Payer archetypes and decision-making in the United States (US): A framework for generalised cost-effectiveness analysis (GCEA) value elements to optimize patient access and equity

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PURPOSE

- Consider different payer archetypes in the United States (US) and assess how generalised cost-effectiveness analysis (GCEA) value elements may further support decision-making.
- To understand the GCEA value elements that may be most relevant to each payer archetype and illustrate the proposed approach with a case study.
- Develop a framework for decision-makers to map GCEA value elements to payer archetypes and raise awareness of the benefits that GCEA can bring to payers.

BACKGROUND

- In the absence of a standardized technology assessment process in the US, there is renewed emphasis on pricing systems.
- Value assessment frameworks are being explored; however, they face challenges regarding consistency, perspective, and transparency.
- Traditional cost-effectiveness analysis (CEA) falls short in capturing the full value added by innovative treatments, necessitating a more comprehensive approach to evaluation.[1,2]
- GCEA is a novel approach to cost-effectiveness evaluation which considers additional value elements which are not typically included in traditional CEA approaches.[5]
- In this study, a targeted literature review (TLR) was conducted to identify key value elements relevant to US payers and to assesses how GCEA value elements apply to various US payer archetypes.

CONCLUSION

- The framework can serve as a valuable tool for payers to identify which value elements are the most relevant to their organization, while the case study serves as an example of how one might start thinking of integrating selected value elements.
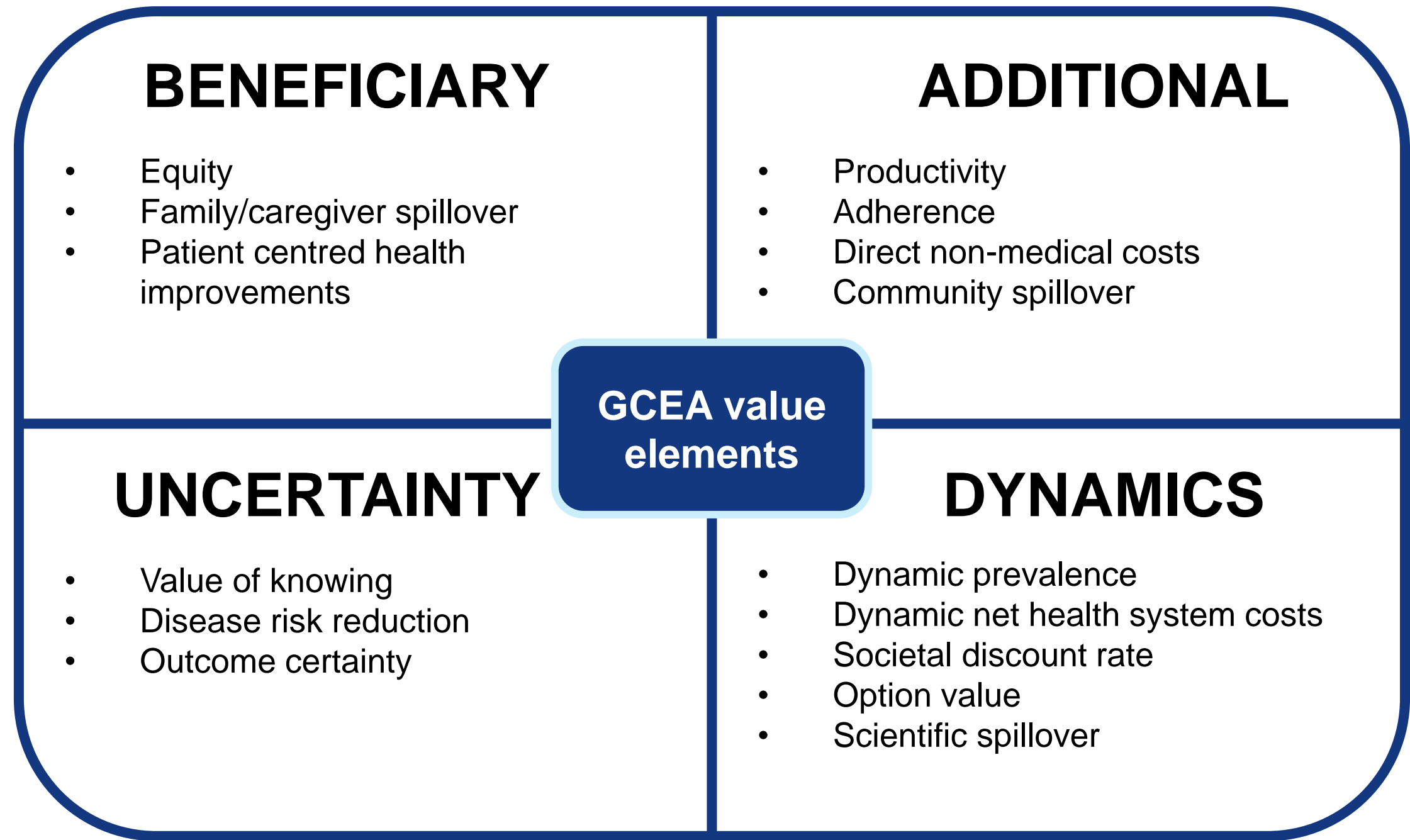
INTRODUCTION

