

From Evidence-Based Medicine to Value-Based Practice in Cancer Care: To Answer the Gap between Patient's Expectation and Reality

Nadra Septiadi, Nicolaus N. Wahjoepramono

Medical Science Program, Faculty of Medicine Universitas Indonesia

Introduction

Cancer care poses an inexorable three-way ethical dilemma between price, value, and burden. Current treatment regimens employ the use of evidence-based medicine to seek out drugs or treatment option which provide a statistical edge over others. This approach to treating human beings debases the value of life and living. Another approach must be considered in which the life a patient is living is just as prioritized as the life the drug prolongs.

Evidence-Based Medicine to Value-Based Practice

To truly answer the riddle of cancer care, the oncologist must tackle the predicament using three perspectives; monetary, efficacy of treatment, and quality of life (QoF). The real question is how to adjust the use of cancer drugs which, in reality, is considered "financially toxic" and also noting that a majority of patients only benefit marginally from the treatment without a significant increase in their quality of life.

No segment of society is better qualified to address the issue other than the multidisciplinary team of oncology physicians, particularly with the rapidly spiraling cost of cancer care. The previous holds true because the oncology community commands the most potential as agents of change in the frontline of cancer care. Oncologists must be able to offer clear guidance by conducting appropriate literary research, interpreting the results, and correctly prescribing chemotherapies or other forms of treatment. However, they must not be bound only by evidence-based practices, but also inquire in value-based medicine and approach the patient as a person with a basis of empathy.

Evidence-based medicine (EBM) is a combination of three skills by which practitioners become aware of, critically analyze and then apply the best available evidence from the medical research literature for the care of individual patients.¹ For most cancer cases, the main application of this

concept is in diagnostic, treatment, and prognostic utilities. For example imatinib, which was introduced in 2001 for the treatment of chronic myeloid leukemia (CML), is proven in transforming a life-threatening form of cancer into a chronic disease that can be managed in the long-term through daily medication. As a consequence of this evidence-proven study, imatinib was placed on the first line list. Doubtless the next questions would be: Would it be worth the cost and risk, and how would a patient be able to afford such expensive treatments in actual clinical settings? The implementation of EBM on its own, is proving to not be able to provide an adequate method of ameliorating the burden of cancer because of the additional expenditures it would rack up without regard to patient preference nor quality of life thereafter.

Increasingly high price of cancer treatments are essentially harming those it intended to treat. The annual cost of imatinib in The United States is around \$92.000, while in Indonesia is around Rp 211.000/tablet and the current prices are too high, unsustainable, and may compromise the accessibility of highly effective therapy to needy patients as well as the sustainability of our national healthcare systems.² The astronomical costs debilitate patient rates of adherence and reduces their chances of survival. The CML patients survival data provides evidence of this. The 10-year survival rates of CML are 80% in Sweden, where drug therapy is supplied to patients free of charge. By contrast, the 5-year survival rate is only 60% in the United States, where CML patients have to pay a proportion of the drug costs which become a main reason of discontinued treatment. Worse luck befalls developing countries with only 20-30% of all CML patients able to afford these life-saving medications.³

The spiraling costs of cancer care, particularly the cost of cancer therapeutics in which the majority only "marginally" benefits the patient, is under increasing scrutiny. However, the debates in health care should consider not only the costs, but also the values of the breakthrough drugs. An

analysis which was published online suggests that many of the innovative treatments may provide reasonable value for money.² But the next question is how to count the value within itself? Are the units we use to measure value a comprehensive model able to evaluate all necessary aspects? Value-based medicine (VBM) provides a standardized methodology able to integrate critical situations, patients, quality-of-life preferences, and societal costs to allow the highest quality at the most cost-effective care.⁴ Nowadays, VBM and cost-effectiveness studies are more or less empty gestures and have become an academic exercise of no meaningful consequence.

