Health-Related Quality of Life

A Pharmaceutical Outcomes Measure That Actuaries Need to Understand

HEALTH PLANS ARE UNDER ENORMOUS PRESSURE to curb the rise in health care costs while simultaneously providing the best health care available. They operate within lean budgets and must carefully consider the addition of any technology that may increase their costs.

Since pharmacy benefit costs have been rising at trend rates higher than those of total claims in recent years, extra scrutiny is applied to possible new drug technologies to ensure their value. While actuaries understand health outcomes in terms of utilization and dollars and may also be fairly familiar with clinical outcome measures, many actuaries are unfamiliar with another common outcome measure used to assess value: the health-related quality of life.

In this article, I will talk briefly about demonstrating value for the purposes of pharmacy benefit decision-making and then focus on introducing basic concepts regarding health-related quality of life as an outcomes measure.

Value for the Money

Pharmaceuticals are an important and integral part of health care management. They're effective and inexpensive treatment options providing good value for the money spent. According to J.D. Kleinke, writing in *Health Affairs*, "high-priced new drugs may be the cheapest weapon we have in our ongoing struggle against rising overall medical expenses."

Given the current financial environment of health plans, however, demonstrating the value of new pharmaceuticals is more important than ever. This value needs to be demonstrated to decision-makers outside the pharmacy and therapeutics committees, including health plan actuaries.

At the root of good pharmacy benefit decision-making is evaluation of clinical and financial data. To be worthwhile, pharmaceuticals need to provide safe and effective treatment, and do so while offering good value for the money spent. Guiding principles for clinical decision-making are listed below:

- Assess the findings of peer-reviewed medical outcomes research and pharmacoeconomic research;
- Employ published practice guidelines developed by an acceptable evidence-based process;
- Compare efficacy, effectiveness, value, and therapeutic interchangeability;
- Compare drugs on patient compliance; and
- Thoroughly evaluate benefits, risks, and adverse drug reactions.

Note that while the clinical considerations are many, the demonstration of value is also a factor in sound clinical decision-making.

In an effort to help formulary managers obtain complete information for making better, timelier decisions, the

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Academy of Managed Care Pharmacy (AMCP) developed and disseminated the format for Formulary Submissions in 2000. The Format is a guideline that specifies what information health plans want to see in a standardized "dossier" from drug manufacturers. Version 2.1 of the format was released in April 2005 providing specific requirements regarding the requested economic modeling report. This latest version of the format specifies that pharmaceutical companies should provide a cost-effectiveness model.

Since cost-effectiveness analyses are specifically requested to demonstrate the value of new pharmaceutical technologies, it's important for actuaries to become familiar with the outcomes that will be used in pharmacy benefit decisions. These decisions will affect the entire health plan budget, especially as more high-cost biotech drugs become part of a health plan's treatment repertoire.

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FIGURE 1

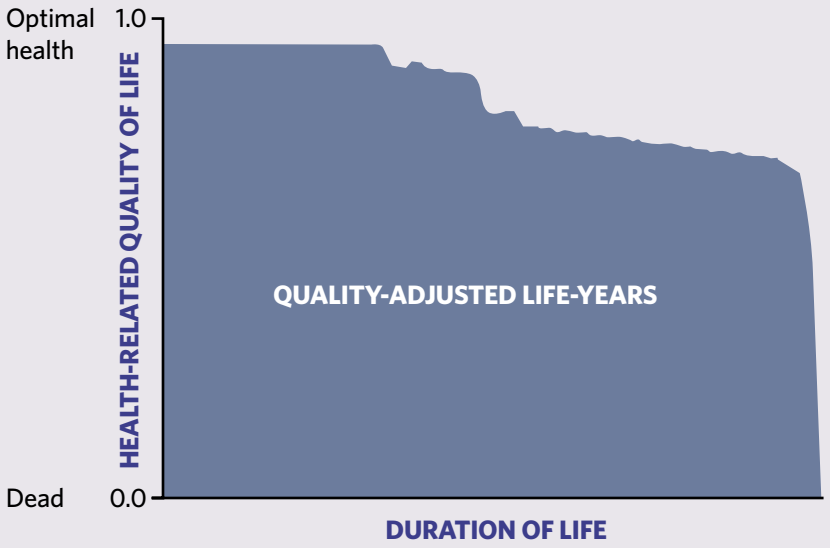
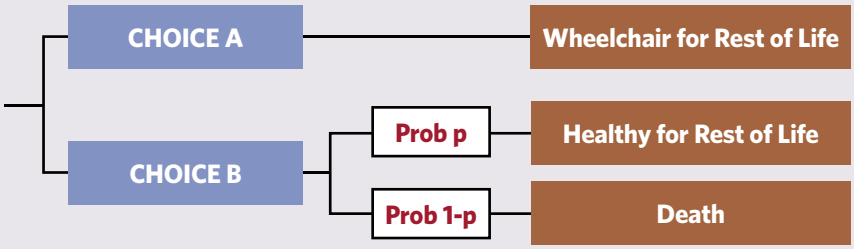


FIGURE 2	Person in Health State A	Person in Health State B
Pain	Moderate pain in shoulders	Mild pain in shoulders, moderate abdominal pain
Function	Able to conduct normal work and self-care but cannot play tennis	Able to play tennis

FIGURE 3



Cost-effectiveness studies provide results such as the cost per unit of relevant outcome. For instance, this ratio could present a drug's incremental cost per case of disease averted or life-years saved. This allows the user of this information to quantify the value of the drug—the number of additional life-years purchased, for example.

