



Influential Factors on the Economic Justifiable Price: Systematic Investigation of Factors and Mechanisms Beyond the Incremental Cost Effectiveness Ratio

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Abstract:

Objectives:

The economically justifiable price (EJP) reflects the maximum price that can be set for a healthcare intervention whilst still being regarded as an efficient use of limited healthcare resources. This study aims to describe the interdependencies between the EJP, the Incremental Cost-Effectiveness Ratio (ICER), and the Willingness-To-Pay (WTP) threshold in health economic evaluations and assess any observed patterns.

Methods:

A conceptual three-state partitioned survival model was used to assess the relationship between these three parameters in evaluating a hypothetical novel late-stage oncology drug. Various factors, including clinical endpoints, costs (drug acquisition, drug administration, patient follow-up, adverse events), discount rates (costs, effects), and utility values, were varied within plausible ranges to evaluate their potential impact.

Results:

At a constant WTP, any input that increases the ICER generally reduces the EJP for the novel drug. Inputs related to survival and utility values have the largest bearing on ICERs and EJPs, whereas the impact of adverse events and administration costs generally appear to be more limited. The importance of discount rates and the cost of patient follow-up increases with survival extending. Five distinct categories were identified: Scenario 1, wherein the EJP remains constant despite changes in input factors for ICER; Scenario 2, involving increased ICER and decreased EJP due to changes; Scenario 3, where both ICER and EJP increase; Scenario 4 in which both ICER and EJP decrease; and Scenario 5 leading to decreased ICER and increased EJP.

Conclusions:

This analysis demonstrates that numerous factors can influence EJP levels and counterintuitive scenarios are possible. The EJP can vary between countries, even if they apply the same WTP threshold.

Background:

In the realm of healthcare economics, particularly in the assessment and pricing of pharmaceuticals, the notion of Economic Justifiable Price (EJP) plays a pivotal role in determining how drugs are valued and priced within healthcare systems. This concept intersects significantly with cost-effectiveness analyses, where the Incremental Cost-Effectiveness Ratio (ICER) is a critical metric. ICER is employed to compare the cost and effectiveness of a new treatment relative to existing alternatives, often measured in terms of cost per Quality-Adjusted Life Year (QALY) gained or Life Years Gained (LYG) (Figure 1). A common benchmark in the United Kingdom, as referenced by the National Institute for Health and Care Excellence (NICE), is an ICER threshold of approximately 30,000 GBP per QALY or LYG. This threshold is a guideline for determining whether a new healthcare intervention offers value for money and should be funded by the National Health Service (NHS).

The simplistic interpretation of EJP as merely the cost of a drug leading to an ICER that falls at or below this threshold has been a matter of debate. This interpretation assumes a direct and linear relationship between the drug's cost and its deemed cost-effectiveness, neglecting several nuanced factors that play critical roles in healthcare decision-making. The assumption overlooks the complexity of drug pricing, the multifaceted nature of value in healthcare, and the broader economic and ethical implications of such a simplification.

This study will utilise scenario analyses and sensitivity analyses to systematically explore the impact of varying these parameters on the ICER. Scenario analyses will allow for examining different hypothetical situations (e.g., best-case, worst-case, and most likely scenarios) to understand the range of possible outcomes. Sensitivity analyses will assess the robustness of the ICER to changes in individual parameters, identifying those that have the most significant impact on cost-effectiveness conclusions.

