

Commentary

Undermining Patient Values: The ASCO Value in Cancer Care Task Force Framework

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ABSTRACT

As stated in a recent article in the *Journal of Clinical Oncology*, ASCO established a Value in Cancer Care Task Force, with the goal of “developing a framework for comparing the relative clinical benefit, toxicity, and cost of treatment in the medical oncology setting.” In developing this framework or tool, the Task Force runs roughshod over basic facts to create a metric that—while established to promote patient centered care—strives mightily to achieve the exact opposite outcome.

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AS STATED IN a recent article in the *Journal of Clinical Oncology*, ASCO established a Value in Cancer Care Task Force, with the goal of “developing a framework for comparing the relative clinical benefit, toxicity, and cost of treatment in the medical oncology setting.” In developing this framework or tool, the Task Force runs roughshod over basic facts to create a metric that – while established to promote patient centered care – strives mightily to achieve the exact opposite outcome.

WRONG FROM THE START

From the very outset, the Task Force misrepresents the contribution of the spending on new cancer drugs on total health care costs. It claims that while new cancer drugs are a fraction of total health spending, “its contribution to health care cost escalation is increasing faster than those of most other areas because of several factors: the increasing prevalence of cancer due to the overall aging of the population and better control of some causes

of competing mortality; the introduction of costly new drugs and techniques in radiation therapy and surgery; and the adoption of more expensive diagnostic tests.”

This statement is breathtakingly untrue. New cancer drugs are expensive no doubt. Yet they account for only account for 0.7 percent of the \$2.9 trillion we spend on health care.¹ Cancer spending has increased in 1995 from \$42 billion to about \$130 billion today. But its share of total health spending declined from 4.7 percent to 4.4 percent during the same time period.²

The Task Force notes the average launch price of cancer drugs has climbed \$8,500 per year from 1995 to 2013.³ But during that time cancer survivorship surged from

- 1 IMS Health Finds Global Cancer Drug Spending Crossed \$100 Billion Threshold in 2014 <http://bit.ly/1F4hEmT>
- 2 Agency for Healthcare Research and Quality. Total Expenses and Percent Distribution for Selected Conditions by Type of Service: United States, 1996–2012. Medical Expenditure Panel Survey Household Component Data. Generated interactively.(June 09 2015) <http://1.usa.gov/1cIYL2a>
- 3 Howard, David H., Peter B. Bach, Ernst R. Berndt, and Rena M. Conti. 2015. “Pricing in the Market for Anticancer Drugs.” *Journal of Economic Perspectives*, 29(1): 139–162.

10 million to 14 million people and life span expressed by 36 million life years worth about \$3 trillion.⁴

The Task Force acknowledges that out-of-pocket drug costs are rising in large part because of an increase in the cost sharing for drugs taking place largely in plans available in state and federal health exchanges.

Yet if the price and cost of new cancer drugs were so profoundly driving up the cost of health care in general, then capping cost sharing and eliminating adverse tiering would require much more than the than 50 cents per person per month recent Milliman studies have established would be sufficient to achieve that goal.⁵

New medicines reduce the cost incurred by a cancer diagnosis, for instance in part by reducing hospitalization. In 1996 drugs were 3.7 percent of cancer spending and 62.4 percent went to hospitalization. By 2012, drug spending was 9.3 percent of cancer costs while the share going to hospital stays dropped to 41.3 percent.⁶ If we were allocating the same proportion of money to hospitals today, as we were in 1996, we’d be spending about \$18 billion more a year on cancer. And we have yet to see the full benefit of the cancer drugs not yet included in these estimates.

BELITTLING THE VALUE OF HOPE

No matter. The Task Force doubles down on attacking the very patient preferences it has pledged to respect and integrate into its tool by claiming that the ‘crisis’ of cancer

- 4 An Economic Evaluation of the War on Cancer Eric C. Sun, Anupam B. Jena, Darius N. Lakdawalla, Carolina M. Reyes, Tomas J. Philipson, and Dana P. Goldman NBER Working Paper No. 15574 December 2009. We arrived at the number of life-years gained using the approach in this paper and updating it. We multiplied the average increase in life years (2 million) by the number of years between 1995 and 2013. (18) 2x18=36 million. We then multiplied the additional life-years by a conservative estimate (\$82,000) of what people think (in dollar amounts) they would gain by living another year. 36x82=2.952 trillion.
- 5 Pharmacy Cost Sharing Limits for Individual Exchange Benefit Plans: Actuarial Considerations. Milliman Client Report, March 5 2015. <http://bit.ly/1F4mKQ0>
- 6 Agency for Healthcare Research and Quality. Total Expenses and Percent Distribution for Selected Conditions by Type of Service: United States, 1996–2012. Medical Expenditure Panel Survey Household Component Data. Generated interactively. (June 09 2015)

drug spending is being driven by “sometimes unrealistic patient and family expectations that lead clinicians to offer or recommend some of these services, despite the lack of supporting evidence of utility or benefit.”