A problem with simply measuring life-years is the notion that all life years are not created equal. Abraham Lincoln summed it up well, saying: "And in the end, it's not the years in your life that count. It's the life in your years." To capture this, many health economic studies are done using quality-adjusted life-years (QALYs) as outcomes. Such an analysis is called a cost-utility analysis, the result of which is a cost per QALY.

Health-Related Quality of Life

Utility is the good and bad in life. This is also called quality of life, and it seems fairly intuitive in its implications. Variables that affect quality of life include friends, health, and good sleep (good sleep, in utility terms, is worth several hundred thousand dollars in salary).

The concept of health-related quality of life is used to measure health outcomes beyond basic survival. QALYs capture both quantity and quality of life: in terms of gains from reduced morbidity (quality gains) and reduced mortality (quantity gains).

Quality of life is typically measured on a continuum from 0.0 to 1.0, where 0.0 equals death and 1.0 equals optimal health. A particularly low quality of life can be negative, meaning worse than death.

A quality adjusted life year is one year of life multiplied by a rating of the quality of life. This creates the metric that incorporates both quality and quantity of life. Figure 1 illustrates the QALYs realized over the course of a hypothetical lifetime. The x-axis represents the duration of the life, and the y-axis represents the quality of life at any point in time. The area under the curve represents the total QALYs over the course of the lifetime.

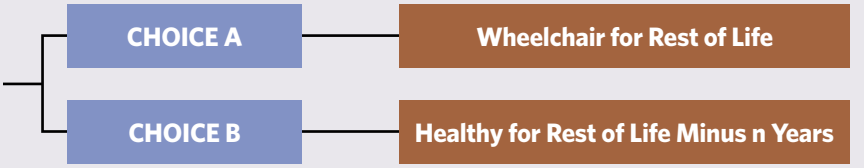
Imagine a treatment that extends life only. For some conditions, there is no other choice. Recall Terri Shiavo. She lived for 15 years after the onset of her brain injury, but the quality of those years lived could reasonably be characterized as very low. Alternatively, imagine a treatment that completely cures a person, such as the removal of a tumor followed by 15 years of cancer-free life. The quality of life gained with the second treatment can appropriately be deemed to be worth more, although both people lived for 15 years. An analysis that simply measures life-years gained might assess the outcomes of the two treatments to be the same.

While Figure 1 illustrates an obvious difference in quality of life, many choices

aren't so clear. In Figure 2, which person is better off?

The answer to this question might vary depending on the respondent. Tennis great Steffi Graf's answer might be different from soccer star David Beckham's, for example.

FIGURE 4



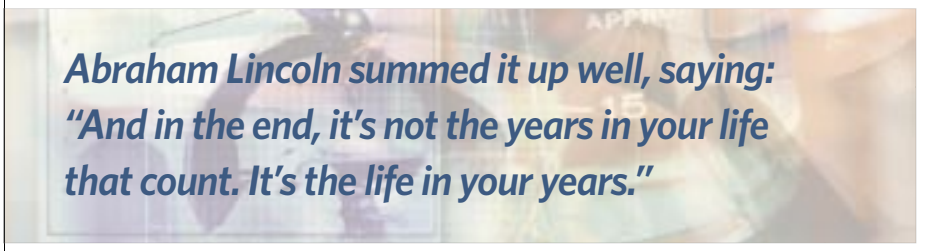
Assessing Health-Related Quality of Life

There are two categories of methods for assessing health-related quality of life: preference-based and nonpreference methods. For preference-based methods, individuals score the alternative states of health based on their own judgments of quality. For nonpreference methods, elements of an individual's state of health are assigned scores that are then summed to produce a total score.

Preference-based methods include both utility approaches and psychosocial approaches. Utility approaches, while possibly complicated for many research subjects to understand, are methods that would likely appeal to actuaries since they involve making choices based on understanding risks.

The first utility approach is the standard gamble. For this assessment, subjects are presented with a scenario as shown in Figure 3.

The scenario presents a choice between the certainty of remaining in a wheelchair (Choice A) and a gamble (Choice B). The gamble has two possible outcomes: optimal health for the rest of a normal life and immediate death. The subject chooses the probability p that determines the likelihood of the positive outcome from the gamble such that Choice A and Choice B are equally attractive. Since we know that optimal health has a quality measure of 1.0 and that death has a quality measure of 0.0, once we know the probability p that



will make somebody indifferent between Choice A and Choice B, we can calculate the quality of life of being confined to a wheelchair.

