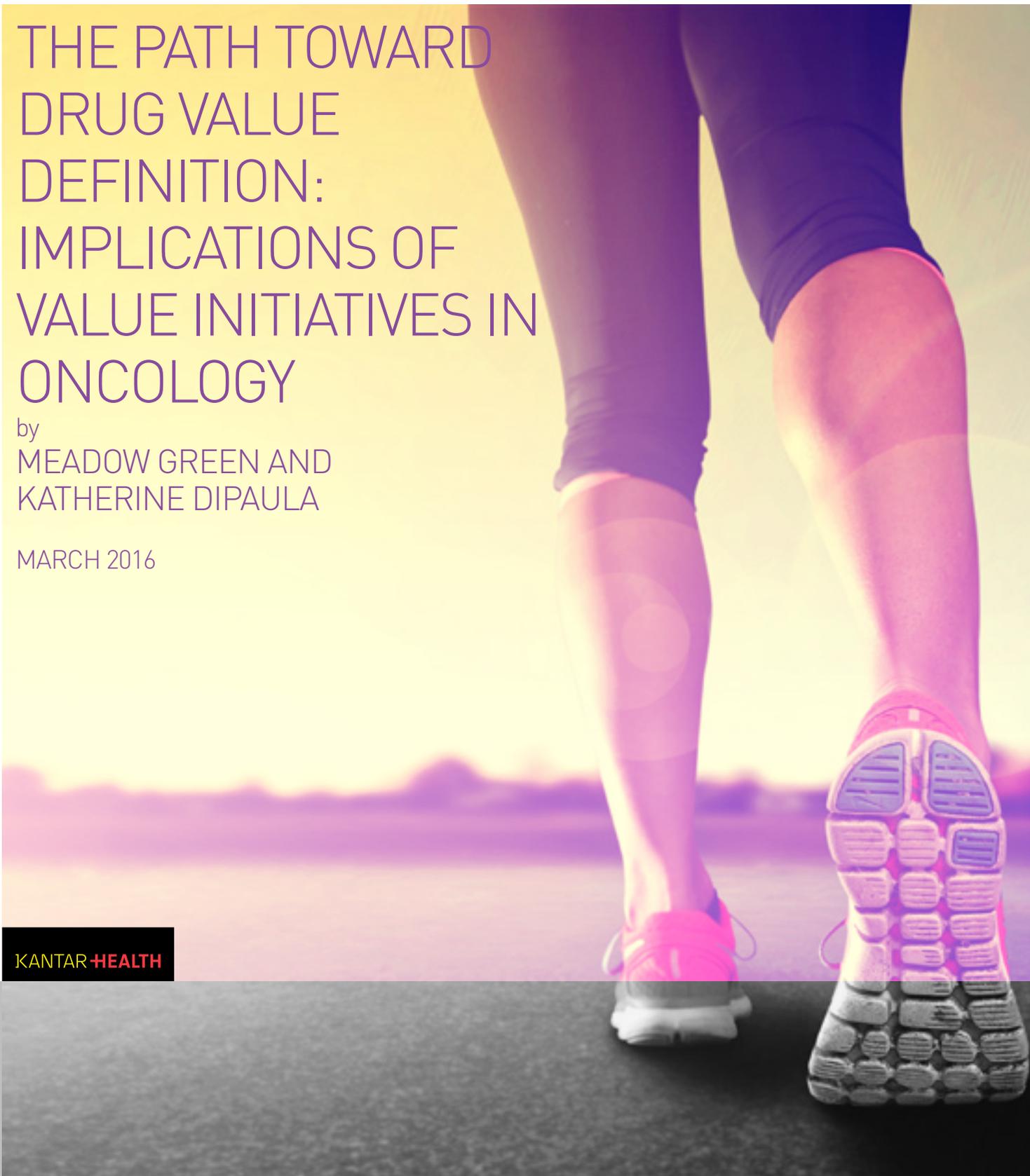


THE PATH TOWARD DRUG VALUE DEFINITION: IMPLICATIONS OF VALUE INITIATIVES IN ONCOLOGY

by
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INTRODUCTION – INCREASING SCRUTINY AROUND DRUG VALUE

The debate about oncology drug value and pricing is not new. With the advent of exciting (and pricey) immunotherapies, monoclonal antibodies and targeted oral therapies, the criticism of oncology drug pricing increased. But these issues were not truly in the public eye until 2012, when an editorial in the *New York Times*¹ by Peter B. Bach, M.D. and Leonard B. Saltz, M.D. – whose names are now almost synonymous with thought leadership on the topic – caused an uproar by harshly criticizing Zaltrap® (ziv-aflibercept, Sanofi/Regeneron) pricing. Payers wondered whether this was a harbinger of public and provider support for pricing controls. This one article fueled hopes that an accelerated debate about value versus price would turn the tide of increasingly expensive oncology products and provide the foundation for more definitive cost control measures.

