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Strategic flexibility in healthcare: an exploration of real options

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Abstract

Purpose – This survey explores the application of real options theory to the field of health economics. The integration of options theory offers a valuable framework to address these challenges, providing insights into healthcare investments, policy analysis and patient care pathways.

Design/methodology/approach – This research employs the real options theory, a financial concept, to delve into health economics challenges. Through a systematic approach, three distinct models rooted in this theory are crafted and analyzed. Firstly, the study examines the value of investing in emerging health technology, factoring in future advantages, associated costs and unpredictability. The second model is patient-centric, evaluating the choice between immediate treatment switch and waiting for more clarity, while also weighing the associated risks. Lastly, the research assesses pandemic-related government policies, emphasizing the importance of delaying decisions in the face of uncertainties, thereby promoting data-driven policymaking.

Findings – Three different real options models are presented in this study to illustrate their applicability and value in aiding decision-makers. (1) The first evaluates investments in new technology, analyzing future benefits, discount rates and benefit volatility to determine investment value. (2) In the second model, a patient has the option of switching treatments now or waiting for more information before optimally switching treatments. However, waiting has its risks, such as disease progression. By modeling the potential benefits and risks of both options, and factoring in the time value, this model aids doctors and patients in making informed decisions based on a quantified assessment of potential outcomes. (3) The third model concerns pandemic policy: governments can end or prolong lockdowns. While awaiting more data on the virus might lead to economic and societal strain, the model emphasizes the economic value of deferring decisions under uncertainty.

Practical implications – This research provides a quantified perspective on various decisions in healthcare, from investments in new technology to treatment choices for patients to government decisions regarding pandemics. By applying real options theory, stakeholders can make more evidence-driven decisions.

Social implications – Decisions about patient care pathways and pandemic policies have direct societal implications. For instance, choices regarding the prolongation or ending of lockdowns can lead to economic and societal strain.

Originality/value – The originality of this study lies in its application of real options theory, a concept from finance, to the realm of health economics, offering novel insights and analytical tools for decision-makers in the healthcare sector.

Keywords Real options theory, Medical decision-making, Public health strategy

Paper type Research paper

1. Introduction

Health economics operates within an environment characterized by uncertainty, in which decision-makers face various risks and unknown outcomes. Traditional economic models often struggle to capture the complexities of decision-making under uncertainty. The

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decisions should be based on expected net benefit (NB), so that when comparing mutually exclusive treatment strategies for a particular disease, the optimal strategy is simply the one with the greatest expected NB (Claxton, 1999). Nevertheless, decisions based on expected NB are appropriate only if there is also some consideration of whether current evidence is sufficient for allocating health-care resources, based on an assessment of the consequences of decision uncertainty. If the decision uncertainty and the consequences of adopting a suboptimal strategy are large, the decision-maker may wish for additional evidence on which to base the adoption decision (Sculpher and Claxton, 2005). This article explores the application of real options theory as developed by Dixit and Pindyck (1994), in healthcare decision-making, examining its implications for healthcare investments, policy analysis, and patient outcomes.

Options theory is a branch of finance that focuses on valuing and analyzing financial derivatives known as options. Options provide the holder with the right, but not the obligation, to buy or sell an underlying asset at a predetermined price within a specified time period. Dixit and Pindyck (1994) expanded options theory to address the complexities of economic decision-making under uncertainty. They recognized that economic agents face uncertain future outcomes and have the flexibility to make strategic choices based on evolving market conditions. Their approach allows for evaluating the value of project opportunities, taking into account the flexibility to exercise or delay projects based on uncertain outcomes. Real options analysis captures the value of waiting, abandoning, or expanding projects, providing a more accurate assessment of economic decision-making.

Real options theory provides an assessment of the value of investing in medical technologies, research and development, infrastructure, and capacity expansion (Palmer and Smith, 2000). By incorporating the flexibility to exercise or delay the option to invest based on uncertain outcomes, it provides a more accurate assessment of the value of healthcare investments. Here, there is special focus on Technology Assessment, since it evaluates the value of adopting new medical technologies, considering the flexibility to exercise or delay adoption based on evolving evidence and market conditions. This approach provides a more comprehensive understanding of the economic value and impact of new healthcare technologies (Fornaro *et al.*, 2021).

The real options theory framework can also be applied to the analysis of patient outcomes under uncertainty. It allows for the evaluation of treatment options, considering the flexibility to adapt treatments based on evolving patient conditions and uncertain outcomes. By incorporating the value of waiting, switching treatments, or exploring alternative therapies, it provides insights into optimal patient care pathways and resource allocation (Driffield and Smith, 2007). Uncertainty plays a significant role in healthcare policy choices. Real options theory assesses the value of policy flexibility and the impact of uncertain policy changes on health outcomes and healthcare costs (Attema *et al.*, 2010). It helps to determine the optimal timing and design of policies, such as insurance reforms, healthcare regulations, and public health interventions, accounting for the strategic behavior of stakeholders.

Three different real options models are presented in this study to illustrate their applicability and value in aiding decision-makers to assess investment opportunities, medical decisions, and public health decisions. The first model is applied to investment in a new technology, and by inputting potential future benefits, discount rates, and the variability (volatility) of these benefits, the model can help to assess the value of the option. In the second model a patient has the option of switching treatments now or waiting for more information before optimally switching treatments. However, waiting has its risks, such as disease progression. By modeling the potential benefits and risks of both options and factoring in the time value, the model aids doctors and patients in making informed decisions based on a quantified assessment of potential outcomes. In the third model, a government has the option to leave lockdown during an ongoing pandemic. Alternatively, they can wait for more information about the virus, but incur the risk of the negative effects that the lockdown measures have on the economy and social well-being. The theoretical model argues that in the presence of uncertainty the possibility of deferring the decision until some later time when better information may become available has an economic value. By delaying it can provide a quantified assessment of whether to leave lockdown now or wait, helping policymakers make evidence-based decisions. Thus, by incorporating strategic behavior and options analysis, the real options approach offers valuable insights into healthcare investments, policy formulation, and patient outcomes. One can make more-informed assessments and recommendations, leading to improved decision-making and outcomes in the ever evolving field of healthcare.

This paper is organized as follows. Section 2 discusses the literature that has applied real options to healthcare decision-making. Section 3 puts forward three formal real options models applied to the healthcare sector. Section 4 examines the implications of the real options approach for healthcare decision-making. Concluding comments are in Section 5.

2. Real options theory in health economics

This section provides an overview of the adaptation of real options theory to the healthcare decision-making. Several studies demonstrate the application of real options analysis across various aspects of healthcare decision-making, encompassing investment evaluations, treatment strategies, cost-effectiveness assessments, and the optimization of vaccination programs, among others.

There are two seminal manuscripts that apply real options theory in healthcare. Palmer and Smith (2000) used a cost-benefit framework, introducing the concept of net social benefit (NSB) to evaluate investments in healthcare technologies, which had not been previously explored; and Driffield and Smith (2007) conducted the first study to apply real options theory in medical decision-making. The authors applied real options theory to the concept of watchful waiting, demonstrating how real options analysis can guide decisions regarding when to pursue a watchful waiting strategy for specific patients.