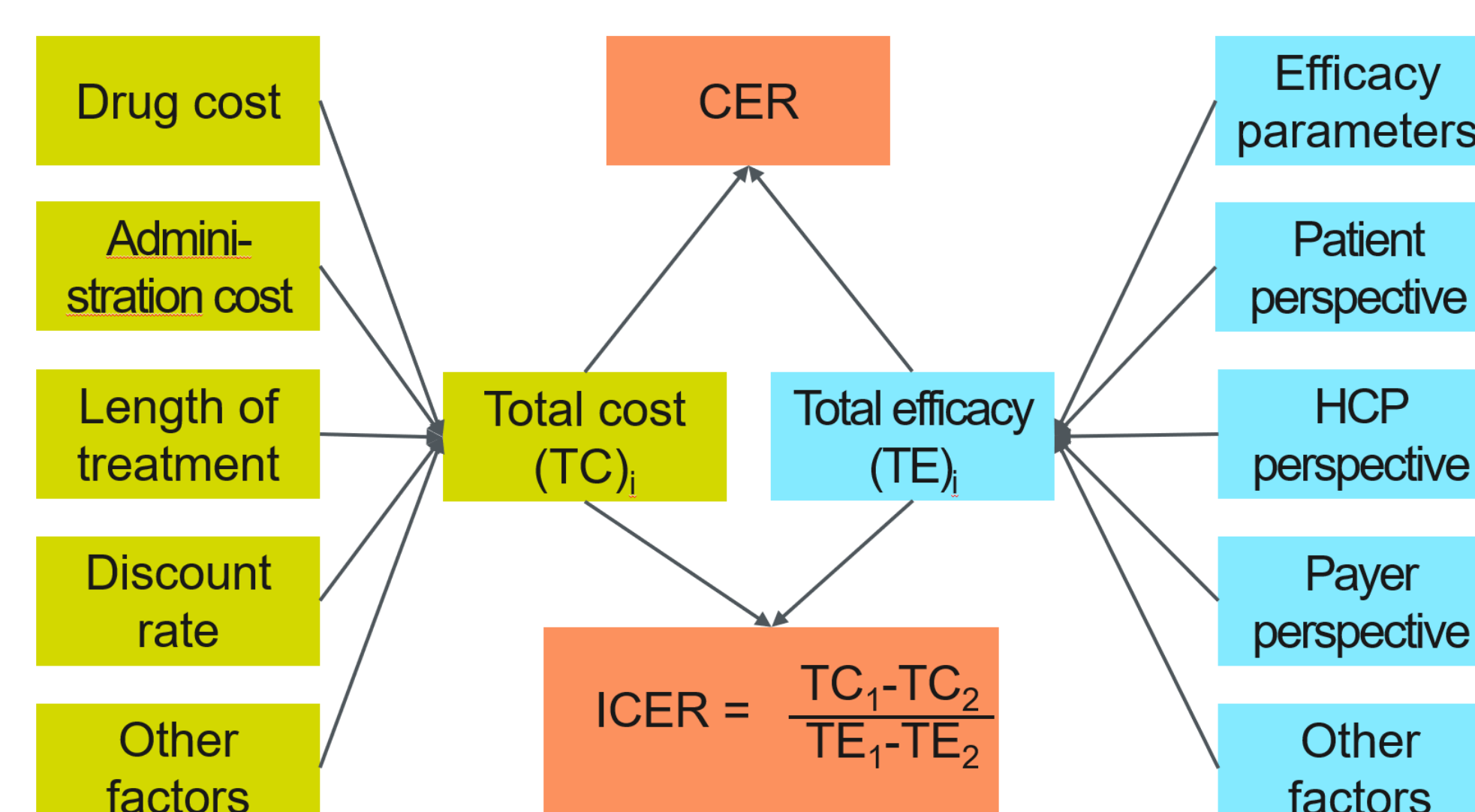


Figure 1: Illustration of factors influencing the ICER of a specific drug / treatment / health technology

Methods:

Expanding on the methods for our comprehensive evaluation, a conceptual three-state partitioned survival model was methodically applied within a cost-effectiveness framework to dissect the financial and health outcomes of a new oncology medication targeting late-stage cancer. This advanced modelling allowed us to map the journey of patients through three distinct health states—disease progression, stability, and death—over time, capturing the nuanced transitions and their economic implications. The sensitivity analysis was extended into five dimensions to meticulously scrutinise the variability in costs associated with drug procurement, administration, ongoing patient monitoring, and managing adverse reactions, alongside the critical survival parameters that influence the drug's effectiveness and overall value. Each parameter was carefully varied within plausible ranges derived from existing literature and expert opinion to simulate a wide array of scenarios. This strategic approach enabled a thorough investigation into the impact of each cost and clinical factor on the ICER, offering a detailed exploration of the drug's economic feasibility and potential placement within healthcare systems.

