A Novel Method to Value Real Options in Health Care: The Case of a Multicohort Human Papillomavirus Vaccination Strategy

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ABSTRACT

Background: A large number of economic evaluations have already confirmed the cost-effectiveness of different human papillomavirus (HPV) vaccination strategies. Standard analyses might not capture the full economic value of novel vaccination programs because the cost-effectiveness paradigm fails to take into account the value of active management. Management decisions can be seen as real options, a term used to refer to the application of option pricing theory to the valuation of investments in nonfinancial assets in which much of the value is attributable to flexibility and learning over time.

Objective: The aim of this article was to discuss the potential advantages shown by using the payoff method in the valuation of the cost-effectiveness of competing HPV immunization programs.

Methods: This was the first study, to the best of our knowledge, to use the payoff method to determine the real option values of 4 different HPV vaccination strategies targeting female subjects aged 12, 15, 18, and 25 years. The payoff method derives the real option value from the triangular payoff distribution of the project's net present value, which is treated as a triangular fuzzy number. To inform the real option model, cost-effectiveness data were derived from an empirically calibrated Bayesian model designed to assess the cost-effectiveness of a multicohort HPV vaccination strategy in the context of the current cervical cancer screening program in Italy. A net health benefit approach was used to calculate the expected fuzzy net present value for each of the 4 vaccination strategies evaluated.

Results: Costs per quality-adjusted life-year gained seemed to be related to the number of cohorts targeted: a single cohort of girls aged 12 years (€10,955 [95% CI, –1,021 to 28,212]) revealed the lowest cost among the 4 alternative strategies evaluated. The real option valuation challenged the cost-effectiveness dominance of a single cohort of 12-year-old girls. The simultaneous vaccination of 2 cohorts of girls aged 12 and 15 years yielded a real option value (€17,723) equivalent to that attributed to a single cohort of 12-year-old girls (€17,460).

Conclusions: The payoff method showed distinctive advantages in the valuation of the cost-effectiveness of competing health care interventions, essentially determined by the replacement of the nonfuzzy numbers that are commonly used in cost-effectiveness analysis models, with fuzzy numbers as an input to inform the real option pricing method. The real option approach to value uncertainty makes policy making in health care an evolutionary process and creates a new "space" for decision-making choices. (*Clin Ther.* 2013;35:904–914)

Keywords: human papillomavirus, multicohort, real option, vaccination, valuation.

INTRODUCTION

Invasive cervical cancer is a major threat to women's health and accounts each year for >500,000 new cases and 275,000 deaths worldwide.[1] The oncogenic

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strains of the human papillomavirus (HPV) are now conclusively recognized as the etiologic cause of cervical cancer and other malignant genital tumors.[2–4] Since the earliest approvals of anti-HPV vaccines in 2006, access to the HPV vaccination program has become a critical priority for public health authorities worldwide. The main benefit of an expanded HPV vaccination program would be a significant reduction in the HPV infection rate, with a consequent decrease in the incidence and mortality rate of HPV-induced malignancies. Although the vaccination of all women for whom HPV vaccines are indicated (those aged 9–26 years) would be the most equitable approach, it might not be cost-effective. A large number of economic evaluations have already confirmed the cost-effectiveness of different vaccination strategies.[5–14] However, standard economic analyses might not capture the full economic value of novel vaccination programs[15] because even the most sophisticated cost-effectiveness models are ultimately conducible to the accounting paradigm of the net present value (NVP). The NPV is the difference between a single-point discounted mean value for cash inflows and a single-point discounted mean for cash outflows, including the initial investment. The NPV decision rule is simple: assuming that cash inflows and outflows have been discounted at the opportunity cost (usually, but not necessarily, the cost of capital), we should accept the investment if the NPV is positive. When comparing 2 or more exclusive investments, all having positive NPV, the 1 with highest NPV should be accepted.[16] An important criticism of NPV analysis is that it fails to take into account the value of active management. Active management aims to produce valuable information, thereby reducing uncertainty over the future. Furthermore, subsequent to making an investment, management can revise operating plans that underlay an original NPV forecast, such as altering input and output mixes or shutting down plants temporarily to maximize operating cash flows. Thus, active management can affect a project's value, but it is not accounted for in conventional NPV analysis. By leading an investment from beginning to end, management may be able to squeeze its cash flow distribution toward a higher rate of return.[17] This method has led to the development of the idea that because management control can affect a project's payoff in terms of potential profits and losses, control opportunities can be seen as being analogous to financial options and, therefore, may be analyzed by using options pricing theory.[18] Real option valuation is treating the different types of managerial flexibility as options and valuing them with option pricing models.

The logic of option pricing is straightforward: the value of an option is the present value of the chance of occurrence-weighted distribution of the positive future option values, while mapping the negative values as zero. The reason for considering the negative values of the future option value distribution as zero is that the holder of the option has the right, but not the obligation, to exercise the option contract. The holder will not exercise if it would cause a loss but exercises only if profit is created, thus making the downside zero at maximum. Such options and the calculation of their potential value would not be included in the usual NPV analysis. The fuzzy payoff method for real option valuation is a new method for valuing real options, based on the use of fuzzy logic and fuzzy numbers for the creation of the payoff distribution of an investment.[19]

This was the first study, to the best of our knowledge, to use the payoff method to determine the real option values of 4 different HPV vaccination strategies, targeting female subjects aged 12, 15, 18, and 25 years. The aim of the article was to discuss the potential advantages shown by the payoff method in the valuation of the cost-effectiveness of competing HPV immunization programs.

METHODS

Background Procedure

Before discussing the real option valuation, 3 critical methodologic questions must be addressed[20]:

1. When is there a real option embedded in the investment decision?

   After making an investment decision in health care (eg, to initiate a national vaccination program), policy makers can continuously monitor the actual costs and benefits over time and terminate the program if its incremental cost-effectiveness ratio (ICER) falls below a commonly accepted maximum threshold. This option is valuable because it limits the losses that could be accumulated over time without management intervention, whereas the calculation of its potential value would not be included in the usual NPV framework, which assumes that the program would continue for the estimated length of its life. Moreover, management can decide to change the implementation choices made ex ante, on the basis of information that only became available after the investment decision. As an example, when the chosen vaccine becomes