If it hasn’t made its view clear by now, the Task Force also asserts cancer patients “also overestimate the benefits of treatments that sometimes extend life by only weeks or months or not at all. “Oncologists are generally aware of this conundrum but uncertain about whether and how the cost of care should affect their recommendations. Although raising awareness of costs and providing tools to assess value may help to manage costs while maintaining high-quality care, some oncologists see this as being in conflict with their duty to individual patients.”

In fact, several studies show that the value of hope plays a major role in the use of new technologies that actually added more life than “supporting evidence” initially demonstrated. Indeed, the authors themselves acknowledge that treatments that may have initially modest benefit based on clinical trials can have a much higher value in terms of life years saved when used in the real world. A study by Tomas Philipson demonstrated that the “value of hope associated with treatments for HIV patients to be as much as four times as high as standard per capita estimates of treatment effects and as many as two and a half times as high as aggregate values across all cohorts.”⁷ Similarly, a study found that cancer patients place a high independent value on a chance at a long-term survival benefit, above and beyond its contribution to average survival.”

The hope that the Task Force belittles is the impulse that drove the use of HIV drugs, the first wave of which showed little, if any survival, benefit. The Task Force value framework would have assigned AZT little value because of the lack of overall survival, toxicity and cost. In the real world, the use of such medicines kept enough people alive until the next generation of anti-AIDS extended life by years. A study by Tomas Philipson demonstrated that the “value of hope associated with treatments for HIV patients to be as much as four times as high as standard per capita estimates of treatment effects and as many as two and a half times as high as aggregate values across all cohorts.” This value was not only justified, it was essential to spurring future innovation.

The complete dismissal of the cumulative benefits of new medicines is unwarranted. For instance, in 1998 myeloma patients had a median survival of 3 years. Now myeloma patients live much longer, some exceeding

- 7 Terminal Care and The Value of Life Near Its End Tomas J. Philipson, Gary Becker, Dana Goldman, and Kevin M. Murphy NBER Working Paper No. 15649 January 2010 JEL No. H0,I0

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10 years and being cured, mostly because of the FDA approval of 6 new medications. Over the next several years an additional 4 or more drug approval could occur. During the same time span hospitalizations, transfusion and other medical services for myeloma dropped 83 percent.⁸

The authors proceed not only to ignore these preferences *but also argue that they can't be considered because they can't be measured*. Rather, the tool slyly eliminates consideration of every other measure other than cost of increasing median overall survival at or above a specific amount of time by blithely asserting: "It was generally agreed that relative improvements in median OS of at least 20% are necessary to define a clinically meaningful improvement in outcome."

To protect this untenable position the Task Force eliminates consideration of every meaningful patient centered preference. First it asserts "we did not find quality-of-life data or patient-reported outcomes to be end points reported in clinical trials with enough consistency or reliability to be informative in our assessment of clinical benefit."

This is nonsense. As the price and number of new treatments increases, their value increases too. A recent Bureau of Economic Analysis study found between 2000-2010 that "medical technology (for treating cancer and other costly illnesses) is improving over time, leading to better health outcomes at a lower cost per patient."⁹

A PATIENT-CENTERED VALUE FRAMEWORK THAT IGNORES PATIENT VALUES?

Next, the framework penalizes the use of new technologies by ignoring "quality-of-life data or patient-reported outcomes", placing a premium on median overall survival and penalizing the use of data regarding response rates and PFS. Indeed, the Task Force concluded "relative improvements in median OS of at least 20% are necessary to define a clinically meaningful improvement in outcome."

This statement is the strongest expression of the determination of the Task Force to eliminate the ability of patients to express a preference for long-term survival over and above improvements in median overall

8 <http://www.bloodjournal.org/content/124/21/1326?sso-checked=true>

9 Using Disability Adjusted Life Years to Value the Treatment of Thirty Chronic Conditions in the U.S. from 1987-2010 Tina Highfill and Elizabeth Bernstein - BEA Working Paper (WP2014-9)

survival. It is the method the Task Force uses to eliminate the use of medicines it believes are generated by hopelessly optimistic patients who "overestimate the benefits of treatments that sometimes extend life *by only weeks or months* or not at all."