- Rising healthcare costs and budget constraints have increased the significance of CEAs for new treatments. However, traditional CEAs often reflect narrow patient and payer perspectives, and overlook broader value elements that capture the full impact of a novel therapy or diagnostic.[3]
- Incorporating additional value elements offers a more comprehensive view of treatment value beyond standard CEA approaches.
- This study builds on the GCEA Value Flower by Shafrin et al. (2024), introducing a comprehensive framework that guides US payers in evaluating the relevance and feasibility of implementing GCEAs.[4,5] The framework considers critical factors such as risk aversion, key organizational challenges, and resource availability, providing a structured approach to integrate GCEAs effectively.
- This study aims to provide a framework on value element selection, based on payer archetypes.

Figure 1. *GCEA value elements[5]

STUDY DESIGN

- A TLR was conducted to assess and interpret the value elements commonly associated with different US payer archetypes, and how GCEA value elements apply to each archetype to further inform decision making.
- Current payer challenges presented in literature were used to inform and develop a framework to aid payers in selecting the most relevant value elements to support payer discussions.

RESULTS

Figure 2. TLR results (number of extracted studies by value element)
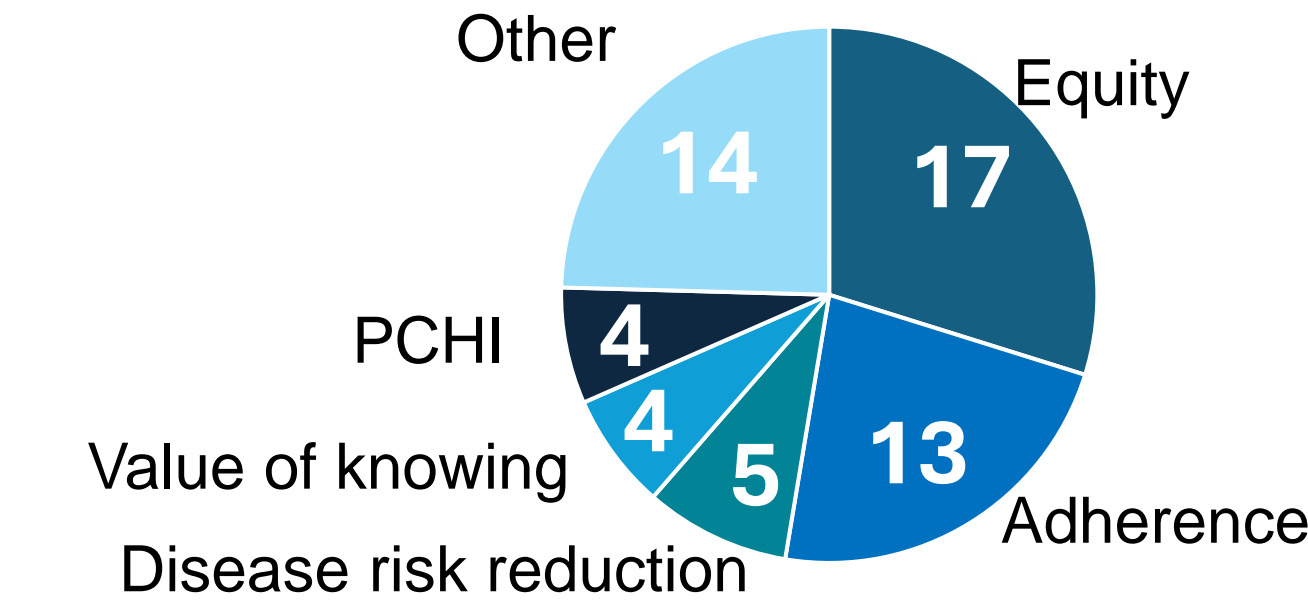
Targeted literature review
- 1,013 studies were identified, of which 57 studies were extracted based on inclusion of key words and themes, indicating payer priorities.
- Figure 2 summarises the most frequently included value elements in payer value discussions.

Data Gaps
- No paper was identified that explicitly rated value elements based on importance or relevance to the payer.
- Definitions of value elements varied across studies and often did not align with the GCEA framework (thus some interpretation based on value element definitions was needed).

