

Why Health Preference Research Matters: From Economic Theory to Regulatory Decision-Making

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Abstract

Health Preference Research (HPR) has become increasingly important in regulatory and health technology assessment (HTA) contexts as healthcare decision-making is characterized by uncertainty, information asymmetries, and institutional constraints. In such settings, market data are often unavailable or distorted, and structured methods are needed to quantify patients' valuation of benefits, risks, and treatment trade-offs. This article examines how HPR has developed across theoretical foundations, methodological advances, and institutional uptake, and clarifies its contribution to healthcare decision-making. This narrative review draws on targeted literature searches and citation tracking to examine key theoretical, methodological, and institutional developments in HPR. It traces developments from stochastic utility theory and Random Utility Models to advances in microeconometrics and discrete choice methods, and examines regulatory and HTA initiatives. Theoretical developments, particularly Random Utility Theory, established a framework for analyzing preferences as latent constructs. Methodological advances enabled the empirical estimation of trade-offs through discrete choice models and experimental designs. These approaches have increasingly been translated into regulatory and HTA contexts, where preference-based evidence is used to inform benefit–risk assessment and reimbursement decisions. At the same time, methodological challenges remain, including questions of external validity, response consistency, and the temporal stability of elicited preferences. HPR represents a coherent extension of established economic and econometric principles and provides a structured framework for integrating patient preferences into healthcare decision-making. Its further institutionalization will depend on methodological rigor, transparent reporting, and alignment with regulatory and HTA requirements.

Keywords

Health preference research; random utility theory; discrete choice experiments; patient preference information; benefit–risk assessment; health technology assessment; regulatory decision-making

1. Introduction

Incorporating individual preferences is essential for informed healthcare decision-making, particularly in contexts characterized by uncertainty, complex benefit–risk trade-offs, and heterogeneous patient values [1]. However, health-related decisions are often shaped by information asymmetries, institutional constraints, and the indirect observability of outcomes, which limit the applicability of standard market-based approaches [2–4].

In response to these challenges, Health Preference Research (HPR) has emerged as an approach to systematically elicit and quantify preferences for healthcare interventions. HPR is dedicated to understanding how individuals value health and health-related goods and services, based on the premise that choices reveal underlying preferences and define value [5]. A better understanding of patient preferences can support providers, regulators, and policymakers in aligning decisions more closely with patient needs [6].

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Building on advances in microeconomic theory and econometrics, HPR enables the estimation of trade-offs individuals are willing to make between competing attributes of healthcare alternatives [7–9]. It has evolved into a distinct field within health economics and outcomes research, with a growing body of conceptual and methodological work defining its scope and applications [5,10]. Regulatory and health technology assessment (HTA) bodies and large-scale research initiatives have increasingly recognized the relevance of HPR for decision-making [11]. In addition, recent systematic reviews and research have underlined opportunities and growing expectations associated with integrating patient preferences into regulatory and HTA processes [12–14].

Despite these developments, the conceptual foundations, methodological evolution, and institutional uptake of HPR are often discussed separately. This article aims to bring these dimensions together and to clarify their interrelationships and combined contribution to the development of the field.

To this end, the article synthesizes key developments in HPR across three dimensions: (i) theoretical foundations, (ii) methodological advances, and (iii) institutional uptake, and situates them within the broader context of health economics and regulatory decision-making.

2. Methods

This narrative review synthesizes key theoretical, methodological, and institutional developments in HPR. The objective was to identify and contextualize influential contributions shaping the field across these three dimensions.

A narrative review approach was selected because the research objective requires the synthesis of heterogeneous sources across multiple dimensions that are not amenable to quantitative meta-analytic methods. Narrative reviews are particularly appropriate when the aim is to construct a broad conceptual framework and to integrate findings across methodologically diverse studies, rather than to answer a narrowly defined empirical question [15,16]. Unlike systematic reviews, which follow a strict protocol to address a specific clinical or empirical question, narrative reviews allow for interpretive synthesis and thematic structuring of the literature, which aligns with the conceptual and descriptive objectives of this article [16,17].