Indeed, this cut-off will discourage use of new agents or end of life treatments even though the Task Force acknowledges may have a greater benefit "when used in an adjuvant or curative setting or when a biomarker can identify patients most likely to benefit from the treatment."

Finally, the Task Force excludes the value of treatments to patients and their families on a day to day basis by once again claiming that the data is just not good enough to use: "Obtaining reliable data for all the potential dimensions of cost (e.g., hospital use, emergency department use, earnings lost, travel time, childcare costs) is extremely challenging from the standpoint of data collection. In addition, many costs are difficult to anticipate when treatment decisions are being made."

TASK FORCE MEASURES VALUE BY COST OF DRUG

It is for this reason, the Task Force states: "we have chosen to use the cost of the drugs themselves as a readily available, although admittedly incomplete, estimate of cost."¹⁰

Incredibly, the Task Force then uses the "cost of the drug itself" to evaluate the impact of innovative and expensive medications on society as a whole even though it admits the framework ignores other costs and potential cost offsets.

In essence, the Task Force is asserting that it has no good evidence with which to assess the value of treatments to patients in developing a tool in which the patient's perspective is of central importance in defining value but it that the cost of a drug can be used for everything else it wants to evaluate:

Moreover, the Task Force quietly rejects using any medicine at any cost unless a minimum amount of

10 "ASCO acknowledges that this method of calculating the NHB does not permit assessment of the relative value of regimens that were not directly compared in clinical trials and that the observed improvement in NHB for a new regimen might be influenced by whether the comparator was best supportive care or active treatment. Nevertheless, ASCO believes this method to be one that is well grounded in the available medical evidence and provides the most objective assessment of NHB."

survival is generated by treatments: "It was generally agreed that relative improvements in median OS of at least 20% are necessary to define a clinically meaningful improvement in outcome."

Many treatments that are now considered standard for treating disease – AZT for AIDs, interferon for chronic myeloid leukemia, SSRI's for depression – failed to meet this threshold. Many tumors, particularly pancreas, lung brain and stomach that have the lowest 5-year survival rates would fail to meet this threshold. But the Task Force completely eliminates treatments that would advance survival below it's pre-ordained, one size fits all threshold.

That is because the Task Force is, as noted earlier, biased against the use of treatments that offer hope but not much average survival. Rather, the Task Force has a clear cost containment agenda: "oncologists should be aware of the value of an intervention in terms of societal cost. Clearly, increasing health care costs are eventually transferred to the consumers of health care, if not in the form of out-of-pocket costs, then in the form of higher insurance premiums, higher taxes, or limited wage increases as employers confront the escalating costs of providing health care to their employees."

To restate: the Task Force therefore states that the savings and benefits to consumers in the form of lower premiums, higher income and productivity, lower cost of treating disease can't be counted but the societal cost of cancer drugs can be measured solely by how much it contributes to overall spending and therefore to higher premiums, etc.

In fact, there is an abundance of research measuring the contribution of new medicines to society as well as the negative impact the absence of treatments have on productivity, premiums, wages, etc.^{11,12,13}

11 Lichtenberg, F. R. (2007), Benefits and costs of newer drugs: an update. *Manage. Decis. Econ.*, 28: 485–490. doi: 10.1002/mde.1355

Frank R. Lichtenberg Has medical innovation reduced cancer mortality? NBER Working Paper No. 15880 Issued in April 2010

12 *Int J Cancer*. 2015 Feb 15;136(4):E136-45. doi: 10.1002/ijc.29105. Epub 2014 Sep 4. Measuring the societal burden of cancer: the cost of lost productivity due to premature cancer-related mortality in Europe. Hanly P¹, Soerjomataram I, Sharp L.

13 *BMC Cancer*. 2014 Mar 26;14:224. doi: 10.1186/1471-2407-14-224. The cost of lost productivity due to premature cancer-related mortality: an economic measure of the cancer burden. Hanly PA¹, Sharp L. See also *J Natl Cancer Inst*. 2008 Dec 17;100(24):1763-70. doi: 10.1093/jnci/djn384. Epub 2008 Dec 9. Productivity costs of cancer mortality

In the Orwellian understatement of the year, the Task Force states: "it anticipates that cost will be interpreted by the patient in the context of the net health benefit (NHB) offered by each treatment option." It acknowledges that this method of calculating the NHB does not "permit assessment of the relative value of regimens that were not directly compared in clinical trials and that the observed improvement in NHB for a new regimen might be influenced by whether the comparator was best supportive care or active treatment."