Following Palmer and Smith (2000), who analyze healthcare technologies using the cost-benefit framework and the concept of net social benefit, there is a group of studies that focus on analyzing investments in machines, technologies, pharmaceuticals stocks, health insurance plans, public health initiatives, new treatments, infrastructure, and health systems. These studies represent traditional applications of real options, wherein investors analyze whether investing their capital in a particular project yields returns that are expected to be greater than the company's cost of capital. Smyth and Swinand (2002) apply real options theory to evaluate capital investment opportunities, capturing the value of flexibility. They emphasize that managerial flexibility is particularly valuable in high-risk investment opportunities. (Williams *et al.*, 2007) discuss the application of real options to support investment decisions for a hospital's new imaging department. (Levaggi and Michele, 2004) analyze optimal investment decisions in new healthcare technologies in uncertain environments. Pertile (2008) uses real options theory to analyze the timing of investment in new technologies by healthcare providers, considering competition for patients and alternative payment systems. Pertile *et al.* (2009) present an economic evaluation from a hospital's perspective on the investment in positron emission tomography (PET). Levaggi *et al.* (2009) employ a real options framework to evaluate investments in new technologies and Pertile (2009) incorporates option values into the economic evaluation of PET.

Following Driffield and Smith (2007), the group of studies addressing watchful waiting and switching patient therapies aids physicians in deciding whether to initiate treatment immediately or delay it until a future time. This approach incorporates the patient's health condition as part of the risk equation. The authors highlight the potential benefits of postponing decisions to gather more relevant information and avoid irreversible or risky treatments. When analyzing situations in which current treatment decisions have irreversible implications for the treatment of future diseases, and decision-makers are choosing between competing interventions with differing temporal consequences, Zivin and Neideill (2009) find that irreversibility raises the value of treatment modalities that preserve future treatment options. However, introducing some reversibility can either increase or decrease the option's value, depending on the distribution of patient types. These authors also examine the relationship between option values and the biological and economic parameters that characterize any given set of technologies. Grutters *et al.* (2011) examine the adoption of proton therapy compared to stereotactic body radiotherapy for the treatment of inoperable stage I non-small cell lung cancer. Meyer and Rees (2012) analyze the treatment decision at a general level. They determine optimal threshold values for initiating the intervention, and derive comparative statics results with respect to the model parameters. In particular, an increase in the degree of uncertainty over the patient's health state makes waiting more attractive in most cases. However, this may not hold if the patient's health state has a tendency to improve. Forster and Pertile (2013a) use real options theory to decide whether to adopt a new health technology instead of an existing one in patient treatment. de Mello-Sampayo (2015) explores the timing of switching to second-line antiretroviral therapy (ART) under health uncertainty and in the absence of viral load monitoring. de Mello-Sampayo (2022) finds that under irreversibility of time spent in treatment, low-risk patients must use teledermatology as soon as possible, which is precisely when it is least valuable.

Related to public health decision-making, Attema *et al.* (2010) apply real options theory to assess the value of stockpiling antiviral drugs as a precautionary measure against potential influenza pandemics. Their analysis incorporates the option to defer action. Favato *et al.* (2012) apply the payoff method to determine the real options values of four different human papillomavirus vaccination (HPV) strategies. According to the authors the payoff method offers distinct advantages in assessing the cost-effectiveness of competing healthcare interventions. Pertile *et al.* (2014) present a Bayesian sequential economic evaluation model for health technologies, allowing flexibility in the decisions regarding the timing to cease research. Park (2016) analyzes the optimal vaccination strategy for pandemic diseases, considering the stochastic diffusion process of the disease.

Real options theory has been applied in other areas of healthcare. Sengupta and Kreier (2011) develop a dynamic framework for analyzing individual choices between Preferred Provider Organizations (PPOs) and Health Maintenance Organizations (HMOs) using real options theory. Their approach evaluates the benefits and flexibility associated with different healthcare provider options. Smith and Yip (2016) highlight the importance of option pricing theory in developing treatable methods that address the complexity and interconnectedness of health systems. Regardless of whether the real options concept is applied to patient treatment, public health strategy analyses, investment analyses, or other areas, the central idea remains consistent: reducing uncertainty pertaining to decisions made at present.

Finally, Smith (2007) evaluates the value of option contracts that provide the right to use specific drugs in the future. This analysis focuses on the option value and the potential future health benefits. This type of option assists decision-makers in managing risks arising from uncertainties surrounding health conditions and treatment availability. More recently, (Garrison *et al.*, 2017) emphasize the significance of considering real options in cost-effectiveness analyses and Lakdawalla *et al.* (2018) demonstrate that real options are considered an essential element in healthcare value assessment. The fundamental objective underlying these operations is to reduce future uncertainty and maximize results, such as saving patients' lives, extending their life expectancy, or improving survival conditions.

3. Real options models

First, we present a very simple stylized model within a cost-benefit framework to analyze investment in health technology. Then we present its application to the medical decision-making and finally to the public health decision-making.

3.1 Real options model applied to investment

Following Palmer and Smith (2000), we present a very simple stylized model within a cost-benefit framework in order to highlight some ideas underlying the real options model, i.e. irreversibility and the ability to invest in the future. We begin with a simple example in which investment decisions are made at two discrete moments at time. Consider an investment opportunity in a new healthcare technology that costs an initial amount (*C*) which yields expected benefits (*B*) in perpetuity. Uncertainty in real options models is treated as a stochastic process [1] in which the variable affected by uncertainty evolves over time randomly. Usually the stochastic process is modelled by Brownian motion or by a Poisson process, depending on the nature of the variable of interest. If we are modelling a continuously varying variable such as the prevalence of a disease or price of a technology, the Brownian motion is applied where the random variable, or Wiener process [2], varies incrementally with known variance (σ) in each time period. Usually the Wiener process has a "drift" or a systematic trend (α), e.g. trend in the price of a technology, independent of the random element. If we are modelling a discrete variable, e.g. emergence of a new technology, the Poisson process is applied in order to model uncertainty. Here the random variable usually takes only two values and has a fixed probability in each time period of changing from one to the other.

We assume the benefits of the technology (B) to evolve over time according to the geometric Brownian motion, such as:

$$dB = \alpha B dt + \sigma B dz, \tag{3.1.1}$$

where the increment of the Wiener process is $z = \varepsilon_t \sqrt{dt}$ and $\varepsilon_t N(0,1), E(\varepsilon_t, \varepsilon_s) = 0$for $s \neq t$. Here, B is the state variable (the benefit of the technology), dB is its movement in small time dt, α is the drift of B, and σ is the standard error of the random change per unit time period.

