Cost, Quality, and Value in Healthcare: A New Paradigm

May 15, 2010
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In this issue of Oncology, Dr. Kilbridge details the incorporation of nontraditional outcome measures in the evaluation of cancer therapies—the importance of which is underscored by the passage of the sweeping healthcare reform bill that will alter the landscape of healthcare delivery for years to come.

In preparation for the reform package, Congress had already allocated over $1 billion for comparative effectiveness research (CER) with the Institute of Medicine (IOM) identifying CER as a high priority research focus. Unfortunately, the IOM did not go far enough in mandating cost as a required evaluation of CER, although it did not exclude economic considerations. There are currently countries already using cost-effectiveness analysis to evaluate the addition of drugs to their formularies.[1,3] Certain health insurance plans in the US are also using cost-effectiveness analysis during formulary submissions.[4] It is when costs and benefits of treatments are considered together that we can then fully understand the value of each intervention.

Healthcare costs have risen considerably over the past decade, in part as a result of increased use of expensive imaging technologies and the development of more complex interventions, such as the advent of high-priced targeted cancer therapies. According to the Centers for Medicare and Medicaid Services (CMS), national healthcare expenditures topped $2.3 trillion in 2008, accounting for 16.2% of the gross domestic product (GDP), and rose to account for 17.3% of GDP in 2009. Unchecked, this healthcare expenditure trend will continue, increasing to 19.3% of GDP by 2019.[5]

The increase in the cost of care can be justified, however, if an increase in value, which can be defined simply as outcome/cost, is realized. The addition of health related quality of life (HRQOL) indicators will be an important addition to standard outcome measures such as disease-free survival and overall survival. It will be important to determine if the incremental gains in disease-free or overall survival are offset by a decrease in HRQOL. For example, an upsurge in the number and type of HRQOL measures has been reported over the past 20 years for NCI-sponsored phase III clinical trials.[6]

As stated by Kilbridge, there is some controversy over the exact definition of what constitutes CER. What is agreed upon, however, is the need for CER to provide guidance to healthcare providers to determine which treatment provides the most value. The randomized phase III clinical trial has been long held as the gold standard for level-1 medical evidence. However, this vehicle may not be the best method for determining the most efficacious treatment for a disease in which a number of viable treatment options exist, such as in localized prostate cancer.

A randomized phase III trial comparing intensity-modulated radiotherapy (IMRT), brachytherapy, proton beam therapy, and radical prostatectomy most likely could not be completed because of the inherent biases among radiation oncologists and urologists. But a CER study using a registry with appropriately matched patients could provide important information by comparing these treatments and determining the most appropriate therapeutic course for difference subgroups of patients. Patient reported outcomes can be divided into descriptive health status and patient preference weights. While providing more detailed information regarding disease-specific treatment-related toxicity, patient-reported descriptive health status instruments are not helpful in comparing patient treatments across disease sites. Therefore, an intervention for prostate cancer will not be able to be compared with an intervention for diabetes or heart disease. This is important when trying to rank treatments or programs if healthcare budget constraints exist. Patient preference weights allow the comparisons between diseases by distilling the results down to a single number, the quality-adjusted life-year. (QALY). Interventions could then be ranked with the intervention with the highest QALYs at the top and the intervention with the lowest QALYs at the bottom.
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Published on Diagnostic Imaging (http://www.diagnosticimaging.com)

The difficulty in achieving this quality-adjusted intervention rank is in the measurement of the patient preference weights. Measuring patient preference weights with the standard gamble or time trade-off methods is time-intensive and costly. As mentioned by Kilbridge, the impracticality of using the standard gamble and time trade-off can be overcome by the use of health state classification systems such as the EuroQol or the Health Utilities Index (HUI). Of the two, the EuroQol system is much simpler and easier to use; it consists of only five questions and a visual analog scale. The user only has to register his or her study on the EuroQol website, which does not charge for access. The Radiation Therapy Oncology Group (RTOG) has incorporated the EuroQol instrument, the EQ-5D, in several recent clinical trials.

A potential problem in incorporating HRQOL instruments in clinical trials is that these instruments have been developed in a homogenous population. Differences in HRQOL exist between women with breast cancer of different races. African American breast cancer survivors reported worse physical functioning and general health compared with white breast cancer survivors.[7] Was the difference seen between African American and white breast cancer survivors a function of poorer HRQOL or culturally insensitive instruments?[8] Moreover, health literacy may pose a problem in collecting patient-reported outcomes, specifically with the more involved methods of collecting patient preference weights such as the standard gamble and time trade-off methods. Obstacles need to be overcome in terms of how to effectively measure HRQOL in a literacy-challenged population.[8]

Research into the best treatment for a given disease in a specific patient population will need to adapt in the future to include measurement of HRQOL in addition to the standard outcome measures such as disease-free and overall survival. Only then will we be able to determine which treatment provides the best value in an age of increasing healthcare expenditures and diminishing healthcare budgets.

Financial Disclosure: The author has no significant financial interest or other relationship with the manufacturers of any products or providers of any service mentioned in this article.

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