The value-based evaluation of any drug should already be a given. The best way to integrate this in cancer case is to construct a unit which incorporates not only the treatment cost, but also the impact on the patients' length and quality of life. The best unit able to represent all of these is a ratio of a drug's total cost per patient quality-adjusted life year (QALY) gained, which is called cost-utility ratio. National Institute for Health and Clinical Excellence (NICE) defines the QALY as a measure of a person's length of life weighted by a valuation of their health-related quality of life. By converting it to cost-utility ratios, this arithmetic product will indicate the additional costs required to generate a year of perfect health.⁵ The lower cost-utility ratio (cost/QALY ratio) the more favorable it will be. Cost/QALY ratio represents more efficient way to quantify health gains from treatments. It will also provide better information to prioritize expenditure on drugs that will result in the best incremental treatment benefit at a lower incremental cost per quality-adjusted life year.

To meet the EBM and VBM criteria, some nations have enforced relating drug manufacturing expenditure thresholds to its cost-effectiveness. For instance, in The United Kingdom, NICE use a value of around \$55.000/QALY as a cut-off for allowing drugs to be available within the National Health Services (NHS).^{2, 6} This means that the cost of a patient's drug treatment should not exceed \$55.000 for a year of healthy survival. Thus, drugs that do not fulfill this criteria by the NHS would only be available to patients who can afford to pay for them privately. The next problem is that a QALY worth in the United States or United Kingdom is obviously not the same as what a QALY is worth in Asia, especially Indonesia.

When oncologists fail to explain what a treatment can and cannot do for a patient in the context of the patient's diagnosis, prognosis, and

current condition, or worse; offer treatments that are unlikely to provide any significant physiological benefit to a patient, this is a failure of informed choice. The act of offering the drug implies that the drug has more value than what it is actually worth. A higher price may further imply that said drug is newer, better, and more worth it. Oncologists should make every effort to learn what a patient truly values in their life, as it may not necessarily be the same in each person. Is a longer life truly worth the suffering that comes with painful treatments? Is a slightly longer life, together with an increased quality of life worth the knowledge that his predicament has brought debilitating financial instability within his family? Will it be that being able to do certain things the patient's goal? Or is it staying out of the hospital? Oncologists and other health care professionals should recognize and translate these values and preferences into goals of care as a framework for considering the benefits and burdens of different treatment options. The only way to achieve this is through empathy and to be able to place the patient's values and expectations together with our best efforts in bringing the highest QALY a patient can achieve, in accordance with evidence-based practice.

A compelling ethical argument to oncology professionals that prescribing practices must evolve so that clinicians do not signal to the manufacturers of tacit acceptance of ever-higher prices as a status quo.^{7,8} Even if clinicians cannot influence price, as professionals, oncologists have to discuss these issues with the patients. The use of effective, empathic communication to talk about costs strengthens the physician-patient relationship, facilitates negotiation, and enhance the assurance in shared decision-making around care options.

Conclusion

By implementing the consideration of QALY into treatment options for the patient in conjunction with evidence-based therapy, oncologist can provide a personalized and holistic care. This will of course increase the bond of trust between the doctor and patient which will further boost the effects of the therapy. After all, the goal of every health care professional is not to blatantly prevent death, but to ameliorate the patient condition and facilitate what was once unbearable in becoming at least tolerable. To cure sometimes, to treat often, to comfort always; *ne'st ce pas?*

References

1. Jonathan Belsey. What is evidence-based medicine? 2nd ed. England: Hayward Medical Communications; 2009.
2. Chustecka Z. High price of cancer drugs 'one of biggest issues in healthcare'. Available from: http://www.medscape.com/viewarticle/804655_3 (accessed 9 March 2015).
3. Chustecka Z. Blood cancer drugs may offer 'reasonable value for money'. Available from: <http://www.medscape.com/viewarticle/839528> (accessed 9 March 2015).
4. Huber B, Doyle J. Oncology drug development and value-based medicine. 1st ed. USA: Quintiles library; 2014.
5. Phillips C. What is a QALY? 2nd ed. England: Hayward Medical Communications; 2009.
6. Mulcahy N. Sky's the limit for us cancer drug prices, says top doc. Available from: <http://www.medscape.com/viewarticle/840487> (accessed 9 March 2015).
7. Berlinger N. Why clinical oncologists should talk about the price of cancer drugs. AMA Journal of Ethics. 2013;15(8):677-80.
8. Mulcahy N. Time to consider cost in evaluating cancer drugs in united states? Available from: <http://www.medscape.com/viewarticle/705689> (accessed 9 March 2015).