The value of the technology is expressed in terms of net benefits, i.e. the value of benefits at time t ($B\|$), minus the cost of that technology ($C\|$). The net benefit is:

$$NB_t = B_t - C_t. \tag{3.1.2}$$

Under uncertainty, the decision to adopt a particular technology is based on expected present discounted value (PDV) of the net benefit, so that when comparing mutually exclusive strategies, the optimal strategy is simply the one with the highest expected PDV.

Proposition 3.1.1. Uncertainty increases the expected Net Benefits (NB) associated with the technology.

Proof: See Online Appendix A.

The expected NB is positively proportional to B and as a result, uncertainty affecting the benefits increases expected NB, i.e. the higher the value of σ, the greater the value of waiting.

3.1.1 Option value of the investment. The decision as to whether or not to invest in a new technology constitutes an optimal stopping problem for which the relevant Bellman equation is:

$$F(B,t) = Max\left\{NB;\ \lim_{dt\to 0}\frac{1}{dt}E_B[dF]\right\} \tag{3.1.3}$$

where $F(B, t)$ is the option value of investment, NB accounts for the expected NB that results from opting for investment, and the second term in curly brackets yields the time-discounted expected increment in the value of the option that arises from keeping the option unexercised for an additional period of time, dt. The range of values for which the second term in curly brackets is greater than the first defines the continuation region, where it is optimal not to invest (i.e. not to exercise the option). This is an optimal stopping problem, and so we must find the threshold at which the value of investment is optimum.

Proposition 3.1.2. Investment in the new technology occurs only if the benefits exceed the costs.

Proof: See Online Appendix A.

$$B = \frac{\beta_1}{\beta_1 - 1} C, \tag{3.1.4}$$

B as given by Equation (3.1.4) is the critical value, i.e. once B exceeds B, the technology should be implemented. Since $\beta_1 > 1$, Equation (3.1.4) implies that $B > C$, meaning that the decision-maker will engage in investment only if the expected benefit after investing exceeds its costs. Put differently, contrary to what the PDV principle would suggest, the set of parameters' values for which the decision-maker is indifferent between engaging in, and abstaining from, investment yields a benefit after investment strictly greater than its costs. The critical value, B, and the size of the divergence between B and C, depends on the value of β, which is itself determined by the discount rate ρ, the drift parameter α and the stochastic variance parameter σ. In order to illustrate the importance of this result, consider the perfectly reasonable situation in which the annual discount rate is 5% ($\rho = 0.05$), there is no drift = 0), and the estimated value of B has an annual standard deviation of 5%. This implies that $\sigma = 0.05$. Then it can be readily shown that $\beta = 6.8$, and the critical value B becomes 1.17 C. That is, estimated benefits must be 17% higher than costs before immediate implementation is optimal. The higher the amount of uncertainty σ will result in a higher B, given $\rho = 0.05$ and $\alpha = 0$, i.e. a greater value to waiting.

From the comparative statics shown in Online Appendix A, if the uncertainty (σ^2) affecting benefits is high, the decision-maker tends to prefer to hold the option. The higher the drift (α) affecting the benefits, the less the investment option is worth. The reason is the more the investment is worth, the lower the uncertainty that results from engaging in investment. With regard to the discount rate (μ, a higher time preference increases the decision-maker's opportunity cost of not immediately investing. The reduced form of Equation (3.1.4) can be written as follows:

$$\text{Investment} = f\begin{pmatrix} \sigma^2 & \alpha & \mu \\ - & + & + \end{pmatrix}.$$

The model presented gives clear indications regarding investment decisions under uncertainty. It predicts that the higher the volatility of the benefits, the more valuable the option to invest will be and so the fewer investments will be observed. Conversely, the higher the trend of the benefits and the higher the discount factor, the less valuable the option to invest will be and so the more investments one would expect to observe.

3.1.2 The timing and probability of investment. It would be interesting to ascertain, from any point within the continuation region, the likelihood that investment will become optimal in the future. It is important for the decision-maker to know the expected time that will transpire until the decision of investing becomes optimal.

Using standard properties of the Brownian motion and the lognormal distribution (see Dixit (1993)), closed-form solutions for the probability $Q(B)$ and expected time $T(B)$ for the process B to hit the barrier B from any point inside the continuation region, are given by:

$$Q(B) = \begin{cases} 1 & \text{if} \quad \alpha \leq \dfrac{1}{2}\sigma^2 \\ e^{\left[\frac{\left(\alpha - \frac{1}{2}\sigma^2\right) ln(B/B)}{\sigma^2}\right]} & \text{if} \quad \alpha > \dfrac{1}{2}\sigma^2 \end{cases}, \tag{3.1.5}$$

$$T(B) = \begin{cases} \infty & \text{if} \quad \alpha \geq \dfrac{1}{2}\sigma^2 \\ \dfrac{ln(B/B)}{\alpha - \dfrac{1}{2}\sigma^2} & \text{if} \quad \alpha < \dfrac{1}{2}\sigma^2 \end{cases}, \tag{3.1.6}$$

where $\alpha - \frac{1}{2}\sigma^2$ and σ^2 are respectively, the drift and variance parameters of the process $ln\,(B)$. Equations (3.1.5) and (3.1.6) indicate that the probability and expected time until the investment becomes optimal depend on the variability and trend of the benefits. The greater is the variability, σ^2, the higher is the likelihood that B diverges away from the threshold that triggers the investment, and so the lower the probability that investment will ever become optimal. Similarly, the higher the drift, α, the more likely long excursions of B away from the critical ratio become, and so, the more time the system is expected to take until hitting the threshold beyond which using the second-line treatment is optimal.

Investment will become optimal with certainty provided that $\alpha < \frac{1}{2}\sigma^2$ and it is expected to occur sooner the higher is B. For the limiting case in which $\alpha = \frac{1}{2}\sigma^2$, even though the probability is 1, the expected time for it to occur is infinite. The intuition behind this paradoxical result is that if the drift of B is zero, long diversions away from the barrier might occur. Thus, since the probabilities for successively longer hitting times do not fall sufficiently quickly, the expectation, which is the average of the possible hitting times weighted by their respective probabilities, diverges. This argument is presented in (Dixit (1993)).

For the set of parameters for which B has a positive drift, i.e. when $\alpha > \frac{1}{2}\sigma^2$, there is still a positive probability that investment will become optimal at some time in the future, as given by Equation (3.1.5). This is because, in spite of B drifting away from the critical ratio, there is the possibility that a combination of positive shocks might just bring the system toward the threshold barrier. However, the expected time for this event is infinite, as seen in Equation (3.1.6), given that there is a positive probability that B never reaches B that drives the expectation into diverging.

The real options model presented above evaluates the optimal timing and probability for making an investment in health technology, considering uncertainty and irreversibility. The results of the model reveal that optimal investment should take longer the higher the uncertainty regarding the future benefits of the new technology. By waiting, one avoids the risk of investing heavily in a technology that might not yield the expected benefits. If there is a positive trend in the technology's benefits (i.e. the benefits are increasing over time), the model suggests that it is better to invest sooner. This is because capturing these benefits early can provide significant value, especially if they are growing rapidly. A higher discount rate implies that future benefits are worth much less in today's terms. Thus, if the discount rate is high, it is better to invest sooner to realize the benefits before they are heavily discounted. Delaying investment would mean that even if the technology's benefits are realized in the future, their present value (due to the high discount rate) would be much diminished.