To some extent, payers' early hopes have been realized. The majority of oncologists believe the cost of cancer is increasing, and drug prices are the primary driver cited in our 2016 Oncology Market Access survey (Figure 1). Meanwhile, leading oncology societies (e.g., the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO)) weighed in on value, formalizing "affordability" and "cost" as a factor in clinical decision making. Stakeholders agreed that value determinations should be made in a systematic, credible and unified manner.

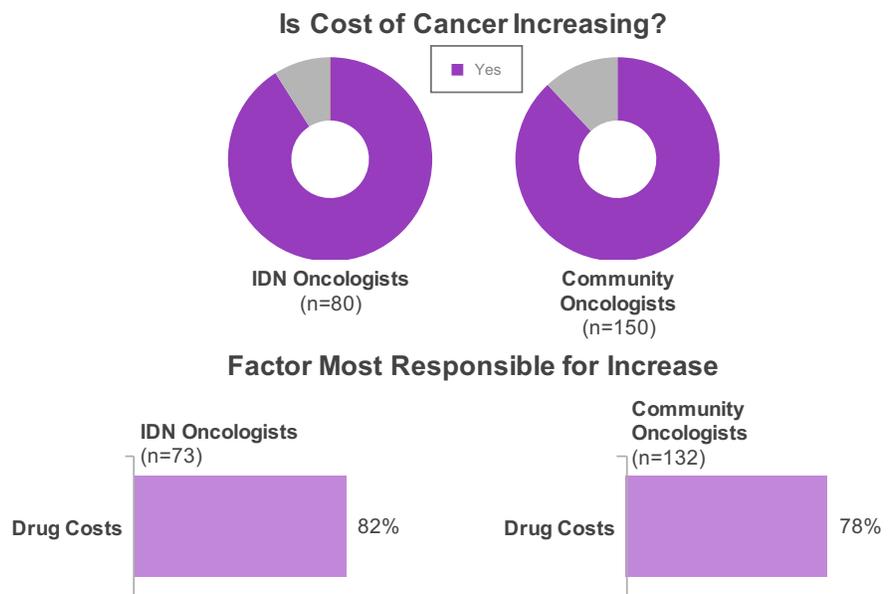


Figure 1: Providers overwhelmingly report that the cost of cancer is rising primarily due to drug costs

FRAMEWORKS EMERGE

Within the period of a year, three major organizations and a top cancer hospital each launched their own approach to measuring value. The frameworks from NCCN, ASCO, Memorial Sloan Kettering and the Institute for Clinical and Economic Review (ICER) are all representative of how costs are now being systematically included in oncologists' thinking about drug value.^{2,3,4,5} Further, in an environment where value is scrutinized, about half of oncologists and payers expect these frameworks will affect their assessment of drug value (Figure 2).

