

ASCO VALUE FRAMEWORK UPDATE

Frequently Asked Questions

What is the ASCO Value Framework?

The value framework was developed to help doctors and patients assess the relative value of cancer treatment regimens that have been studied head-to-head in clinical trials. The framework defines value as a combination of clinical benefit, side effects, and improvement in patient symptoms or quality of life in the context of cost. The initial version of the conceptual value framework was published last year for public comment. Based on feedback received, ASCO published an updated framework on May 31, 2016 in the *Journal of Clinical Oncology*.

How will the value framework be used?

The updated value framework will be the basis of a software tool that doctors can use to inform shared decision-making with their patients about treatment options. The software tool is intended to facilitate personalized discussions about treatment, and will not replace physician judgment or limit patient choices.

The tool will be designed to be easily used on a laptop or tablet in the clinical setting where physicians can use it to engage patients in a conversation about their specific treatment options. We also plan to update the software tool as new clinical evidence becomes available. The tool will allow physicians to personalize the Net Health Benefit score to address each patient's needs and preferences, by adjusting the weighting of clinical benefit and side effects.

Why is the value framework needed?

Cancer costs are rising quickly, and cancer drugs are the fastest-growing component of these costs. New cancer drugs cost an average of \$10,000 per month, and some exceed \$30,000 per month. Many patients want, but often don't receive, clear information about the benefits, risks, and costs of treatment options. Even well-insured patients are often surprised by, and unprepared for, the high out-of-pocket costs associated with some drugs. Too often, that leads to severe financial strain and even bankruptcy—and to sub-standard care for those patients who skip or delay treatment because of cost. Physicians have a responsibility to help address this problem.

Who developed the value framework?

The framework was developed and revised by the ASCO <u>Value in Cancer Care Task Force</u>, a multidisciplinary group of physicians and other representatives of the oncology community. The Task Force serves with guidance and leadership from ASCO's Board of Directors.

How is the updated value framework different from the initial version?

ASCO has made several changes to the value framework, while retaining a rigorous adherence to scientific standards. Most notably, ASCO modified the Net Health Benefit score—a weighted measure of a treatment's benefits and side effects—to better reflect true differences between treatments. For example, to calculate the efficacy of a treatment, the framework now uses hazard ratios when available, rather than absolute improvements in survival. In addition, the framework now considers all side effects, not just the most severe, high-grade toxicities; this change reflects feedback from patients who emphasized that even mild side effects can have a major impact on quality of life. Furthermore, in addition to awarding bonus points for symptom palliation, as in the original framework, additional points are given for improvement in quality of life.

What is a Net Health Benefit? Does a low score mean the drug doesn't work?

The Net Health Benefit (NHB) is a combined and weighted measure of clinical benefit and side effects. The NHB represents the *additional* benefit of one drug compared with the prevailing standard as tested against each other in a randomized clinical trial. A low NHB means there is little *added* benefit; a high NHB means there is significant additional clinical benefit and/or less toxicity. An NHB of zero means that the two agents studied in a clinical trial are equivalent—not that the new agent does not work. In all cases, the framework is intended to help inform discussion between doctors and patients—and not used as a substitute for physician clinical expertise or judgment. All clinical scenarios included in the framework are illustrative only.

Isn't the NHB score arbitrary? Wouldn't it be more meaningful to provide an absolute score for clinical benefit or toxicity?

In the framework, the NHB score is derived from the key efficacy elements of overall survival (OS), progression-free survival (PFS), response rate, symptom palliation, time off treatment, and quality of life (QoL), along with the comparative toxicity of treatment regimens. In the advanced disease setting, the framework attributes the greatest weight to improvements in OS; less weight is given for improvements in PFS and still less if a trial only reports a response rate. Thus, the NHB represents the considerations patients must understand as they make treatment decisions, and that oncologists use to make treatment recommendations.

Why does the value framework only evaluate treatments that were studied head-to-head in clinical trials?

We considered a number of approaches, but the bottom line is that there is no scientifically valid way to compare regimens that have not been tested head-to-head in clinical trials, given differences in trial designs, patient populations, cancer stages, and other factors.

Why is the framework focused on the cost of cancer drugs? What about other aspects of cost in cancer care?

We recognize that the cost of drugs is only one component of overall cancer care costs. However, evidence shows that drug costs are among patients' biggest concerns, in large part because they pay a significant share of these costs through co-pays. Also, many cancer care costs are not readily available, nor are they easily quantified for any given group of patients.

Why doesn't the value framework consider patient-reported outcomes?

Patient-reported outcomes (PROs) are very important, and may be included in <u>future</u> versions of the value framework. Unfortunately, to date, clinical trials haven't adequately measured or reported PROs. ASCO hopes to be able to consider these data as they are more rigorously collected and reported in future trials.

ASCO made a significant effort to receive stakeholder input into the development of the value framework. Will there be an opportunity to provide feedback as the software tool is developed? ASCO will work closely with stakeholders, particularly patient advocates, to ensure the development of the tool fully considers the needs and preferences of patients. We will also provide educational resources to physicians so that they are prepared to incorporate this decision-making tool into communications with their patients.

Is the framework intended to drive public policy discussions about drug pricing?

No, the framework as currently constructed is not intended to be a policy tool. It is intended for doctors to use with their patients in clinical settings, and to help facilitate individual treatment discussions.

Where can I find more information about ASCO's Updated Value Framework?

To download "Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received" and learn more about this and other ASCO efforts to ensure high-quality, high-value cancer care, please visit <u>www.asco.org/value.</u>

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About ASCO

Founded in 1964, the American Society of Clinical Oncology (ASCO) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter,LinkedIn, and YouTube. Cancer-related policy developments can be found at asco.org.