Relevant literature was identified through targeted searches conducted between January and February 2026 in databases including PubMed and Web of Science, complemented by discipline-specific sources such as *Value in Health*, a leading journal in health economics and outcomes research, published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Search terms included combinations of "health preference research," "discrete choice experiment," "health economics," and "random utility." Additional sources were identified through citation tracking. In May 2026, recent regulatory and institutional sources were checked for currency, and one source was updated where necessary. Literature was included if it contributed to (i) the theoretical or microeconomic foundations

relevant to HPR, (ii) the methodological development of preference elicitation methods, or (iii) the institutional uptake of patient preference evidence in regulatory and HTA decision-making. Sources were excluded if they addressed adjacent fields without direct relevance to preference elicitation, health utility measurement, or health economic evaluation, or if they were not available in English or German.

In addition, targeted searches were conducted on websites of key regulatory and HTA institutions, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and German institutions such as the Institute for Quality and Efficiency in Health Care (IQWiG) and the Federal Joint Committee (G-BA). These sources were selected due to their documented engagement with and integration of patient preference evidence into regulatory and HTA decision-making.

Because this article follows a narrative review approach, searches were not designed to produce an exhaustive evidence inventory, and formal record counts were not collected. Instead, sources were selected purposively based on their relevance to the three dimensions outlined above, i.e., their contribution to the theoretical foundations, methodological development, or institutional uptake of HPR. Overall, 42 sources were included in the main narrative synthesis presented in the Key Findings section, comprising both database-identified literature and targeted institutional sources.

The selection of literature was guided by relevance to foundational theoretical contributions, major methodological developments, and regulatory applications. Particular emphasis was placed on seminal works, key methodological papers, and influential guidance documents. The review proceeded iteratively. Database and institutional searches were used to compile an initial pool of sources, which was subsequently refined through relevance screening against the thematic scope of the three dimensions. Retained sources were reviewed in full and thematically assigned. The process was complemented throughout by citation tracking to capture seminal works not retrieved through database searches.

Sources were ultimately included in the review based on their relevance to the narrative and their contribution to illustrating key theoretical, methodological, or institutional developments in HPR, with priority given to seminal works, widely cited methodological papers, and authoritative guidance documents.

The identified literature was synthesized thematically and structured along the three defined dimensions, reflecting the cumulative and interdependent development of the field.

3. Key Findings

3.1. Theoretical Foundations

This section outlines the theoretical foundations of HPR, focusing on the development of economic models of choice and utility. It highlights how random utility theory (RUT) and related concepts provide the basis for understanding preferences as latent constructs that can be inferred from observed or stated choices.

3.1.1. *The Conceptual Breakthrough of Random Utility-Based Choice Models*

In the mid-20th century, the growing need to understand individual choices in economic decisions presented a major challenge: How can we measure preferences when the alternatives are not directly observable, and when individuals' choices cannot always be explained by visible, market-driven behavior? Random utility theory (RUT), initially formulated by psychologist Louis Leon Thurstone in 1927, laid the groundwork for understanding preferences in the context of choice under uncertainty [7]. Thurstone introduced the concept of stochastic utility to explain how individuals make choices between alternatives that are not perfectly observable. Later, economists such as Daniel McFadden formalized and extended Thurstone's theoretical framework into econometric models known as random utility models (RUMs), thereby providing the basis for modern discrete choice analysis and applied microeconomic modeling of individual choice behavior [8]. McFadden's key contribution was to show that hypothetical choices in surveys could be treated as real, meaningful preferences, similar to market decisions, as long as they followed a clear utility structure based on both observable and unobservable factors. This conceptual understanding of unobservable preferences serves as the theoretical reference point for econometric choice models that enable the empirical estimation of preferences from observed or stated-choice data.

In 2000, the contributions to discrete choice econometrics were recognized with the Nobel Prize in Economic Sciences. The Royal Swedish Academy of Sciences awarded the prize jointly to Daniel McFadden and James Heckman. McFadden was specifically honored for his development of theory and methods for analyzing discrete choice [18]. This recognition underscores the scientific legitimacy of discrete choice models as a foundation for applied preference-based decision analysis.

The method broke away from traditional models by showing that RUMs could quantify choices made between distinct alternatives, even when those alternatives were hypothetical. This revolutionary insight led to the development of logit models, which McFadden formalized in his paper "Conditional Logit Analysis of Qualitative Choice Behavior" [8]. These models offered a framework for estimating preferences in markets where traditional data were lacking, such as in transportation, energy, and environmental economics.