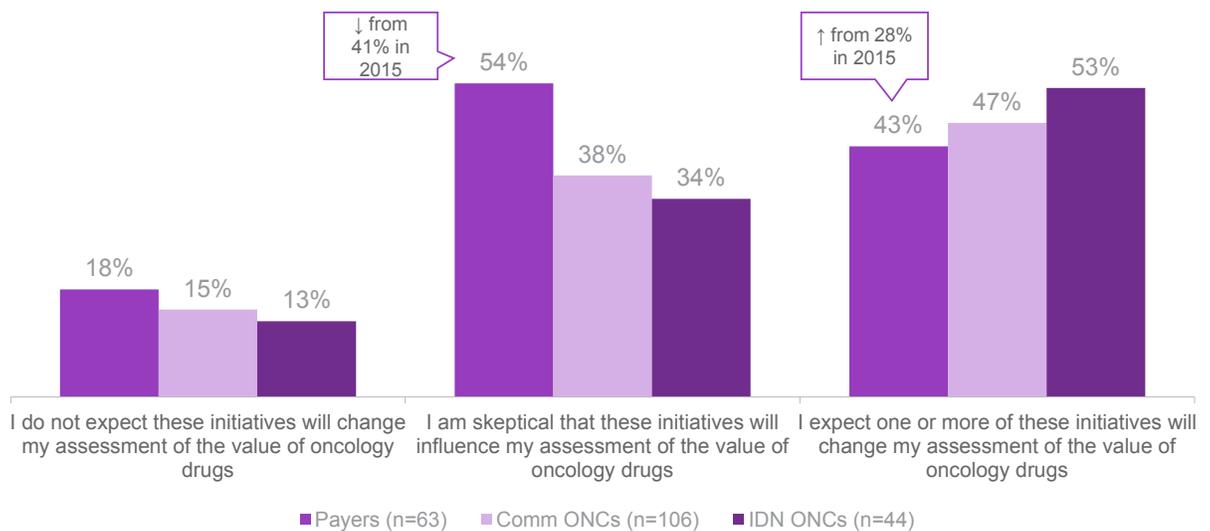
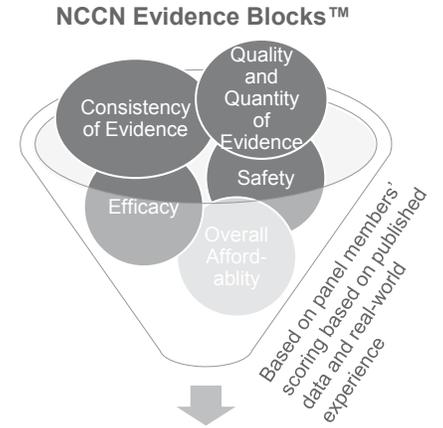
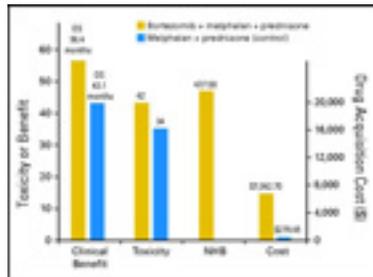
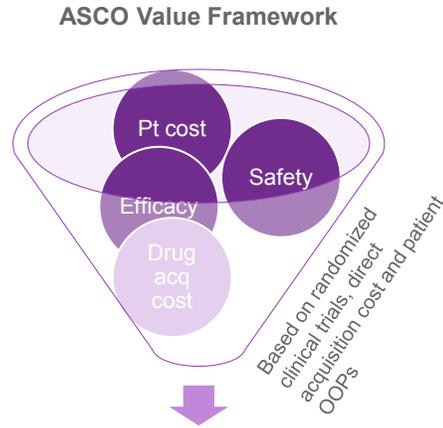


Figure 2: Impact on Assessment of Oncology Drug Value

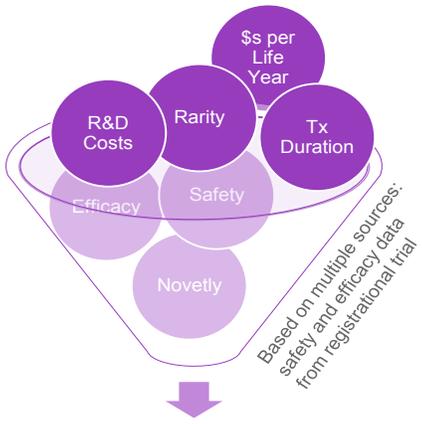
Are these frameworks really designed to – or even capable of – influencing drug pricing or garnering support for increased drug management (e.g., the selection of preferred therapies)? An understanding of the objectives and outputs of the current frameworks is important and largely drives the potential impact of treatment decisions.

OBJECTIVES AND OUTPUTS OF THE FOUR FRAMEWORKS

Each of the frameworks was created with different objectives and applications. Therefore, the output and implications of the frameworks are somewhat divergent from each other (Figure 3). ASCO and NCCN both are created to inform joint treatment decision making between patients and oncologists. Relevant information in terms of safety, efficacy and other clinical factors is provided in summary form and is shown alongside out-of-pocket (OOP) cost or affordability to inform decisions on a case-by-case basis.