Base Case Definition

For the purpose of this analysis, we define a base case scenario centred around the introduction of novel drug treatment. The assumptions underlying this scenario include the achievement of the Economic Justifiable Price (EJP) with an incremental life-year gain (LYG) of 0.4 years, paired with an incremental cost of 16,000 US\$. This base case serves as the reference point against which the cost-effectiveness of the new drug treatment is initially assessed. It embodies a hypothetical, yet plausible scenario designed to reflect the complexities and strategic considerations inherent in pharmaceutical pricing and health economic evaluations.

Sensitivity Analysis

Following the establishment of the base case, the study will employ a five-way discrete sensitivity analysis to investigate the influence of varying key parameters on the cost-effectiveness outcome. This sensitivity analysis is structured to methodically vary one parameter at a time while keeping others constant, thereby isolating the effect of each parameter on the Incremental Cost-Effectiveness Ratio (ICER). The parameters selected for this sensitivity analysis include clinical efficacy, drug cost, drug administration cost, adverse event incidence, and treatment duration.

Each parameter will be varied according to a predefined set of discrete scenarios, reflecting realistic variations that could occur in clinical practice and health economic evaluations. The outcomes of the sensitivity analysis will be reported in terms of their impact on the ICER, with particular attention to changes that result in the ICER crossing established cost-effectiveness thresholds.

Interpretation of Sensitivity Analysis Results

The sensitivity analysis results will be interpreted to provide insights into the robustness of the base case conclusions and to identify the parameters with the most significant impact on the cost-effectiveness of the new drug treatment.