One of the most influential early demonstrations of this new approach was McFadden's work on the Bay Area Rapid Transit (BART) project in the 1960s. At the time, planners sought to estimate how many commuters in the San Francisco Bay Area would switch to a newly built rail system [19]. Instead of relying on engineering-based traffic forecasts, McFadden collected household survey data and modeled individual travel choices using early RUMs. Based on this survey data, the model predicted that only about 6% of commuters would use the new transit system. When BART became operational, the observed usage rate was remarkably close to this prediction [20,21]. The importance of the BART study lay not only in its predictive accuracy but also in its broader methodological implications. It provided compelling empirical evidence that hypothetical choices elicited in

surveys, when analyzed within a random utility framework, could outperform traditional forecasting approaches based solely on aggregate flows and engineering assumptions. As a result, the BART project played a decisive role in convincing planners and policymakers that preference-based choice models offer a reliable foundation for infrastructure and environmental decision-making [21]. This episode is therefore widely regarded as a pivotal moment in the rise of discrete choice econometrics.

Although originating outside the healthcare sector, this example illustrates a principle that later became central to HPR: well-designed hypothetical choice tasks can yield valid and decision-relevant insights in contexts where revealed preference data are unavailable.

The conceptual importance of McFadden's contribution extends beyond improved prediction accuracy. By embedding choice behavior in RUT, McFadden provided a formal economic justification for analyzing choices that are not directly observed in markets. The random component of utility is not interpreted as mere noise or measurement error, but as a structured representation of unobserved preferences, constraints, and contextual factors. This insight marked a fundamental turning point for stated preference methods. It established that hypothetical choices, if framed as choices between clearly defined alternatives, can be analyzed within the same utility-theoretic framework as revealed market behavior. As a result, preferences elicited in surveys became amenable to welfare-consistent interpretation, including the estimation of trade-offs, marginal rates of substitution, and willingness-to-pay measures.

In this sense, RUM enabled the transformation of stated preferences from descriptive opinion data into economically meaningful evidence. This conceptual shift laid the foundation for discrete choice experiments (DCEs) and for HPR.

3.1.2. *Microeconometrics as the Foundation for Analyzing Individual Decisions*

The analysis of discrete choices forms part of a broader development in microeconometrics, which, since the 1970s, has focused on the statistical analysis of individual household and firm decisions. This development was enabled by the increasing availability of detailed micro-level data and growing computational capacity. Within this field, micro-level data are frequently discrete, nonlinear, and characterized by substantial heterogeneity across individuals.

Cameron and Trivedi [22] conceptualize microeconometrics as a methodological toolkit for analyzing cross-sectional and panel data in settings where individual decisions, rather than aggregate outcomes, are the primary object of interest. Within this framework, models for discrete outcomes such as logit and probit play a central role, as they allow researchers to link observed choices to underlying preferences and constraints [22]. These models provide the statistical foundation for discrete choice analysis by translating individual-level decisions into estimable preference parameters.

Wooldridge [23] provides a complementary perspective by emphasizing the importance of identification and inference when working with individual-level data. He distinguishes between assumptions about the underlying population and

those related to the sampling process, and discusses how issues such as missing data, clustering, and endogenous regressors affect empirical conclusions in cross-sectional and panel settings [23].

The theoretical foundations linking individual choices, preferences, and demand are developed in the seminal work by Deaton and Muellbauer [24], which formalizes household behavior under various constraints and explicitly connects preference theory to observable demand patterns. Building on this approach, Deaton [25] demonstrates how household survey data can be used for empirical analysis and argues that such data are informative for understanding economic behavior.

3.1.3. Health Economics as a Distinct Framework for Analyzing Healthcare Decisions

Health-related goods and services differ fundamentally from standard consumer goods. Their benefits and risks are often difficult to observe, information is frequently asymmetric, and decisions are typically made under uncertainty within institutional, regulatory, and collective financing arrangements [2]. At the individual level, information asymmetries give rise to well-known decision problems, including principal-agent relationships in which one party must rely on the actions or recommendations of another whose incentives or information may differ [2,3]. As a defining feature of healthcare systems, such relationships pose specific challenges for modeling individual decision-making and associated welfare outcomes. These challenges limit the applicability of standard market-based models and motivate the development of health economics as a distinct field that integrates microeconomic decision analysis with welfare economics.