Key payers
- Payers that were considered in the TLR and are a target audience for this framework can be categorised into four groups: **Payers & Insurers, Healthcare service providers, Regulators & Educators,** and **Administrative** entities. Across these payers, common challenges interpreted from literature include inequity in healthcare access, lack of trust from the public, long and short-term planning due to a fast-paced market, rising costs, lack of innovation (i.e. stable drug approval over the years in general and lack of focus on certain indications), and unfavourable or inconsistent patient outcomes.[7-15]
- These challenges provided the context for the proposed framework, allowing payers to potentially tackle these concerns through the incorporation of suggested value elements. However, due to the scarce literature, further validation and key opinion leader (KOL) engagement is necessary.

Figure 3. Key payer groups analysed in this study
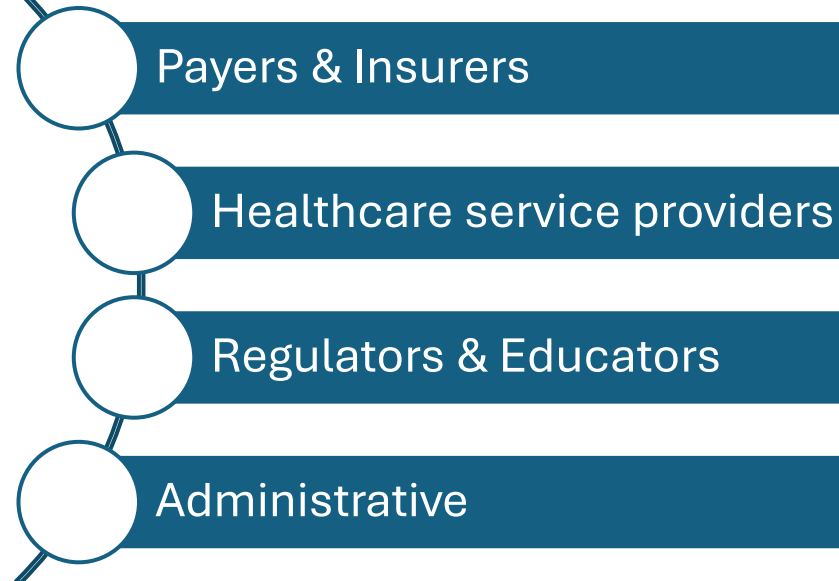
Proposed value element framework
- The proposed framework (Fig. 4) was developed to consider the risk preferences (Questions 1 and 2) and key payer-specific challenges (Question 3) of US payer archetypes to aid decision-making when evaluating novel therapeutics.
- This framework is designed to guide payers through key considerations. It follows a structured, checklist-style approach to streamline the selection of value elements for consideration. This guides users to answer all three proposed questions and consider any GCEA value elements that may be applicable based on the questions developed.
- **The risk preference question and proposed value elements** were directly taken from Padula et al. (2024). The publication outlines a non-linear relationship between health utility and value, capturing the spectrum of relative risk attitudes that decision-makers—such as payers —may land on.[6] We build on this concept by deriving three categories of payers stratified by risk, linking each to specific value elements using our proposed framework.
- However, payers are unlikely to fit neatly into these categories. Instead, they are more likely to fall at varied points along the risk spectrum and should interpret the "extreme" categories as conceptual anchors rather than fixed groups.
- Importantly, payers may change their risk category depending on the indication, environment and strategy. Furthermore, risk-stratification is one of the many potential payer categorization approaches. Further work may investigate payer categorization by goal (profit, growth etc.).
  - **Risk-Averse**: these organizations are not willing to take greater risks on smaller health gains, for instance an insurer that may avoid covering high-cost therapies with marginal health gains, especially for rare diseases or preventative interventions with long-term payoffs.
  - **Risk-Seeking**: these organizations may benefit more from treatments that offer significant improvements in health outcomes, especially in severe or rare diseases.
  - **Risk-Neutral**: these organizations assume a linear relationship between costs and QALYs, which can lead to oversimplification of complex decision-making processes.