The second utility approach is the time trade-off (Figure 4). For this assessment, subjects are asked how many years of life in a less-than-optimal health state they would be willing to give up to obtain perfect health. The time in the perfect health state is decreased by this amount of time such that the two states are equally attractive. The trade-off can be illustrated in Figure 4, similar to Figure 3.

Psychosocial approaches to valuing health-related quality of life are more straightforward evaluations of alternative scenarios. These include the following: the paired-comparison approach where subjects are presented with a series of choices between pairs of health states and asked to choose the more desirable; the rating scale approach where subjects are asked to assign scale values to various health states; and magnitude estimation, where subjects are asked to compare a sample health state against a standard and rate it as better or worse.

Nonpreference methods involve the collection of quality of life information from questionnaires that access several possible dimensions of health-related quality of life. These instruments can be generic or specific by condition or disease.

Activities of daily living (ADLs), commonly used to assess eligibility for long-term care insurance benefits, are an example of a generic instrument that measures health-related quality of life. State-Trait Anxiety Inventory (STAI), used to measure anxiety, is an example of a disease-specific instrument that measures health-related quality of life.

Pharmacy Benefit Decision-Making

There are a number of ways to assess health-related quality of life, and the use of these measures relies on the creation of the cost-effectiveness (CE) ratio or cost per outcome. The value of many drugs can be assessed by looking at their CE ratio. If the CE ratio is higher than a previously determined threshold, the drug is deemed to have low cost-effectiveness. Conversely, if it has a CE ratio lower than this threshold, it's considered cost-effective. Typical thresholds used for health care interventions are $50,000/QALY or even $100,000/QALY.

The Figure 5 on page 81 presents the CE ratios for several hypothetical treatments. The lower right quadrant is for cost-saving treatments that increase QALYs. These are clearly the most desirable. Treatments to the left of the y-axis decrease QALYs and are less desirable. The upper right quadrant is for treatments that cost money and increase QALYs. It's in this quadrant that careful consideration is required. Treatments that fall above the diagonal line have CE ratios higher than $50,000/QALY, and those below have CE ratios lower that the threshold. If $50,000 is the cut point for a treatment to be considered cost-effective, those above the line would be rejected and those below the line would be considered.

Conclusion

Cost-effectiveness analyses are geared toward supporting "yes" or "no" decisions regarding health care technologies. Although CE ratios and other results from health economic analysis may not tie directly to the types of information actuaries typically use to price or monitor claims experience, it's this type of information that's being requested and used by pharmacy benefit (and other) decision-makers within the health plan.

The ability to read and understand elements of this research is becoming necessary for actuaries as departments within health plans abandon the much-maligned silo mentality. The well-conducted and well-documented cost-effectiveness or cost-utility study can provide a lot of data regarding drug costs, assumed related treatment costs, rates of side effects, and drug compliance rates. To the extent that pharmacoeconomic and other health economic research becomes better and more plentiful, actuaries may find these results useful for other typically actuarial purposes. ●

Resources

Neuman, P., Sandberg., E., Bell, C., et al. "Are Pharmaceuticals Cost-Effective? A Review of the Evidence, *Health Affairs*, March/April 2000; 19:2;92-109.

Kleinke, J.D., "The Price of Progress: Prescription Drugs in the Health Care Market," *Health Affairs*, 20 (2001): 5, 43-60.

Pharmacy Benefits Management Strategic Healthcare Group, Department of Veterans Affairs, "Principles of a Sound Drug Formulary System," available at http://www.amcp.org/data/nav_content/drugformulary%2Epdf, accessed July 23, 2005.

The *AMCP Format for Formulary Submissions*, Version 2.1, April 2005, available at http://www.fmcpnet.org/data/resource/Format~Version_2_1~Final_Final.pdf, accessed July 23, 2005.

Kahneman, D., "Determinants of Health Economic Decisions in Actual Practice: The Role of Behavioral Economics," First Plenary Session at International Society for Pharmacoeconomics and Outcomes Research, Washington DC, May 2005.

Gold, M.L., Siege, J.E., Russell, L.B., and Weinstein, M.C., *Cost-Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*. New York: Oxford University Press, 1996.

Torrance, G.W., Feeny, D., "Utilities and quality-adjusted life years, *International Journal of Technology Assessment in Health Care*, 1989;5(4):559-75.

Camilleri-Brennan J., and Steele R.J.C., Measurement of quality of life in surgery, *J. R. Coll. Surg. Edinb.*, 44, August 1999, 252-9, available at http://www.rcsed.ac.uk/Journal/vol44_4/4440010.htm, accessed July 22, 2005.

Schwartz ,A., and Elstein, A., MHPE 441: Medical Decision Making, Lecture notes: Week 10, Cost-Effectiveness Analysis, available at http://www.pennmush.org/~alansz/courses/mhpe441/week10.html, accessed July 23, 2005.

Milliman USA. 2003 Intercompany rate survey.

FIGURE 5 CE Ratios