Memorial Sloan Kettering Cancer Center Drug Abacus



ICER Value Framework

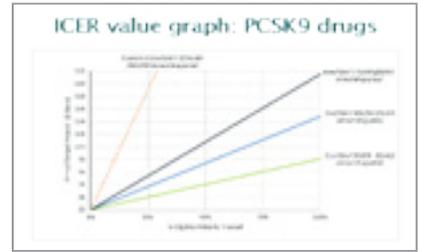
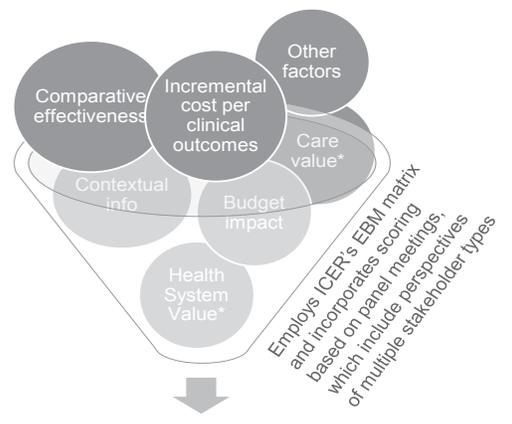


Figure 3: Framework Considerations and Outputs

In contrast, Memorial Sloan Kettering's Drug Abacus' intended purpose is to produce a "value price" comparison to the products' actual price – often an unfavorable comparison. To some degree, the tool can accommodate the personalization and individualization of value by allowing the user to modify the weighting of each value component.⁴ However, the outputs are not intended to inform clinical decision making.

ICER also aims to identify a value-based price but also focuses on how they are evaluated. ICER produces reports that analyze new drugs' comparative effectiveness, cost effectiveness, and potential budget impact and calculate a value-based price.⁵ ICER also engages a wider range of stakeholders (e.g., payers/pharmacy benefit managers, patient organizations, physician organizations and manufacturers) and accounts for more nuance in assessment of the clinical evidence and other considerations than any other framework (e.g., level of certainty regarding additional clinical benefit, consideration of non-clinical benefits to patients or the health system, contextual considerations like unmet need).

APPLICATION AND IMPACT OF THE FOUR FRAMEWORKS

With such disparate approaches to framework design and intended use, how can these frameworks be leveraged to influence drug pricing or support increased drug utilization management? There are certainly opportunities for payers to use these frameworks in decision making today. For example, the types of comparisons that are made about drugs within NCCN's Evidence Blocks and ASCO's Value Framework are highly analogous to the comparisons made between drugs that are considered in the design of a treatment pathway. Also, coming from respected professional societies, these frameworks are likely to be considered for informational purposes at Pharmacy and Therapeutic drug reviews and, where applicable, may be used to create step or preferred therapies when multiple options and large price differentials exist. Nonetheless, neither ASCO's or NCCN's framework is suited – or intended – to serve as the foundation for new, more stringent drug policies or price negotiation within the next 12 months. In contrast, the framework produced by ICER is designed to identify the clinical rationale for a numerical value price of treatments, and there is some interest from payers, including Medicare, in applying its findings in this way.⁶

However, no single tool will likely emerge as the determinant of value, since stakeholders need multiple characteristics in a value tool:

- + Flexibility in accommodating any mitigating factors that influence value
- + Evidence support for population health decisions and define relative value (e.g., set price and preferred therapies)
- + Ability to accommodate individual preferences and allow for personalization
- + Widespread acceptance from all key stakeholders – each of whom has different information needs and intended uses for the tool's outputs

Because none of the frameworks currently possess all of the characteristics, their impact in the near term is likely to be restricted to use on a case-by-case basis by oncologists and as a data reference for payer decision making.

MANUFACTURER IMPLICATIONS

Given the likely muted immediate impact of these value frameworks, their intermediate-term strategic implications are unclear. There are certainly opportunities to consider how a drug may be evaluated within frameworks as they stand today, and identify how the communication and publication of additional data could maximize scoring. However, it is possible that none of these frameworks will mature into an impactful arbiter of drug choice or price. Nonetheless, over the longer term the movement toward value assessment in the U.S. market is likely to continue. Therefore, it would be a mistake to dismiss the importance of careful consideration of how best to engage in the process of defining – and providing the evidence package to support – value in the context of these and other frameworks.

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3. NCCN Evidence Blocks. Referenced with permission from the National Comprehensive Cancer Network® (NCCN®), Inc. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc. <http://www.nccn.org/evidenceblocks>. Accessed March 28, 2016.
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Ms. Green supports the development of our multiclient subscription offer as well as custom engagements, with particular focus on the U.S. and global market access landscape, novel reimbursement arrangements, pricing strategy, and channel dynamics. Prior to joining Kantar Health, Ms. Green gained industry experience in market access, pharmaceutical data and product strategy with Roche Pharmaceuticals (Ireland), SDI Health/Verispan, and Heron Evidence Development. Ms. Green combines a deep expertise in oncology, landscape assessment and product strategy with core skills in analytics and qualitative and quantitative research methodologies.

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