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Exploring the Value of Country-Specific Cost-Effectiveness Models in Early Stages of Drug Development

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OBJECTIVE

- The aim of this study was to identify key factors to consider when deciding to adapt early cost-effectiveness models (eCEMs) in oncology therapies for an advanced tumor type.
- We explored the impact of country adaptations of eCEMs in a variety of scenarios by assessing the influence of country-specific differences in key model inputs on estimated economically justifiable prices (EJPs).
- Impact on incremental cost-effectiveness ratios will be explored in a future iteration of the project.

CONCLUSIONS

- The impact of country-specific differences on CEM outcomes can vary significantly depending on a variety of factors. We highlight the importance of full country-specific eCEM adaptations when there are substantial differences in treatment patterns, timing of generic drug availability, costs of background treatments, and availability of utility data across countries
- Continued introduction of new combination therapies and the growth of HTA bodies globally has increased the need for and value of country-specific adaptations in eCEMS.

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BACKGROUND

- Despite increasing use of cost-effectiveness analyses by health care systems in countries that historically have not utilized them, the United Kingdom (UK) is often one of the first countries for which an eCEM is developed to guide early health economic and outcomes research strategies across global regions.
- Beyond differences in country-specific willingness-to-pay (WTP) thresholds and discount rates, the value of full country adaptation remains to be seen when considering cross-country differences in health state utilities, disease background costs, and comparator drug pricing in early phases of drug development.

METHODS

- We developed a UK-based eCEM to evaluate a hypothetical product for advanced cancer using a standard partitioned survival analysis with the following health states: progression-free survival (PFS), progressed disease (PD) second-line treatment, PD (no active treatment), and death.
  - 2 hypothetical intervention regimens were evaluated:
    - New intervention as a monotherapy (5 additional months of survival)
    - New intervention to be added to current standard of care as part of a combination regimen (10 additional months of survival).
  - Efficacy data (PFS and overall survival [OS] curves) for the hypothetical product and standard of care were generated from published Kaplan-Meier curves, following NICE Decision Support Unit guidelines.[1]
- The base model was adapted to the United States (US) using 2 approaches (Figure 1):
  - **Simple adaptation:** WTP threshold, discount rates, and costs were updated using the hospital price purchasing power parity.[2]
  - **Full adaptation:** Each model input was updated to reflect the US-specific plausible ranges informed by the literature. (Table 1 informs the list of input parameters.)
    - The independent effects of accounting for country-specific costs data, treatment pattern data, and utility data on estimated EJPs were estimated.
    - Each group of key country-specific parameters was varied further to clarify key scenarios for customizing inputs for country-specific models.
    - Inputs pertaining to subsequent therapy patterns and costs, background treatment costs, availability of generic comparator drugs, and adverse event (AE) treatment costs were varied independently.

RESULTS

- Simple adaptation vs. full adaptation (Figure 2):
  - In our hypothetical example, updating utility data by using a US-specific data source affected the EJP by 9% (for monotherapy) to 12% (combination therapy). However, the impact of accounting for country-specific treatment patterns and unit costs were not substantial.
- Illustrative scenario analyses (Figure 3):
  - The parameters with the highest influence on EJPs were the increased costs of subsequent treatment (combination therapy: 14.2%; monotherapy: 17%) and availability of a generic comparator drug (combination therapy: 11%; monotherapy: −18.6%.)
  - Further, increased costs of background treatment had a sizable negative effect on the EJP (combination therapy: −7.8%; monotherapy: −5%).
  - AE costs did not contribute to significant changes in EJPs (< 0.1% regardless of whether the target treatment is mono- or combination therapy).