Within health economics, analytical work has focused on a set of core domains that reflect the institutional and behavioral specificities of healthcare systems. These domains include the analysis of healthcare demand, insurance and reimbursement arrangements, regulatory structures, and their interaction with individual decision-making. Together, these strands of research highlight that healthcare choices cannot be understood solely through standard consumer theory, but, instead, require explicit consideration of institutional constraints, risk pooling, and incentive structures [4].

Building on this perspective, economic evaluation in healthcare has developed as a decision-oriented approach that integrates economic theory with welfare analysis. Rather than focusing exclusively on cost-effectiveness or cost-utility ratios, this literature emphasizes structured decision frameworks, systematic evidence synthesis, and the explicit characterization of uncertainty. A central concern is the translation of complex economic evidence into forms that are informative for real-world decision-makers, reflecting the applied and policy-relevant nature of healthcare decision-making [26].

3.2. Methodological Advances

This section examines the methodological advances that have enabled the empirical estimation of preferences. It focuses on the development and application of discrete choice models and experimental designs that allow for the

quantification of trade-offs and the analysis of preference heterogeneity in healthcare contexts.

3.2.1. Econometrics and Statistical Foundations

In healthcare, many relevant trade-offs cannot be inferred from observed market behavior because decisions are mediated by insurance coverage, physician agency, regulatory constraints, and information asymmetries. The empirical analysis of healthcare decisions, therefore, requires methodological frameworks that allow researchers to elicit and quantify preferences directly while maintaining welfare-theoretic consistency [9,24]. While health economics provides the conceptual framework for understanding healthcare choices under uncertainty and institutional constraints [2,4], advances in microeconometrics and discrete choice analysis enable the operationalization of preference measurement by translating stated preferences elicited through surveys or choice experiments into economically meaningful parameters for decision-making and resource allocation [9,22,27].

Discrete choice models are grounded in the statistical theory of limited dependent variables and maximum likelihood estimation. Within this framework, the central insight of RUT leads to a probabilistic representation of choice behavior in which choice probabilities are derived from assumptions about the distribution of unobserved utility components [9]. Under the assumption that these unobserved components follow a Type I Extreme Value distribution, the multinomial logit (MNL) model arises with a closed-form likelihood function that can be estimated using standard maximum likelihood techniques [8]. In practical terms, the MNL model estimates the probability that an individual chooses a given alternative based on its attributes relative to the available options. This tractability has contributed to its widespread use in applied choice analysis.

A well-known limitation of the standard MNL model is the independence of irrelevant alternatives (IIA) [9], which assumes that the relative probability of choosing between two options is unaffected by the presence of other alternatives. This assumption is often implausible in healthcare settings, where alternatives may be perceived as close substitutes. Mixed multinomial logit models, commonly referred to as mixed logit models (MXL), address this limitation by allowing preference parameters to vary across individuals [27]. This reflects the empirical reality that patients differ systematically in how they value treatment attributes. MXL models can approximate any discrete choice model derived from RUT arbitrarily closely by using random coefficients. Estimation of these models relies on simulated maximum likelihood methods, allowing for flexible preference distributions and more realistic substitution patterns [27].

From an empirical perspective, a recurring theme in the analysis of discrete choice data is the distinction between observed variation that reflects genuine behavioral differences and variation that arises from model specification or measurement limitations. The treatment of unobserved heterogeneity is therefore critical, as systematic preference differences across individuals, if not adequately modeled, can lead to biased parameter estimates and misleading welfare conclusions [9,28]. MXL models address this challenge by explicitly capturing heterogeneity through random

coefficients, thereby providing an econometrically coherent approach to modeling diverse preference structures [27].