Figure 4. Proposed value element framework to support value element selection
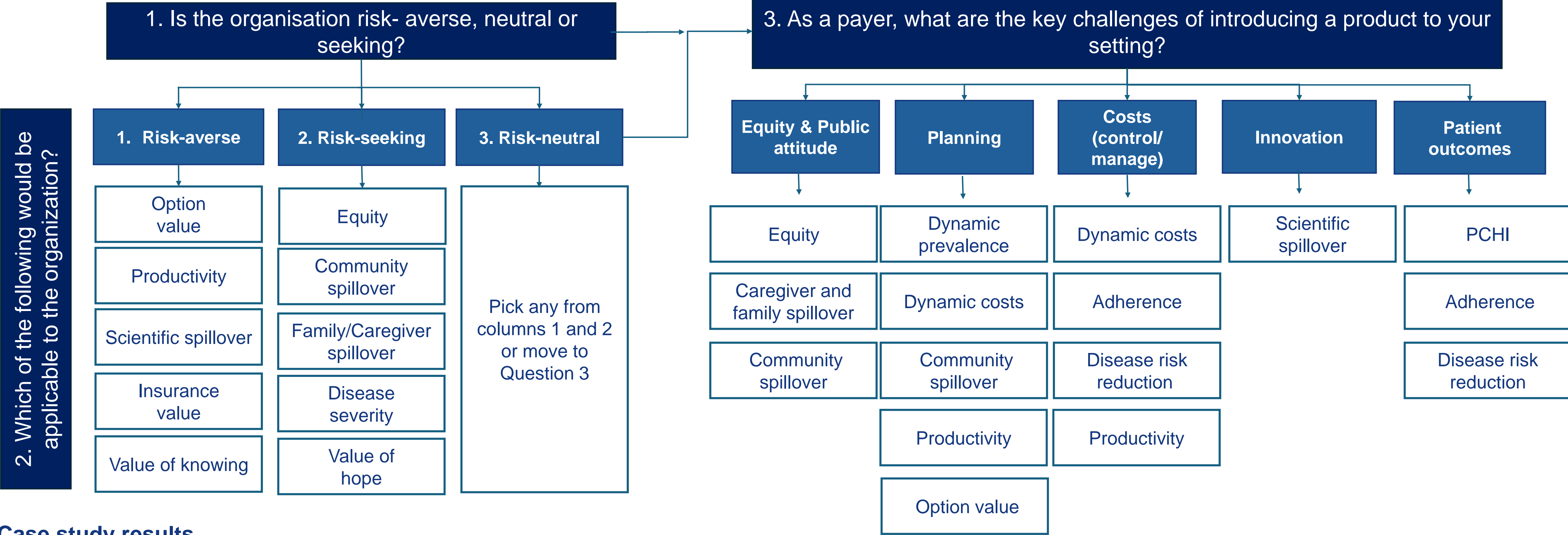
Case study results
- The current case study considers a hypothetical risk-seeking payer for a novel oncology therapeutic. Here, an example of the key challenges include costs, equity and public attitude. Additionally, when selecting the relevant value elements, the key factors that should be considered are highlighted in Table 1.

Table 1. Case study results for a risk-seeking payer evaluating an oncology product

Framework question	Factors to consider[†]	Details	Value elements to consider
Relative risk attitude (risk-seeking)	Stage of cancer	Late-stage cancer patients face limited treatment options and are thus more risk-seeking to improve worsened baseline QoL	Disease severity, value of hope
	Treatment landscape	Specific types of cancer or subgroups have limited treatment options, or innovative treatment development has stagnated	Equity, disease severity, value of hope, family/caregiver spillover
	Rare disease	Patients face difficulty in diagnosis, with limited treatment options and evidence base	Equity, value of hope
Key challenges (equity & public attitude, costs)[††]	Socioeconomic or ethnic disparities in diagnosis and survival[7-11]	Some cancer types are historically associated with worse outcomes for specific patient subgroups	Equity, caregiver and family spillover
	Costs	Personalised targeted treatments may be more costly than options such as chemotherapy, and changes in long-term treatment adherence affects costs	Dynamic costs, adherence

[†] It is essential that payers evaluate and apply context-specific factors pertinent to their unique setting, product, and environment.
[††] An example of how GCEA value elements may help in addressing disparity and cost challenges within an oncology context: Equity addresses societal value in reducing health disparities across patient subgroups. Caregiver and family spillover elements address wider impact of disease on all areas of patient lives ensuring appropriate considerations are in place. Dynamic costs and adherence both aid long- and short-term planning considering exclusivity period and product wastage.

DISCUSSION

- It is complicated to select appropriate novel value elements as there is limited empirical knowledge on the GCEA topic among all payer archetypes. Therefore, this framework serves as a foundational guide for facilitating an initial understanding of which novel elements may be most relevant to different payers. Further research and validation, such as through payer discussions, is required to demonstrate the validity of this framework and its real-world application. This framework could help accurately capture and reflect the comprehensive value of new treatments and diagnostics, addressing the current challenges traditional CEA fail to capture.

To support the future application of this framework, users could evaluate the selected elements by assessing the feasibility of their integration through the following questions:
  - How complex is the value element (in terms of data requirements and additional analysis)?
  - Does the company have sufficient resources to research additional elements that lack data?
  - Is the company willing and able to wait long-term to see a potential return on investment from integrating novel value elements?
  - How likely will this change to be accepted by all stakeholders, and what are the anticipated effects on the wider population?

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