3.2 Real options model applied to medical decision

We follow de Mello-Sampayo (2014) to illustrate the role that uncertainty and irreversibility can play in determining the decision regarding whether to move a patient to the next treatment in a sequence. First, a sector model is set up that allows health capital to be augmented through public investment. Here, it is assumed there are two lines of treatment in treating a chronic disease, denoted by L_1 and L_2, respectively. The first-line treatment consists of using exclusively one technology denoted by T_1. The second-line treatment consists of using a higher dosage of T_1 and then starting with a different technology, denoted by T_2. Then, we determine the net benefit of using $T_i, i = \{1, 2\}$. Finally, we define each line of treatment and show that when the patient is using L_1 the decision as to whether or not to use the second-line treatment, L_2, constitutes an optimal stopping problem.

Assume a one-sector model that allows health capital to be augmented through public investment. An individual's health status is determined by public health measures such as provision of clinical facilities, sanitation, inoculation, and disease control programs (see Chakraborty (2004)). Population individuals are endowed with one unit of labor which is inelastically supplied to firms and receive wage income at the rate w_t. Public health expenditure in period-t is financed through a constant tax $\tau \in (0, 1)$ on labor income so that health investment per person equals τw. Such investment adds to private health capital through a constant returns technology:

$$h_t = \tau w_t. \tag{3.2.1}$$

Decision-makers observe and decide the viability, utility, and characteristics of healthcare goods and services only after using those products or services. Thus, the quality of a healthcare good or service can be ascertained only upon its consumption. In such cases, a drop in price is often interpreted by the prospective consumer as a drop in quality or utility of the product or service. Indeed, it is possible for the demand curve for medical care to be upward sloping [3], even though medical care is a non-inferior good, a relationship that has some empirical support (Hoi and Robson, 1981; Hau, 2008; Dusansky and Cagatay, 2010). Under this condition the demand for medical care is given by:

$$T_i = Bh_t^{\varphi}, \tag{3.2.2}$$

where $T_i, i = \{1, 2\}$ is the total quantity demanded of healthcare good or service at time t, B is the benefit gain at time t, and φ is the parameter for the elasticity of demand. We consider that medical care operates where patient's demand for treatments is inelastic, $0 < \varphi < 1$. From Equation (3.2.2), the benefit function of a representative patient is given by:

$$B = \frac{T_i}{h_t^{\varphi}}. \tag{3.2.3}$$

The benefit increases with the number of healthcare goods or services demanded (T_i), but it is inversely related with the per capita health investment. The higher patient's health capital, the fewer healthcare goods or services he needs for the same benefit.

The cost of the technology, $C, i = \{1, 2\}$, is a nonlinear function of patient's particular characteristic, x, that evolves over time:

$$C = rkx_t^2, \tag{3.2.4}$$

where r is the interest rate, k is the capital invested in the technology, and x is the level of the state variable that represents the random shock of the cost side at time t. For analytical tractability, the state variable is assumed to evolve according to a geometric Brownian motion:

$$dx = \alpha x dt + \sigma x dz, \tag{3.2.5}$$

where $dz = \varepsilon_t \sqrt{dt}$ is the increment of a Wiener process and $\varepsilon_t N(0,1), E(\varepsilon_t, \varepsilon_s) = 0$for $s \neq t$. Equation (3.2.5) implies that the current value of the random shock is known, but the future values are log-normally distributed with a variance growing linearly with the time horizon.

Proposition 3.2.1. Treatment switch occurs only if the relative benefit associated with T_2 exceeds the present value of the relative cost of T_2.

Proof: See Online Appendix B.

$$\widetilde{x} = \left[\frac{\beta_1}{\beta_1 - \delta} \times \frac{\mu - \alpha\delta - \frac{\delta(\varphi-2)}{2\varphi}\sigma^2}{\pi^{\frac{1}{\varphi}} - \phi^{\frac{1-\varphi}{\varphi}} \left[e^{-\mu(\widetilde{t})} \right]} \times \frac{\pi^{\frac{1}{\varphi}} \theta^{\frac{1-\theta}{\theta}} (1-\theta)\tau}{\varphi(1-\varphi)^{\frac{1-\varphi}{\varphi}}} \times \frac{IC_{QALY}}{\mu} \left(1 - e^{-\mu t^{\sim}} \right) \right]^{\frac{1}{\delta}}, \tag{3.2.6}$$

where β_1 is given by Equation (B18) in Online Appendix B, ϕ is the relative cost of T_2, π is the relative benefit of T_2, μ is the discount rate, and $\delta = 2(\varphi - 1)/\varphi$. Equation (3.2.6) is the trigger value separating the region in x space where the patient's option of using L_2 remains unexercised from the one where immediate exercise of that option is perceived as optimal.

It follows from Equation (3.2.6) and the assumptions on the parameters that the value of x is greater than zero if $\pi^{\frac{1}{\varphi}} > \phi^{\frac{1-\varphi}{\varphi}} [e^{-\mu(t)}]$ implying that the decision-maker will switch to second-line treatment only if the relative benefit associated with T_2 exceeds the present value of the relative cost of T_2 weighted geometrically by the elasticity of demand, which is due to the uncertainty of treatment's cost.

Following the comparative statics shown in Online Appendix B, the model presented gives clear indications regarding treatment switch (TS) decisions under cost uncertainty. It predicts that the higher the volatility (σ^2) of the patient's particular characteristic, the sooner T_2 is used, the higher the tax rate (τ) and the higher the relative cost (ϕ) of T_2, the more valuable the option of using the second-line treatment will be, and so the fewer switches of treatment will be observed. Conversely, the higher the trend (α) of the patient's particular characteristics, the higher the discount factor (μ) and the higher the relative benefit (π) of T_2, the more switches of treatment one would expect to observe. Thus, for empirical testing purposes, the reduced form of equation (3.2.6) can be written as follows:

$$TS = f\begin{pmatrix} \sigma^2 & \alpha & \mu & t & \tau & \pi & \phi \\ - & + & + & - & - & + & - \end{pmatrix}$$

Where TS stands for treatment switch. These results are confirmed using simulations (de Mello-Sampayo, 2014). The simulations are performed against a benchmark case. The data in the present application consist of the cost-effectiveness of imatinib for gastrointestinal stromal tumors (Meyer and Rees, 2012). The data are described in detail in Online Appendix B.

Figures 1 and 2 illustrate, respectively, the impact of σ and x on the expected probability of treatment switch and on the expected time of optimal treatment switch, as given by Equations (B20) and (B21) in Online Appendix B.