Beyond random coefficients, several complementary modeling approaches address the complexity of preference heterogeneity in healthcare populations. Further insights arise from the literature on hierarchical and multilevel modeling, which emphasizes flexible model specification and the explicit treatment of uncertainty at multiple levels of analysis [29]. These approaches complement MXL models by offering additional tools for structuring heterogeneity and uncertainty in complex empirical settings, including latent class models that identify discrete preference segments and heteroskedastic or scale-adjusted models that account for variation in error variance and decision consistency. Multilevel approaches allow parameters to vary across individuals or groups and offer tools for assessing robustness and sensitivity in empirical results [30–32]. These techniques support the modeling of individual- and group-level effects and facilitate the separation of systematic preference heterogeneity from scale-related variation in the unobserved component of utility [31–33]. By explicitly accounting for heterogeneity and variability in decision consistency, such models strengthen the empirical foundations of preference-based decision analysis in health contexts [33,34].

3.2.2. From Discrete Choice Theory to Applied Choice Modeling

Research on discrete choice has developed along two closely connected lines: the formal modeling of individual choice behavior and the practical implementation of these models for prediction, policy evaluation, and decision support.

A fundamental insight underlying applied choice modeling is that individuals value specific characteristics of alternatives rather than goods as undifferentiated entities. Lancaster's attribute-based approach to consumer theory provides the theoretical foundation for this perspective by decomposing utility into contributions from individual attributes, thereby enabling the estimation of trade-offs and the prediction of preferences for new or hypothetical alternatives [35]. This attribute-based representation of utility is central to the practical implementation of discrete choice experiments (DCEs) and distinguishes preference-based modeling from aggregate demand analysis.

Early foundational work systematized the theory of individual choice behavior and formalized the practical application of logit-based models for analyzing discrete alternatives. Ben-Akiva and Lerman [36] demonstrated how these models could be used for forecasting and policy evaluation in transport and infrastructure planning, showing how individual-level choice models can be aggregated to predict market outcomes while maintaining behavioral consistency at the level of the decision-maker. Subsequent advances in simulation-based estimation enabled more flexible choice models without relying on closed-form probability expressions [9].

Applied choice modeling has increasingly emphasized the integration of theory, estimation, and empirical application. Advances in model specification have expanded the flexibility of applied choice modeling, allowing researchers to represent complex preference structures and heterogeneous decision behavior. In parallel, researchers have incorporated insights from behavioral economics, including

reference-dependent preferences and loss aversion, to capture systematic deviations from standard utility maximization observed in empirical choice data [37].

3.2.3. Discrete Choice Experiments in Health Preference Research

The growing application of DCEs in health economics has generated a substantial body of methodological infrastructure that reflects the field's increasing scientific maturity. Early contributions, often published under the broader term "conjoint analysis," established that rigorous preference elicitation requires careful alignment across research questions, attribute selection, experimental design, data collection, and analysis, providing the foundational standards against which HPR studies are evaluated [38]. Dedicated guidance on experimental design clarified that design choices directly shape statistical efficiency, respondent burden, and the validity of preference estimates, thereby elevating DCEs from exploratory tools to methodologically defensible instruments for decision support [39]. Parallel advances in statistical analysis formalized the conditions under which different modeling approaches, including conditional logit, random-parameters logit, hierarchical Bayesian, and latent class models, yield valid and interpretable preference parameters [34].

What distinguishes more recent methodological developments is their explicit orientation toward the impact on decisions rather than methodological correctness alone. Guidance on decision relevance, stakeholder engagement, and study utility emphasizes that preference studies derive their value from their ability to inform real-world regulatory, reimbursement, and clinical decisions [40]. Complementary frameworks address the transparent documentation of qualitative development work [41], the coherent presentation of decision objects [42], and minimum reporting standards for reproducibility and interpretability [43], collectively forming an infrastructure that enables preference evidence to move from academic research into institutional decision-making contexts. The design, conduct, and use of patient preference studies across the medical product lifecycle have been systematically examined, providing structured guidance for regulators, industry, and HTA bodies on when and how preference evidence should inform decisions [44].

3.3. Institutional Uptake

This section describes the institutional uptake of HPR in regulatory and HTA contexts. It highlights how preference-based evidence has been increasingly recognized and incorporated into decision-making processes across different jurisdictions and stakeholders.

3.3.1. Regulatory Uptake and Practical Implementation

The growing methodological maturity of HPR has also shaped the way regulatory institutions engage with preference evidence. DCEs are no longer confined to academic research but have increasingly been incorporated into regulatory and HTA contexts. This development reflects a broader recognition that structured preference elicitation can provide decision-relevant evidence on how patients evaluate benefits, risks, and treatment trade-offs.