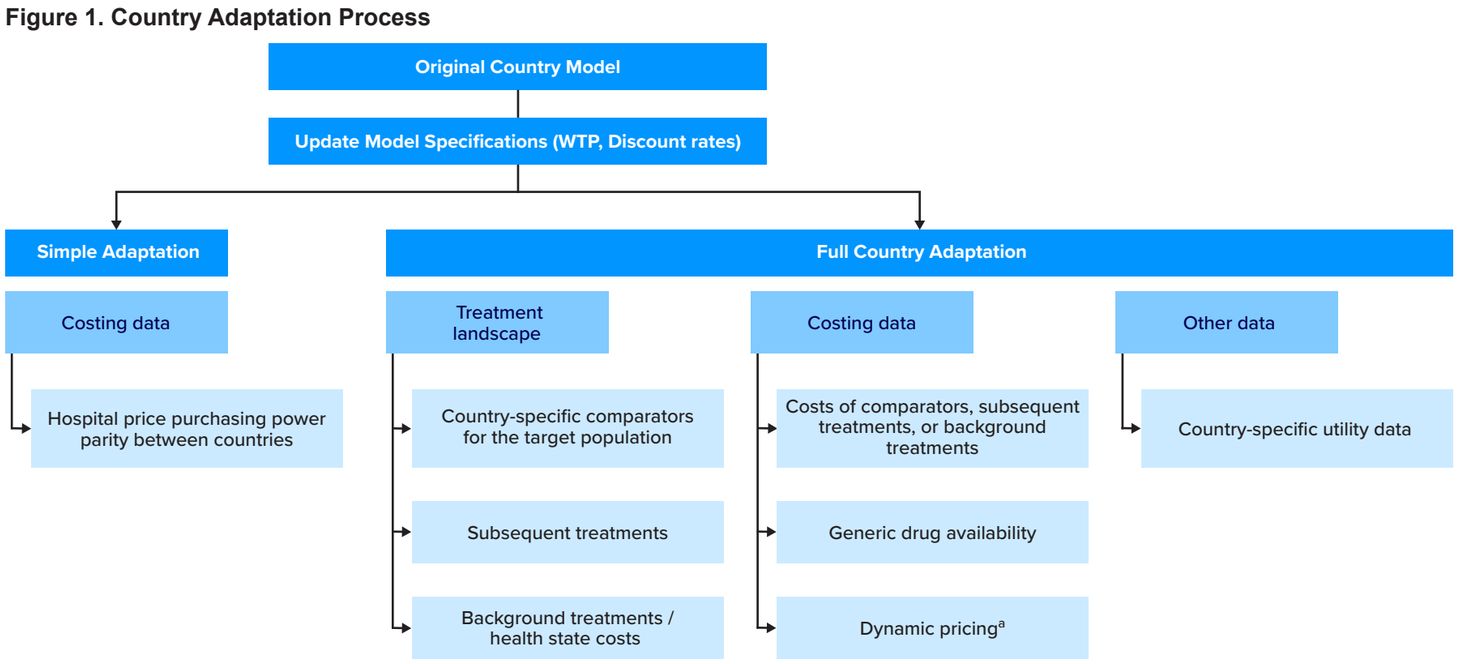
DISCUSSION

- In order to establish global eCEM adaptation strategy and priority, a landscape analysis for developing eCEM across key HTA markets can be conducted to identify key heterogeneity across the markets where the evidence of cost-effectiveness heavily influences payers' pricing and reimbursement decisions.
- As novel pharmaceutical policies such as the Inflation Reduction Act in the US emerge, it is crucial to assess whether different **dynamic drug-pricing** trajectories by country need to be accounted for when evaluating the need to fully adapt an eCEM to another country. Dynamic pricing is also critical when patent expiry affects total cost of therapy in combination treatment.[3]
- Variations in total treatment regimen cost (e.g., combination vs. monotherapy) were found to have significant impact on change in EJP. The impact of full adaptation on CEM outcomes should be assessed carefully, as the development of **combination regimens** in oncology is becoming increasingly common.[4]
- As the number of countries implementing HTA processes continues to grow, additional country-specific requirements for geographical adaptations should be considered in both eCEMs and when transitioning from eCEMs to full launch models.