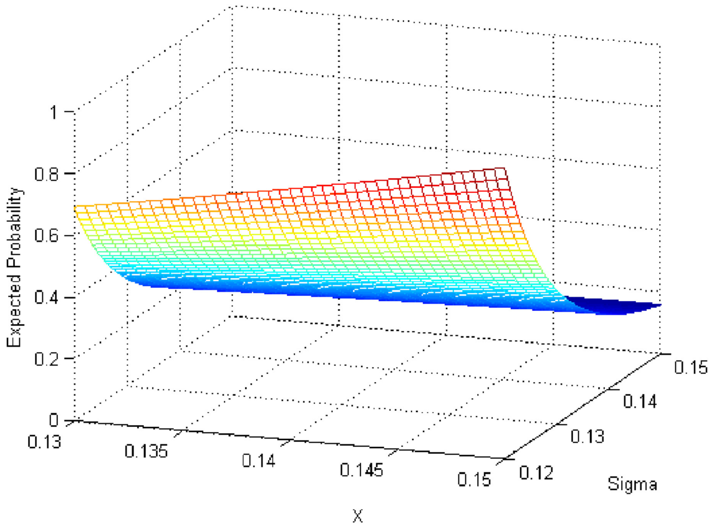


Figure 1. Expected probability for health uncertainty and critical values

Source(s): Created by the author. Originally published in de Mello-Sampayo, 2014

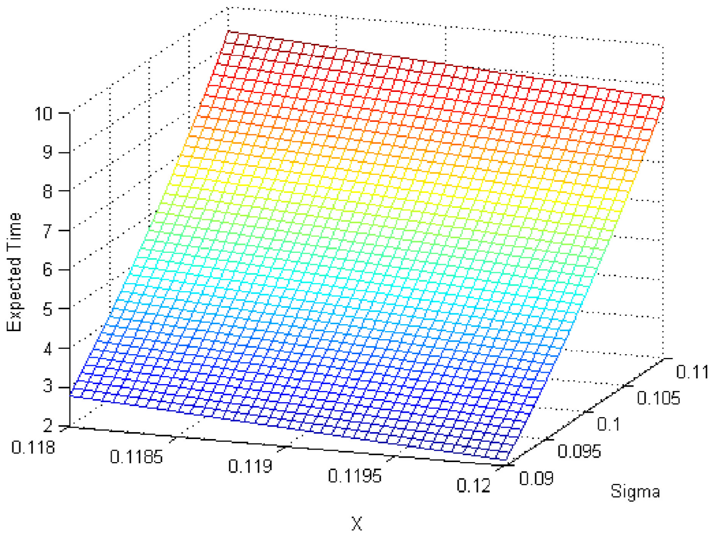


Figure 2. Expected time for health uncertainty and critical values

Source(s): Created by the author. Originally published in de Mello-Sampayo, 2014

Figure 1 illustrates the probability that $\tilde{x}$ will be hit in the future is increasing in x and decreasing in σ^2. This is because, first, the lower is σ^2, the less valuable is the option to switch treatment, and so the more treatment switches will be observed, and second, the higher is x, the more likely it is that the process will be "thrown off-course" by a sequence of positive shocks toward the optimality threshold.

In Figure 2, our simulation benchmark values are expressed in year terms so that the simulations for the expected time for optimal treatment switch can be read in years. Figure 2 shows that the lower is σ^2 and the higher is x, the sooner the treatment switch is expected to occur. However, the further away x is from the trigger value, the greater is the impact of an increase of σ^2 on the delay expected before treatment switch becomes optimal.

Viewed from the perspective of real options theory, the model presented above sheds new light on some debates about switching treatments. de Mello-Sampayo (2014)'s theoretical model suggests that cost uncertainty discourages switching treatments. The stochastic model also illustrates that as technologies become less cost competitive, the cost uncertainty becomes more dominant. With limited substitutability, higher quality of technologies will increase the demand for those technologies disregarding the cost uncertainty. Several key insights emerge. Irreversibility raises the value of the option-preserving treatment. The existence of an option value means that a seemingly poorer treatment may be the better choice when considering lifetime welfare. Optimal decision-making requires a careful comparison of the "costs" of a less effective treatment for a condition today with the "benefits" of more effective treatments in the future.

3.3 Real options model applied to public health

In this section we develop an epidemiological-based real options model based on de Mello-Sampayo (2024) to illustrate the role that uncertainty can play in determining the decision regarding when to exit the lockdown without provoking a resurgence of the disease.

3.3.1 Epidemiological model. A simple epidemiological model for a COVID-19 pandemic for which there is a considerable post-infection incubation period in which the exposed person is not yet contagious, is the Susceptible-Exposed-Infected-Removed (SEIR) model (Hethcote, 2000; Li and Muldowney, 1995; Avery *et al.*, 2020a, b; Blackwood and Childs, 2018). Ignoring births and deaths from non-COVID-19 causes, the population at the start of the epidemic is normalized to 1, and at each time t, the population is compartmentalized based on their infection status: susceptible (S) to infection; exposed (E), i.e. likely to be infected when exposed to the virus, but not yet contagious; infected (I) and contagious; and removed (R), who have recovered or died from the disease. The interaction between the susceptible and infected is permitted through the productive contact SI. Defining β as the rate of susceptible to become infected, the increase in the number of infected individuals is given by the product of the per capita rate at which a susceptible contracts infection times the number of susceptible individuals, i.e. βIS. The progression rate from exposed (latent) to infected is given by δ and the removal rate is γ.

Initially, under certain common assumptions (Jones, 2007), i.e. individuals who are infected remain infectious until they recover or die, infected individuals who recover acquire complete immunity, and ignoring uncertainty, the SEIR model translates into a system of four differential equations to relate the rates at which the population moves from one stage to another, and in which the time unit is one day:

$$\frac{dS}{dt} = -\beta IS, \tag{3.3.1}$$

$$\frac{dE}{dt} = \beta IS - \delta E^{\theta}, \tag{3.3.2}$$

$$\frac{dI}{dt} = \delta E^{\theta} - \gamma I, \tag{3.3.3}$$

$$\frac{dR}{dt} = \gamma I, \tag{3.3.4}$$

where β gives the transmission coefficient of the infected cases to the susceptible; 1/δ is the mean incubation period; γ is the rate at which infected individuals cease to be infectious or die; and θ is the degree of the social distancing measure taken by the government.

At the optimum, the government uses social distancing or mitigation measures to stop the infected population from increasing, i.e. $\frac{dI}{dt} = 0$, Equation (3.3.3) is now given by:

$$I_t = \frac{\delta E_t^\theta}{\gamma}, \tag{3.3.5}$$

where the parameter that captures the flattening effect of the curve due to the social distancing measures is assumed to be θ, $0 < \theta \leq 1$. If θ is equal to 1, there are no mitigation measures, whereas if it is close to zero, the population has to stay at home.

3.3.2 Uncertainty in the spread of the disease. There is uncertainty in the future levels of infection due to environmental and demographic noise associated with the transmission process for infection. The decision-maker is faced with the following choice: should mitigation measures be stopped immediately, or should the decision-maker wait to learn more about the progression of the epidemic? Waiting allows the decision-maker to determine whether the level of infection worsens or improves over time.