Regulatory and harmonization initiatives have increasingly acknowledged the relevance of structured patient preference studies. The International Council for Harmonisation

of Technical Requirements for Pharmaceuticals for Human Use (ICH) has issued guidance addressing general considerations for patient preference studies [45]. This guideline reflects a coordinated effort to clarify methodological expectations and the appropriate use of preference evidence across major regulatory jurisdictions, thereby providing a common framework for the design and interpretation of preference studies in regulatory contexts.

National regulatory authorities have adopted more specific approaches to the use of patient preference evidence.

3.3.1.1. U.S. Regulatory Perspective

In the United States, the U.S. Food and Drug Administration (FDA) formally acknowledged the relevance of patient preference information (PPI) through its final guidance document, Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling [46,47]. This guidance clarifies that PPI may inform regulatory decision-making, particularly in situations involving significant benefit–risk trade-offs. It emphasizes voluntary submission and does not impose new regulatory requirements but establishes a structured pathway for incorporating quantitative patient preference evidence into benefit–risk assessments.

The regulatory shift was preceded by a landmark pilot study sponsored by the FDA's Center for Devices. The study quantified patient tolerance for risks associated with weight-loss devices and demonstrated the feasibility of systematically incorporating patient-preference evidence into regulatory evaluations [48]. The Center for Devices concluded that patient concerns are unlikely to play a meaningful role in benefit–risk evaluations in the absence of valid quantitative evidence on patients' tolerance for treatment-related risks. The study therefore provided proof of concept that patient preference elicitation methods can generate decision-relevant, quantitative evidence for regulatory use [46,47].

3.3.1.2. European Regulatory Perspective

At the European level, the European Medicines Agency (EMA) has acknowledged the importance of patient preference data in evidence generation [49]. The EMA reflection paper positions patient preference data as a potential source of contextual evidence that may inform benefit–risk assessment, especially in situations characterized by clinical uncertainty or heterogeneous patient values. At the same time, it underscores the importance of methodological robustness and transparency in study design and reporting.

Empirical pilot work has demonstrated the feasibility of integrating patient preferences into regulatory discussions. The EMA conducted a quantitative pilot study involving cancer patients, carers, healthcare professionals, and regulators to explore how the systematic elicitation of patient trade-offs could inform regulatory review processes [50]. While patient preference studies were not formally required within marketing authorization procedures, the pilot was designed to gain practical experience and assess the feasibility

of incorporating structured preference evidence into regulatory deliberations. The findings illustrated that such data could clarify stakeholder perspectives and support more transparent benefit–risk discussions in regulatory contexts.

3.3.1.3. German Regulatory Perspective

In Germany, HTA plays a central role in reimbursement decisions. The Federal Joint Committee (G-BA) represents the highest decision-making body in the statutory health insurance system and is responsible for determining the benefit of medical interventions. The Institute for Quality and Efficiency in Health Care (IQWiG) provides scientific assessments that inform G-BA decisions.

The General Methods document of the IQWiG, which provides the binding methodological framework for HTA in Germany and guides benefit assessments submitted to the G-BA, explicitly acknowledges that choice-based methods may contribute additional evidence for decision-making [51].

An earlier pilot project commissioned and conducted within the IQWiG framework explored the feasibility of choice-based conjoint analysis to identify, weight, and prioritize multiple treatment attributes in chronic hepatitis C [52]. The study demonstrated that patient preferences for treatment attributes can be systematically quantified and may provide complementary insights alongside clinical and economic evidence [53].

Although DCEs are not yet formally mandated components of German HTA, their recognition indicates increasing institutional awareness of their potential role in structured decision-making.

HPR methods have transitioned from purely academic tools to instruments capable of informing regulatory and reimbursement decisions. While institutional uptake varies in scope and formalization, the emerging consensus is that structured, quantitative evidence of patient preferences can enhance transparency in benefit–risk evaluation and support more patient-centered decision-making across the medical product lifecycle.

4. Discussion

This article examined the development of HPR across three dimensions: theoretical foundations, methodological advances, and institutional uptake.