LIMITATIONS

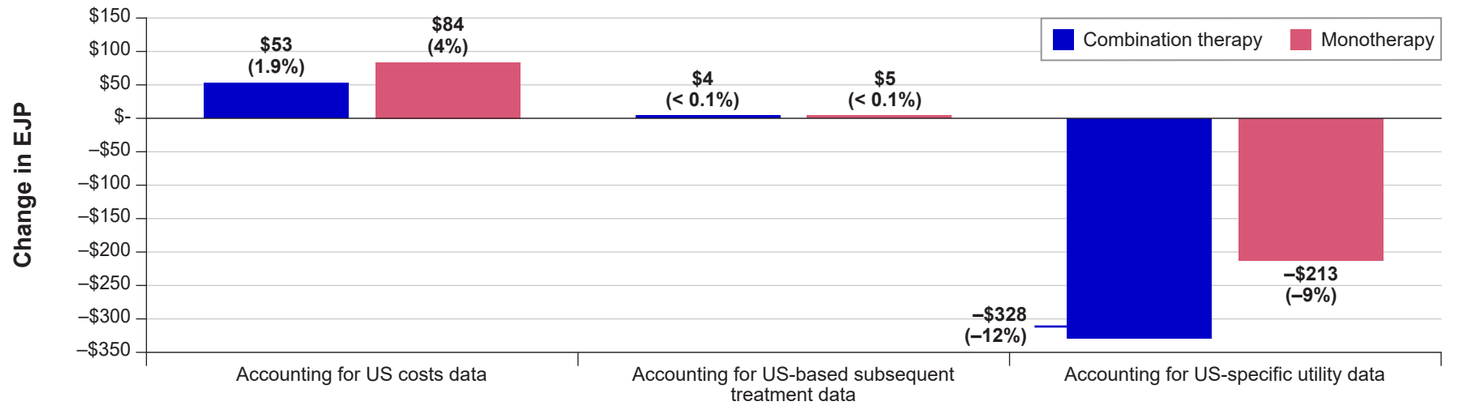
- Selected scenarios were presented for illustrative purposes and are not exhaustive. Directional results presented below depend on selected model parameters and may not be generalizable to all eCEM adaptations.
- Our study did not explore the impact of incorporating country-specific clinical data on eCEM outcomes. If substantial differences in treatment effects, including treatment specific impact on patients' utility values, are expected across countries, these scenarios should be explored in adaptations of eCEMs.

Figure 1. Country Adaptation Process



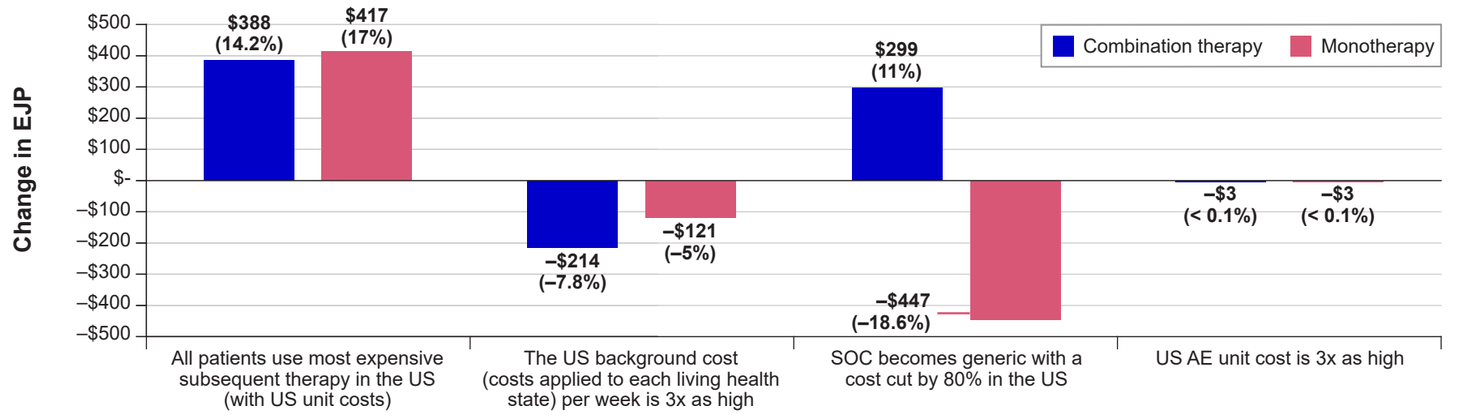
[a] Dynamic pricing scenarios were not included in poster scenarios but are important considerations for full country adaptations.

Figure 2. Effects of Accounting for Country-Specific Cost Data, Treatment Pattern Data, and Utility Data Availability (vs. Simple Adaptation) on the Monthly EJP of a Hypothetical Therapy



Note: Impact of accounting for country-specific treatment landscape and data availability on EJP vs. simple adaptation (EJP = $2,729/month).

Figure 3. Scenario Analyses Exploring Ranges of Effects When Accounting for Subtypes of Country-Specific Costs and Treatment Pattern (vs. Simple Adaptation) on the Monthly EJP of a Hypothetical Therapy



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