To include uncertainty into the decision-making, we assume that the level of exposed, E, can be described by a stochastic process. Traditionally, the geometric Brownian motion, which assumes that the mean level of infection grows exponentially, has been used to characterize stochastic processes (Dangerfield *et al.*, 2018). While such an assumption is a good approximation in the early stages of the epidemic, it does not capture the slowing in the rate of infection as the level of infection becomes large due to the limited number of susceptible individuals. Thus, we assume the exposed population follows a Driftless stochastic process, i.e. our best guess of the exposed population for tomorrow is what we have at the present.

Suppose that the government applies the lockdown (L) as the social distancing measure (θ), i.e. a mandate for citizens to stay at home (h), and for citizens who because of the nature of their work (e.g. nurses, doctors, refuse collectors) cannot stay at home, the government mandates the use of masks (m) in closed spaces, out-of-doors crowded spaces, and in public transportation. Since the factors that affect the exposed population behave differently between stay-at-home to not-stay-at-home citizens, we must characterize exposed citizens who stay at home and those using masks differently. As our best guess of the exposed population at time t+1 (E_{t+1}) is what we have at time t (E_t), we assume that E follows a Driftless stochastic process (also called Martingale [4]) by which:

$$dE_h = \sigma_h E_h dz_h, \tag{3.3.6}$$

$$dE_m = \sigma_m E_m dz_m, \tag{3.3.7}$$

where the subscripts h and m denote stay-at-home and use-of-masks measures, respectively. The increment of the Wiener process is $\varepsilon_t \sqrt{dt}$ and $\varepsilon_t\, N(0,1), E(\varepsilon_t, \varepsilon_s) = 0$for $s \neq t$. Exposed population's variability, σ, can be interpreted as the uncertainty affecting the Exposed population, with $\sigma_h, \sigma_m \geq 0$, $E(dz\|h, dz_m) = \rho dt$ and ρ is the correlation coefficient between the random shocks affecting Exposed citizens subject to stay-at-home measure and use-of-masks measure.

The exposed population under lockdown becomes an average of both exposed at home and using masks weighted by the share of population assigned to each group:

$$E_L = E_h^\phi E_m^\psi, \tag{3.3.8}$$

where E_L denotes the exposed population under lockdown, ϕ and ψ are the shares of population of stay-at-home and not-stay-at-home, respectively, with $\phi + \psi = 1$.

Now, assume that the government is searching for a way to exit the lockdown without provoking a resurgence of the disease. For that we analyze the timing and probability of exiting the lockdown under uncertainty.

Proposition 3.3.1. The government will end the lockdown when the expected Exposed population staying at home is higher than that attained when just using masks.

Proof: See Online Appendix C.

The decision-maker will choose to relax the measures only if the Exposed population associated with staying at home exceeds that of a situation of only using masks, i.e.

$$\frac{\widetilde{E}_h}{\widetilde{E}_m} = \left\{ \frac{\mu - \frac{\theta}{2}\left(\phi(\theta\phi - 1)\sigma_h^2 + \psi(\theta\psi - 1)\sigma_m^2 + 2\theta\rho\phi\psi\sigma_h\sigma_m\right)}{\mu - \frac{\theta(\theta-1)}{2}\sigma_h^2} \times i \right\}^{\frac{1}{\theta\psi}}, \tag{3.3.9}$$

where μ is the discount rate. For values of the ratio $\frac{E_h}{E_m}$ lower than $\frac{\widetilde{E}_h}{\widetilde{E}_m}$ it is optimal not to relax the measures. Conversely, if the value of the ratio is greater than the critical value, the government should end the lockdown. It follows that Equation (3.3.9) defines the line that divides the $(E\|h, E_m)$ space into two regions: one in which it is optimal to exercise the change of measures option and the other in which it is not. Following the comparative statics shown in Online Appendix C, the reduced form of Equation (3.3.9) can be written as follows:

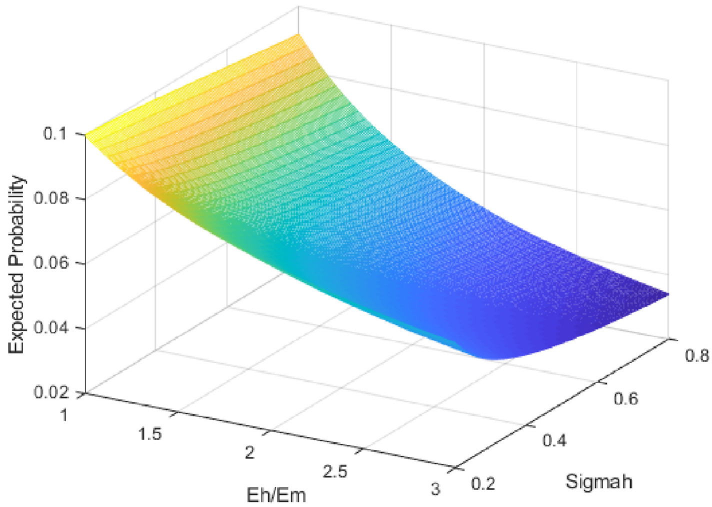
$$\text{Exit Lockdown } f\begin{pmatrix} \sigma^2 & \alpha & \mu & \phi & \theta \\ - & + & + & - & + \end{pmatrix}.$$

Thus, the model presented gives clear indications regarding the exit of lockdown decision under uncertainty. It predicts that the higher the uncertainty (σ^2) affecting the exposed population, the later the exit of lockdown is made, the higher the correlation (ρ) between the exposed population staying at home and using masks, the less valuable the option of exiting lockdown will be, and so the more exits of lockdown will be observed. With regard to the discount rate (μ, a higher time preference increases the decision-maker's opportunity cost of not immediately stopping the stay-at-home measure. Conversely, the higher the share of population staying at home (the lower the share of population just using masks) and the higher the effect of the mitigation measure (low θ), the fewer exits of lockdown one would expect to observe. This is because change of policy always includes some degree of irreversibility such that an increase in the share of population just using masks (not staying at home) raises the society's overall risk of exposure.

These results are confirmed using simulations. The simulations are performed using Portuguese data on COVID-19 between 2020 and 2021 from various sources. Table C1 in Online Appendix C presents the range and the base value of each parameter.

