the need to make trade-offs in health spending, assessing the value of cancer medications has taken center stage in the discussion of drugs and drug prices."

Submitted: 15 June 2016; **Accepted for publication:** 16 June 2016; **Published online:** 14 July 2016

Keywords: cancer • frameworks • oncology • value

Ram Subramanian
Author for correspondence:
Simon-Kucher & Partners, One Canal Park, Cambridge, MA 02141, USA
ram.subramanian@simon-kucher.com

Kevin Schorr
Simon-Kucher & Partners, One Canal Park, Cambridge, MA 02141, USA

Drug pricing is all over the news lately. Rarely does a day go by without seeing headlines like "The inexplicable and relentless rise of cancer drug prices" (Washington Post, 2 May 2016) or "Doctors Object to High Cancer-Drug prices" (Wall Street Journal, 23 July 2015). These are only a couple of examples of news outlets proclaiming that spending on cancer therapies is unsustainable. Implicit in the panic about cancer drug spending is the fundamental value question: "What is a cancer therapy worth?"

Several physician organizations have begun to question the relative value of cancer therapies and to that end have attempted to quantify the clinical benefit offered by cancer therapies based on clinical trial data. Prominent among these physician organizations are the American Society of Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO), and the National Comprehensive Cancer Network (NCCN). Each of the aforementioned organizations has developed its own version of a value framework.

Value frameworks

In mid-2015, ESMO released the first version of the ESMO Magnitude of Clinical Benefit Scale – a tool that uses a "structured and consistent approach to derive a relative ranking of the magnitude of benefit" that can be expected from a cancer therapy [1].

Around the same time that ESMO came out with their tool, ASCO published the first version of its Value Framework – a physician-guided tool to help the physician and patient with shared decision-making [2]. The ASCO Value Framework enables "comparison of a new treatment regimen with the prevailing standard of care for a specific clinical cancer indication" based on data derived from a prospective randomized clinical trial. The framework calculates a net health benefit (NHB) score by awarding (or subtracting) points for clinical benefit and toxicity. The NHB is paired with the direct cost of treatment, to provide an overall summary assessment.

Toward the end of 2015, NCCN published its NCCN Evidence Blocks™ that are intended as a visual representation of five key measures (efficacy, safety, quality of evidence, consistency of evidence and affordability) that provide important information about specific recommendations contained within the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). According to NCCN, the goal of the NCCN Evidence Blocks is "to provide the healthcare provider and the patient information to make informed choices when selecting systemic therapies based upon measures related to treatment, supporting data and cost" [3].

Emerging themes

A close inspection of the various value frameworks reveals three broad themes.

Value is more than just a number

While all three frameworks attempt to quantify value based on clinical benefit, they dif-

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fer in their approach, applicability and methodology. As a result, the value of a product cannot be completely captured by a single 'number'.

Approach – ESMO states that their tool is to "address the public policy issue of value in cancer care and help frame the appropriate use of limited resources" while the ASCO and NCCN frameworks aim to help physicians and patients make informed choices when selecting treatments.

Applicability – While the ASCO and NCCN approaches apply for all cancers, the ESMO approach works only in solid cancers. Single-arm studies (the basis for accelerated approval of some breakthrough therapies) cannot be evaluated by the ESMO approach but can be in the ASCO approach. Only the ASCO and NCCN frameworks highlight therapy costs.

Methodology – The scales used to score therapies are different and vary from continuous scales to 1–5 ratings. The weighting applied to components of the value assessment also differ across frameworks leading to final scores that cannot be compared.

Value is in the eye of the beholder

The subjective nature of a value assessment is apparent in the importance given to end points when assigning value scores. The ESMO and ASCO approach for non-curative therapies (advanced disease) prioritize overall survival over progression-free survival over response rate but operationalize it differently. The highest clinical benefit grade that can be obtained in the ESMO framework varies from 2 to 4 depending on the end point reported (i.e., response rate, progression-free survival, or overall survival). The NCCN approach on the other hand relies on expert judgement by NCCN panel members. NCCN panel members score each measure (efficacy, safety, quality of evidence, consistency of evidence and affordability) using a standardized scale from '1' to '5' with '1' being the least favorable and '5' the most favorable. The resulting data are analyzed and final scores are a rounded average of responses based on all responding panel members.

Furthermore, quality of life data and opportunities for bonus points are treated differently among the frameworks leading to further differences in the value assessment. The end result of the aforementioned differences is that a therapy could score well in one framework but poorly in another.

Value can change over time

The first version of the value frameworks came out in 2015, but ASCO recently revamped its approach based on over 400 comments during the 60-day public comment period. Version 2 of the ASCO framework is substantially different from version 1 (priority of end points, scoring scale, weights assigned, among others) [4]. This highlights the conceptual as well as subjective nature of quantifying value. There will always be room for debate as to which approach/methodology is better, more accurate, or more comprehensive. To ASCO's credit they have revised their approach and incorporated the constructive feedback from various stakeholders. The bottom-line is that value assessments cannot be 'static' and will need to be continually adapted to reflect changes in treatment paradigm.

Looking ahead

Value frameworks are in their nascency, and there will be more refinements in the coming years. But there are already some lessons for industry practitioners. The lessons are threefold:

- Know the evaluation criteria – value frameworks evaluate a limited set of weighted criteria. The final score granted to a therapy is not an absolute representation of the product's value – it is the result of the criteria choices made by the evaluating organization;
- Understand differences in methodology – while similar in many respects, the frameworks have fundamental differences in methodology which result in variable valuations. Even small differences in grading criteria, metrics and cutoffs can have a significant impact on the valuation of a product;
- Be prepared to defend your product – in the event of a poor evaluation, a manufacturer may effectively defend the value of the product by directly addressing the limitations of the evaluation criteria/methodology when appropriate. Identifying additional ignored or underweighted metrics can help further bolster a product's value.

Conclusion

With increasing budget constraints and the need to make trade-offs in health spending, assessing the value of cancer medications has taken center stage in the discussion of drugs and drug prices. Several organizations have taken steps to guide the medical community in assessing the value of cancer therapies by releasing their value assessment frameworks. However, the frameworks are not identical and there are several instances where therapies appear to be valued differently. As manufacturers and the medical community get more familiar with these frameworks and start to implement them, it is important to know the details of each framework and the resulting implications.

Financial & competing interests disclosure

R Subramanian is a Director in the Life Sciences Practice of Simon-Kucher & Partners based in Cambridge, MA, USA. K Schorr is a Consultant in the Life Sciences Practice of Simon-Kucher & Partners based in Cambridge, MA, USA. Simon-Kucher & Partners is a global consulting firm with 30 years of experience providing strategy and marketing consulting. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

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2 Schnipper LE, Davidson NE, Wollins DS *et al.* American Society of Clinical Oncology statement: a conceptual framework to assess the value of cancer treatment options. *J. Clin. Oncol.* 33(23), 2563–2577 (2015).

3 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with NCCN Evidence Blocks™. www.nccn.org/evidenceblocks/

4 Schnipper LE, Davidson NE, Wollins DS *et al.* Updating the American Society of Clinical Oncology Value Framework: revisions and reflections in response to comments received. *J. Clin. Oncol.* doi: 10.1200/JCO.2016.68.2518 (2016) (Epub ahead of print).