In plain English: patients will be presented with a value measure that:

1. Requires a predetermined minimum increase in average survival that ignores genetic and biological variations in tumor;
2. Cannot measure the relative value of treatments;
3. But does measure only the cost of the medicine in terms of average survival or more specifically, the patient's share of the drug cost ordered by its health plan.

STEERING PATIENTS INTO STEP OR FAIL FIRST THERAPY

Indeed, the main goal of the value framework is to steer cancer patients to the treatments regimens consistent with the administrative controls payers and PBMs use to restrict access to new medicines. As the Task Force notes, it hopes the framework will help policymakers and payers as they consider preferred management options and evaluate the relative value of new treatments introduced into the cancer marketplace. "

The framework measures the value of a drug in the same way health insurers does: by the price of the medicine without regard to patient or social value. And it focuses on the out of pocket cost of medicines as determined by the health insurers: "When considering the NHB of a treatment, patients may consider the cost they must incur to receive that treatment and make decisions in accordance with their personal goals for their health and their financial realities."

That is an Orwellian way of stating that the value framework is designed not to challenge cost sharing strategies inconsistent with patient wellbeing but to make them more efficient by presenting patients with

in the United States: 2000-2020. Bradley CJ¹, Yabroff KR, Dahman B, Feuer EJ, Mariotto A, Brown ML.

a win-lose scenario in which the out of pocket cost of a treatment becomes fait accompli.

The Task Force completely ignores the reliable scientific data generated from molecular diagnostics and tumor profiling as a way of advancing truly personalized medicine. Indeed, the Value Framework is silent on such diagnostics even though the Task Force admits that when a biomarker can identify patients most likely to benefit from the treatment, it can improve the value to the patient by eliminating less effective care in favor of more targeted therapies.

The expressed goal of the Task Force is to support health insurers in the “development of benefit structures, adjustment of insurance premiums, and implementation of clinical pathways and administrative controls.” It succeeds in achieving this objective. But it does so by ignoring patient values, belittling hope, failing to require the use of molecular diagnostics to improve patient response. The Value Framework fails to measure indirect cost savings of new treatments and encourages doctors to accept a one size fits all measure of drug cost en route to giving patients a fait accompli.

Moreover, the Task Force relies on anecdotal evidence and unpublished findings from health plans themselves about the cost savings and quality of specific cancer treatment pathways. In this regard the Value Framework has a double standard: It uses randomized controlled trial data only to establish the one size fits all value of a drug but relies on the conclusions drawn from observational data produced by entities that have a vested interest in demonstrating that the application of step or fail first therapy works.

Indeed, the Value Framework implicitly supports the use of adverse tiering (higher cost sharing for new medicines or medicines that provide less rebates to

plans) and ‘step therapy’ pathways that require patients to fail first on cheaper drugs that are covered before getting one that is more expensive.

The Task Force would therefore support practices such as placing nearly all of the medicines for cancer into the highest cost-sharing category which means patients pay up to 40 percent of the cost of a medicine. Even worse, it does so without acknowledging that such controls often reduce use of treatments and in turn, increases the number of people who get sick and die.¹⁴

Such practices may be civil rights violation. The Department of Health & Human Services has stated: “placing most or all drugs that treat a specific condition on the highest cost tiers discourages enrollment by individuals based on age or based on health conditions, in effect (is) making those plan designs discriminatory.”

In this regard the framework can be used by insurers to expand step therapy and cost sharing at the expense of patient lives and well being.

CONCLUSION

Ultimately, the Task Force Value Framework is a fiasco for patients. It has to manufacture a cancer drug cost crisis to justify its work. And its value framework is not only confusing and unworkable, it ignores the rapid transformation of cancer care into a life long personalized approach to promoting health as opposed to treating disease. Ultimately, the Value Framework imposes a set of values on patients. And to determine if they want to use it, patients have only to ask a simple question: Who would want a doctor to select treatments using a framework that doubles down on health insurance practices that discriminate against cancer patients?

14 Association of Specialty Drug Prescription Abandonment with Increasing Member Out of Pocket Expense https://www.primetherapeutics.com/specialty/assets/pdf/AMCP_2014_Spring_Specialty_Rx_Cost_Share_Associated_Abandonment.pdf. See also, Gleason, P.P., G.C. Alexander, C.I. Starner, et al. Health Plan Utilization and Costs of Specialty Drugs within Four Chronic Conditions. *Journal of Managed Care Pharmacy* 2013;19(7):542–48 and