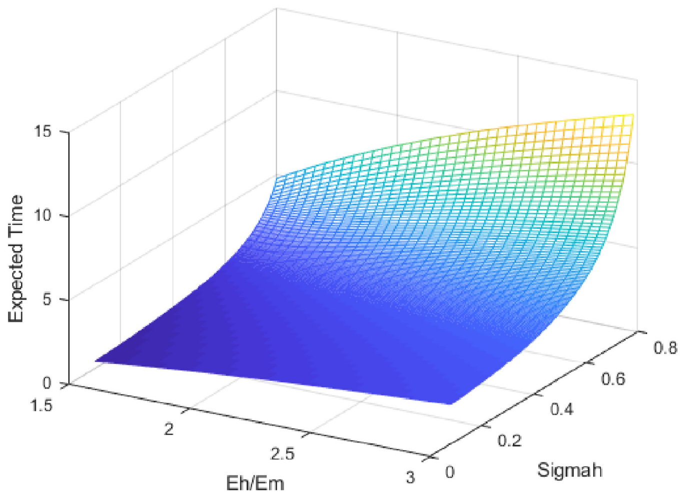
Figures 3 and 4 illustrate the impact of σ_m and $\frac{E_h}{E_m}$ on the expected probability and on the expected time of changing the mitigation measures, respectively, as given by Equations (C15) and (C16) in Online Appendix C.

Figure 3 illustrates the impact of σ_h^2 and $\frac{E_h}{E_m}$ on the probability of optimal policy change. The probability that $\frac{\widetilde{E}_h}{\widetilde{E}_m}$ will be hit in the future is decreasing in both σ_h^2 and $\frac{E_h}{E_m}$. This is because, first, the lower is σ_h^2 the less negative is the drift of the process $\frac{E_h}{E_m}$, and second, the higher is $\frac{E_h}{E_m}$



Source(s): Created by the author. Originally published in de Mello-Sampayo, 2024

Figure 3.
Expected probability for exposed uncertainty and critical values



Source(s): Created by the author. Originally published in de Mello-Sampayo, 2024

Figure 4.
Expected time for exposed uncertainty and critical values

the more likely is that process to be "thrown off-course" by a sequence of positive shocks toward the optimality threshold.

Figure 4 simulates the effect of changes in σ_h^2 and $\frac{E_h}{E_m}$ on the expected time for optimal policy change. It shows that the lower is σ_h^2 and the lower is $\frac{E_h}{E_m}$, the sooner the policy change is expected to occur. However, the more the change of policy option is worth, the greater is the impact of an increase of σ_h^2 on the delay expected before the policy change becomes optimal.

In summary, the lower the uncertainty affecting the exposed population subject to lockdown, the more likely policy change is to become optimal and the sooner it is expected to occur. Moreover, exiting lockdown becomes likelier and is expected sooner, the closer the two processes are, i.e. $E_h \approx E_m$, and so the lower the uncertainty that results from the switch from a situation in which measures of staying at home and using masks to one in which the population can live freely and just use masks in closed spaces and public transportation.

This model extends the literature by applying the real options theory, a framework for decision-making under uncertainty, to an epidemiological model of disease spread. By incorporating uncertainty into the analysis, the study aims to determine the optimal timing for exiting lockdown. The real options approach allows for the evaluation of the economic value of deferring the decision to exit lockdown until more information becomes available.

4. Discussion

This paper presented a mapping of the studies published to date applying the real options theory to various areas of healthcare. Real options theory relates to decision-making under uncertainty and specifically to the value of deferring uncertain unrecoverable decisions to a later time. In the evaluation of healthcare technologies and programs, this dimension of value originates from the possibility of delaying a decision if there is an expectation that better information will become available in the future. The seminal paper of Palmer and Smith (2000) argues that, in the presence of uncertain, irreversible decisions, the possibility of deferring the decision until some later time, when better information regarding costs and benefits may become available, has an economic value that is not accounted for in traditional economic evaluations based on net expected values.

The real options approach has been widely employed in the healthcare sector with a focus on optimizing outcomes. It finds application in diverse areas, investment analysis (Smyth and Swinand, 2002; Williams *et al.*, 2007; Levaggi *et al.*, 2009; Levaggi and Michele, 2004; Pertile, 2008, 2009; Pertile *et al.*, 2009), technology assessment (Eckermann and Willan, 2008; van Loon *et al.*, 2012; Thijssen and Bregantini, 2017; Oliveira and Zambujal-Oliveira, 2018; Tolga, 2020; Chalkidou *et al.*, 2008), decision-making in public health (Favato *et al.*, 2012; Pertile *et al.*, 2014; Park, 2016; Attema *et al.*, 2010; Megiddo *et al.*, 2019), and medical decision-making (Driffield and Smith, 2007; Grutters *et al.*, 2011; Meyer and Rees, 2012; Forster and Pertile, 2013b; de Mello-Sampayo, 2014, 2015; Shechter *et al.*, 2008; Zivin and Neideill, 2009). These earlier studies applying real options theory to decision-making in the healthcare sector often use the option to defer (Fornaro *et al.*, 2021). This option is commonly employed in investment analyses to decide whether to adopt new technologies for treatments, as well as in cases involving the postponement of vaccination or in cases to decide whether, when, and if a treatment should occur, i.e. watchful waiting. Investment analyses in the healthcare sector follow a similar logic to that applied in other sectors, wherein the investor seeks to maximize the expected present value of the payoff. Similarly, in healthcare scenarios such as watchful waiting, the same logic applies due to the presence of irreversibility and risk. For instance, the decision to initiate treatment is irreversible, as the resources allocated cannot be utilized for any other purpose. However, the option to defer treatment remains reversible. For example, Grutters *et al.* (2011) examine the adoption of proton therapy compared to body stereotactic radiotherapy in the treatment of inoperable stage I non-small cell lung cancer, highlighting the relevance of information in selecting the best treatment at a specific time. The value of information is crucial, particularly due to the technical uncertainty involved in certain treatments, which may lead decision-makers to choose treatment options that are not necessarily the most effective. More information mitigates risks and enhances expected returns.

In this study, we began by introducing a straightforward stylized model that applies option pricing principles to assess investments in new technologies, within a cost-benefit framework (Palmer and Smith, 2000). The aim was to highlight the main ideas underlying the real options model, i.e. uncertainty, irreversibility, and the ability to invest subsequently. This type of model has been applied to analyzing investments in diverse areas such as machines, technologies, pharmaceuticals stocks, health insurance plans, public health initiatives, new treatments, infrastructure, and health systems. Those studies represent traditional applications of real options, wherein investors analyze whether investing their capital in a particular project yields returns higher than the company's cost of capital. The options to expand and abandon are particularly relevant when evaluating technology investments. For instance, (Levaggi *et al.*, 2009) illustrate how real options can be used to expand investments strategically, thereby optimizing returns while minimizing the associated risks. In another vein, (Pertile *et al.*, 2014) discuss how the real options approach can be used to evaluate the option to abandon a project when conditions are unfavorable or when better opportunities arise.

