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VALUE IN HEALTH

Automated Current Health Time-Trade-Off Assessments in Women's Health

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ABSTRACT

Objective: To motivate the role for preference assessment in women's health and to report pilot data addressing the performance of automated time-trade-off (TTO) valuations of current health, which were developed to estimate quality-adjusted life years (QALYs) in the women's health setting.

Methods: Values for current health relative to perfect health and death were assessed using an annual time trade-off (1-year horizon and sleep as the trading metaphor), a lifetime time trade-off, and a visual analog scale (VAS). All instruments were administered twice within a 12- to 14-day window among a convenience sample of 27 women.

Results: Valuation of health was similar for both time trade-offs (mean of 0.95 for both), but was significantly lower for the VAS (mean of 0.84, Wilcoxon signed-rank p-value < 0.001). Reliability using the intraclass correlation coefficient was 0.67 ± 0.09 and 0.75 ± 0.07 for the annual and lifetime time trade-offs, respectively, and 0.89 ± 0.03 for the VAS. Construct validity was supported by consistent trends in time-trade-off utilities across tertiles of the Short Form 36 (SF-36) general health subscale (trend test p-value < 0.001).

Conclusion: Automated time trade-offs for current health provide a promising approach for use in women's health studies where impact on QALYs must be measured. Natural areas of application include the economic evaluation of preventive interventions in postmenopausal women.

Keywords: cost-effectiveness, osteoporosis. quality-adjusted life years, utility, women's health.

Introduction

As more women consider long-term use of postmenopausal pharmacological agents, such as hormone replacement therapy (HRT) or selective estrogen receptor modulators (SERMs) to prevent osteoporosis and other diseases, it will become increasingly important to understand the effects of these drugs on health-related quality of life. To assess the economic value of such interventions using quality-adjusted life years (QALYs) as the health end point of interest, quantitative estimates reflecting how women value their health are required. These values, which are sometimes referred to as utilities, are scaled from 0 (death or worst imaginable health state) to 1 (perfect health or best imaginable health state). When estimating QALYs, each year of life is weighed according to its quantitative value estimate or utility. Von Neumann and Morgenstern [1] described the axiomatic basis for utility assessment in the 1940s. Since then a number of approaches to assessing values for health states have been developed, including the time-trade-off (TTO) technique described by Torrance et al. [2].

In contrast to health-status instruments such as the Women's Health Questionnaire [3], the purpose of health valuation is to measure how women feel about their health rather than to characterize their particular functional health state. In the conceptual model of patient outcomes described by Wilson and Cleary [4], values and preferences are noted as influ-

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encing both general health perceptions and overall quality of life. Valuations of current (or global) health aim to measure each individual's preferences for her overall health state [5]. Thus, two women in identical health states as measured by a health-status instrument such as the Short Form 36 (SF-36) [6] who value their health differently would have different utilities for current health.

The importance of such valuations in the economic evaluation of interventions in women's health is nicely exemplified by the findings of the first study to address the cost-effectiveness of estrogen replacement therapy in postmenopausal women. Weinstein [7] showed that the long-term benefits of HRT could be outweighed among asymptomatic women if they felt that HRT side effects reduced quality of life by 2 to 3 days per year. Despite the impact of such side effects on the results of economic evaluations in women's health, very few data reflecting their affect on overall health valuation (i.e., QALYs) are available.

Feeny and Torrance [8] have described the role for utility assessment as an adjunct to usual end points in clinical trials. However, the large resources required for deploying highly trained interviewers at multiple sites are barrier to widespread implementation of such measures. Automated preference-assessment tools such as U-Titer [9] and IMPACT [10] facilitate consistent utility elicitation without a trained interviewer and thereby provide one solution to this problem [11,12].

Another approach to incorporating health-state valuation in clinical trials is to use self-administered preference classification systems, such as the Health Utilities Index (HUI) [8,13–15], EQ-5D [16–18], or SF-6D [19]. A primary advantage of such instruments is that they provide health-state valuations based on societal preferences, which are most appropriate for cost-effectiveness evaluation [20]. For diseases such as osteoporosis, which have a large impact on physical function, preference classification systems may be sufficient for characterizing health valuation. This conjecture is supported by a cross-sectional study of women with fracture where HUI provided similar health-state valuations compared with directly assessed TTO values for current health [21]. However, a primary disadvantage of generic preference classification systems is that they may not be sensitive enough to characterize the influence of menopause and other factors on women's health (e.g., the influence of vasomotor symptoms on health valuation). This is of particular concern in the prevention trial setting where it is essential to account for the influence of treatment side effects on health valuation. Given this uncertainty, preference classification systems should be considered as an adjunct rather than a replacement for direct utility assessment.

As one step toward the economic evaluation of women's health interventions, we developed an automated computer-based interview to assess current health valuation using two TTO techniques. Both an annual TTO, appropriate for valuing overall health or transient health problems, and a more traditional lifetime TTO, appropriate for valuing long-term or chronic health conditions, were implemented. In this paper, pilot data addressing the reliability and validity of these two current health assessments among women are reported. Applications of these instruments in women's health studies are also reviewed.

Methods

Study Population

A convenience sample of women employed by Dartmouth College was recruited for participation in a study to evaluate the reliability of instruments measuring valuation of current health. The pilot study, which was conducted in 1994, was preceded by an investigation into the understandability of study instruments. A primary focus of this study was to assess the performance of an annual TTO for current health for the purpose of evaluating the effect of a pharmaceutical intervention on near-term health. The study was designed with two interviews to be completed within a 12- to 14-day interval. The order of instrument administration in our study was designed to parallel planned clinical trial use of automated utility assessments. At each interview, women completed a practice TTO assessment, an annual TTO for current health, a lifetime TTO for current health, a rating scale instrument, and a subset of SF-36 health-status questions as detailed in the next section [6].

Study Instruments

All current health assessments were implemented using the automated U-Titer utility assessment instrument [9]. U-Titer is a hypercard application implemented on a MacIntosh computer operating system (MacOS), which facilitates the development of customized utility interviews. The automated format facilitates a consistent presentation of questions and enables detailed electronic data collection. U-Titer has been implemented in many disease areas including psoriasis, heart disease, and women's health [22–24].