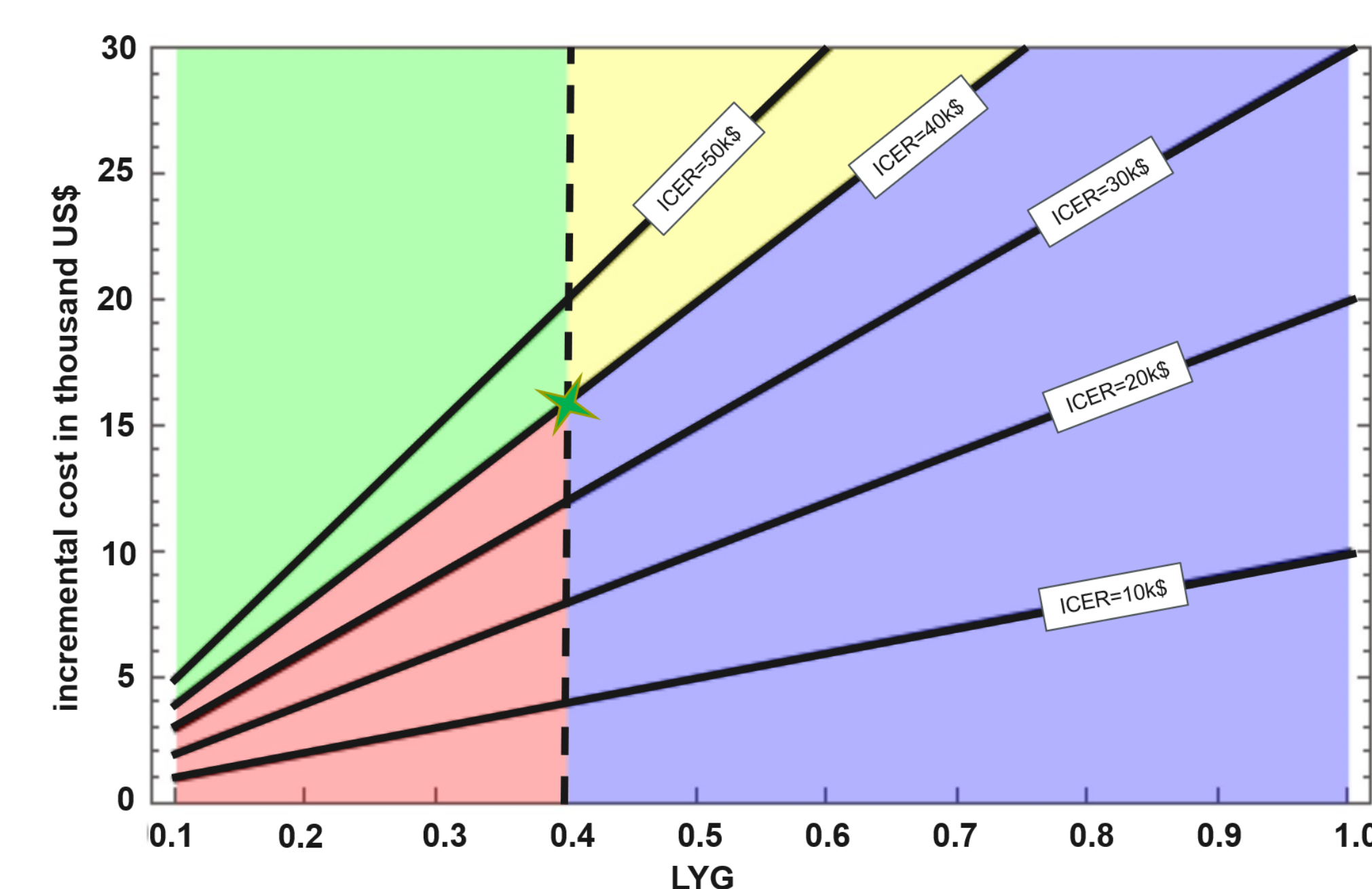


Figure 2: Cost-effective plane showing the hypothetical case of the analysis: Base case is marked with a green star with the outcome of 0.4 LYG and 16k US\$ incremental cost (ICER = 40k US\$)

Dotted vertical line: EJP can remain constant in cases where LYG remains the same with no changes in the sum of incremental costs

Yellow area: increased LYG and increased incremental cost with an ICER GT 40k US\$ can lead to a decreased EJP

Green area: decreased LYG with lower or higher incremental cost with an ICER GT 40k US\$ can lead to an increased EJP

Purple area: increased LYG with lower or higher incremental cost with an ICER LT 40k US\$ can lead to an increased EJP

Pink area: decreased LYG with lower or higher incremental cost with an ICER LT 40k US\$ can lead to an increased EJP

Our analysis, by revealing scenarios where EJP can remain stable despite fluctuations in ICER, increase alongside ICER, or even decrease as ICER lowers, provides compelling evidence against the simplistic notion that cost-effectiveness directly and predictably correlates with economic viability. Particularly, the graph in Figure 2 illustrates how changes in various parameters—ranging from drug costs to survival rates—can lead to unexpected shifts in ICER and EJP values, thereby highlighting the critical need for a multidimensional approach to economic evaluations in healthcare.

This complexity is further exemplified by the diversity of scenarios explored, each underpinned by its unique set of assumptions and outcomes. For instance, scenarios that depict simultaneous increases or decreases in both ICER and EJP challenge the conventional wisdom of inverse relationships and underscore the potential for significant clinical benefits or cost savings to alter the economic landscape of healthcare interventions. Conversely, the existence of scenarios where improvements in cost-effectiveness do not necessarily equate to enhanced economic viability or where cost-effectiveness deteriorates while economic viability improves accentuates the multifaceted and unpredictable nature of healthcare economics.

These findings have profound implications, suggesting that policymakers, healthcare providers, and pharmaceutical companies must adopt a more nuanced perspective when assessing the value and pricing of new healthcare interventions. The simple equation of higher ICER leading to lower EJP is debunked, advocating for a more sophisticated analysis considering the myriad factors influencing these metrics. Such an approach is crucial for ensuring that healthcare resources are allocated efficiently and that patients have access to effective and economically viable treatments.

In conclusion, the intricate interplay between ICER and EJP, as revealed through our analysis and the visual depiction in Figure 2, underscores the limitations of traditional economic evaluations in healthcare. It calls for a more comprehensive and nuanced understanding of how various factors impact the cost-effectiveness and economic viability of healthcare interventions. By moving beyond simplistic assumptions, we can better navigate the complex economic landscape of healthcare, ensuring that innovations not only offer clinical benefits but also represent a prudent use of limited healthcare resources.

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