To illustrate a real options model applied to medical decision-making, we used a stochastic dynamic model of sequential therapeutic regimes that underscores the importance of characterizing uncertainty (de Mello-Sampayo, 2014). Cost fluctuations, among other factors, render the outcome of any treatment switch uncertain, so that decision-makers might have to wait for more information before optimally switching treatments, especially when the incremental cost per Quality-Adjusted Life Years (QALYs) gained cannot be fully recovered later on. Since in most cases decision-makers are not compelled to switch treatments at any specific moment, they hold an option to switch treatments that should only be exercised when it is optimal to do so. The intuition for these results is deepened when we recognize that one of the principal features driving our results is that patients have particular characteristics that make technology's cost uncertain. Thus, under irreversibility, low-risk patients must begin the option-preserving treatment as soon as possible, which is precisely when the second-line treatment is least valuable. As the costs of reversing current treatment impacts fall, it becomes more feasible to provide the option-preserving treatment to these low-risk individuals later on. The study builds upon previous studies such as Driffield and Smith (2007) and Meyer and Rees (2012), acknowledging the unique nature of medical decision-making. These studies address the issue of time-related decisions made by risk-averse individuals and examine how an increase in uncertainty regarding a patient's health state often makes waiting more attractive. Unlike traditional investment portfolios, medical treatments cannot be diversified simultaneously, i.e. there is an inherent limitation in medical treatment strategies that prevent applying multiple different treatments at the same time for a single patient or condition, in contrast to financial investment strategies. In this context, the option to switch treatments becomes critical as discussed by de Mello-Sampayo (2015). Since treatments cannot be diversified simultaneously, decision-makers (like doctors or patients) hold the option to switch from one treatment to another at the most opportune time, based on evolving information about the patient's condition and the effectiveness of the current treatment.

To exemplify how a real options model can be applied to public health decision-making, we derived an options model from a Susceptible-Exposed-Infectious-Recovered (SEIR) framework to analyze the probability and optimal timing of lockdown exit (de Mello-Sampayo, 2024). This analysis was conducted in the context of an ongoing pandemic in which the decision to exit lockdown is uncertain because it depends on the progression of the virus and the effectiveness of control measures. The theoretical model argues that in the presence of uncertainty the possibility of deferring the decision until some later time when better information may become available has an economic value. This concept is especially relevant to the context of the COVID-19 pandemic, in which crucial decisions regarding lockdown measures affect public health, the economy, and societal well-being. In the fight against the pandemic the value of deferring the decision to exit lockdown is underscored by the availability of information related to the disease's transmission dynamics. Key factors contributing to a reduction in uncertainty include a better understanding of how the virus spreads, the dissemination of clear and evidence-based public health guidance, and the development and distribution of vaccines. Information about how the disease spreads, clear public health guidance, and vaccines, decreases the uncertainty regarding exposure and transmission of COVID-19. This study aligns with the findings of related research (Chalkiadakis *et al.*, 2021; Varghese *et al.*, 2021; Abrams and Greenhawt, 2020), which emphasize the role of information and knowledge in reducing uncertainty related to the exposure and transmission of COVID-19. By leveraging a real options model within a SEIR framework, our research contributes to the scientific understanding of how decision-makers can navigate the complex landscape of public health decisions during a pandemic characterized by high levels of uncertainty.

Growth in the availability of treatments for chronic diseases that require permanent intervention, along with general increases in life expectancy, suggests that the impact of omitting option values from evaluations will only become greater. While it is difficult to systematically assess the magnitude of the bias induced from ignoring option values, the only empirical study in the health domain reported an increase in consumer willingness-to-pay of approximately 53% when option values were considered (Smith, 2007). Extending one's life through medical technology provides patients with the option to potentially benefit from future advances in healthcare (Lakdawalla *et al.*, 2018). This real options value emerges when a health technology not only prolongs life but also opens up opportunities for patients to access forthcoming innovations in medicine (Cook *et al.*, 2011). The importance of considering real options when discussing value in healthcare has recently been highlighted (Lakdawalla *et al.*, 2018; Krüger and Svensson, 2009; Garrison *et al.*, 2017; Smith and Yip, 2016). While the economic literature has previously identified real options value as an additional component of value for specific medical products (Smith, 2007; Eckermann and Willan, 2008), it is typically not accounted for in the conventional projections of QALYs gained. These QALYs typically consider expected survival and health-related utility over a patient's remaining lifetime. Investing in life-extending medical technology can be seen as buying an option to benefit from future advances in healthcare. Other things being equal, a technology that extends life in an area with promising innovations holds greater value (Li *et al.*, 2022).

Implementing real options theory in healthcare decision-making faces several limitations. Firstly, the intrinsic uncertainty and complexity of healthcare outcomes challenge the accurate assessment of option values. Unlike financial markets, where assets have readily quantifiable values, the outcomes in healthcare, such as patient health or disease progression, are not easily quantified. Secondly, the dynamic and often unpredictable nature of healthcare policy and regulation can invalidate the assumptions underpinning real options analysis, rendering the conclusions less reliable. Lastly, there's a moral and ethical dimension in healthcare decision-making that is not typically present in financial decision-making. Balancing financial considerations with ethical obligations to patients adds a layer of complexity that real options theory may not adequately address. These limitations suggest that while real options theory can provide valuable insights, it must be applied with caution and in conjunction with other decision-making frameworks in the healthcare sector.

While real options theory offers a valuable approach for decisions under uncertainty and where the timing of decisions is crucial, other models like Cost-Effectiveness Analysis (CEA), decision trees, Markov models, and Bayesian decision models have their respective strengths in different scenarios. The choice of model depends on the specific decision context, the nature of the healthcare problem, the availability of data, and the need for dynamic versus static analysis. For instances, CEA provides a static comparison based on current data but may not fully capture the value of deferred decisions or evolving scenarios and decision tree analysis presents an intuitive way to visualize decision paths, integrating probabilities and potential outcomes. This method is most effective when dealing with a limited set of discrete outcomes (Vassolo *et al.*, 2021). Bayesian Decision Models dynamically update probabilities with new information, suitable for evolving healthcare scenarios, yet they require extensive initial data and are computationally intensive (Luce *et al.*, 2001).

5. Conclusion

Our study shows the versatility of the real options model, demonstrating its applicability in diverse fields in healthcare, where it aids decision-makers in assessing investment opportunities, medical decisions, and public health decisions, among others. By considering strategic decision-making and the value of flexibility, real options theory enhances the evaluation of healthcare investments, policy analysis, patient outcomes, and resource allocation. These applications contribute to a more comprehensive understanding of decision-making under uncertainty in the field of health economics, leading to improved decision-making and outcomes in the ever-evolving healthcare industry.

Notes

1. Stochastic process, also known as a random process, accounts for certain levels of unpredictability or randomness.
2. Wiener process is a stochastic process. The initial value of all Wiener processes is 0; past values of these processes do not influence any future changes in their value (this is what makes the processes stochastic).
3. In this model set-up, the mechanism that leads health to be a Giffen good also involves a wealth consideration. When the price of treatment falls, the patient is effectively wealthier, he can afford more treatments generally, and so he needs fewer treatments of this kind. Housing is another example of a non-inferior good whose own-demand can be upward sloping (see Dusansky and Koç (Dusansky and Koç (2007)).
4. Martingale process: the fluctuations in exposed population are a sequence of random variables for which, at a particular time, the conditional expectation of the next value in the sequence is equal to the present value, regardless of all prior values.

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Online Appendix

The supplementary material for this article can be found online.

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