Theoretical developments, particularly random utility theory (RUT), provide the conceptual basis for understanding preferences as latent constructs. Methodological advances enable the empirical estimation of these preferences through discrete choice models and experimental designs. Institutional developments, in turn, have increasingly translated these approaches into regulatory and HTA contexts.

Taken together, these observations illustrate that HPR has evolved from a theoretical framework into an applied approach that informs decision-making across the healthcare system and highlight its growing relevance in health economics and regulatory science.

4.1. Outlook: Towards Systematic Integration of PPI in Regulatory Frameworks

While regulatory uptake of structured patient preference evidence has progressed considerably over the past decade, ongoing international initiatives indicate that methodological integration remains an evolving process. In particular, large-scale European public-private partnerships have played a central role in consolidating methodological standards and clarifying when and how HPR should inform regulatory and HTA decisions.

The Innovative Medicines Initiative (IMI), now operating as the Innovative Health Initiative (IHI) under Horizon Europe funding, has substantially advanced the structured incorporation of PPI into the medical product life cycle. The IMI-funded PREFER project (Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle) represented a coordinated, multi-stakeholder effort to establish methodological guidance for the systematic assessment and use of patient preference evidence across development, regulatory review, reimbursement, and post-marketing phases [11,12,44,54–56]. PREFER provided empirical case studies, methodological evaluations, and formal recommendations outlining why, when, and how patient preferences should be assessed and integrated into decision-making processes [55]. Importantly, the project moved the field beyond proof-of-concept discussions toward operational guidance for regulators, industry, and HTA bodies. Subsequent work further refined the suitability of different preference methods across stages of the medical product life cycle using multi-criteria decision approaches [57].

Building on earlier initiatives, the UNIFIED project under the IHI extends this work by exploring the alignment of PPI with Clinical Outcome Assessments (COAs) and data derived from Digital Health Technologies (DHTs) [58]. This reflects broader efforts to address fragmentation in patient-centered data generation and to improve coherence across regulatory and HTA contexts.

Taken together, these initiatives illustrate a broader transformation in regulatory science toward more transparent and patient-centered benefit-risk evaluation. Yet this transformation remains incomplete. While HPR has gained increasing recognition across jurisdictions, its formal integration into decision-making processes remains limited and heterogeneous: preference evidence is frequently acknowledged but not consistently required or systematically incorporated [12,13]. At the same time, methodological advances have substantially improved the rigor and applicability of HPR, yet this progress is not yet fully reflected in regulatory standards and requirements [14]. This gap between methodological maturity and institutional implementation represents a central challenge for the field going forward.

4.2. Methodological Challenges and Implications for Regulatory and HTA Use

Challenges span methodological, procedural, and normative dimensions, including questions regarding validity, reliability, and the impact of preference evidence on decision-making [12,13].

Stated preferences elicited in survey-based choice tasks may diverge from actual decision behavior, which raises questions about the external validity of DCE-based estimates [59]. Cognitive demands and framing effects may reduce response consistency and threaten internal validity, especially in complex choice tasks or in heterogeneous and potentially vulnerable patient populations [39,60,61]. In addition, empirical evidence on the temporal stability of elicited health preferences remains limited, and available studies suggest that preferences may vary over time or with changes in health status [62].

Challenges also relate to the evaluation and integration of preference evidence in decision-making processes, including questions of how such evidence should be weighted, interpreted, and combined with clinical and economic data [13]. In addition, requirements regarding study quality, patient understanding, and methodological transparency have been identified as critical conditions for the use of preference evidence in regulatory and HTA contexts [12].

Addressing these methodological challenges is essential for strengthening HPR's contribution to regulatory and HTA decision-making. Patient preference evidence provides unique insights into patient valuations, benefit-risk trade-offs, and preference heterogeneity, and can improve the relevance and transparency of healthcare decision-making [12,14]. These considerations define key areas for methodological advancement, including design strategies that reduce cognitive burden, empirical validation of stated preferences, and approaches to strengthen the integration of preference evidence into HTA frameworks.

4.3. Contribution of This Review

Existing reviews in this field have largely focused on documenting the application of specific preference elicitation methods across empirical studies [59,63,64], on examining their use in specific decision contexts such as priority setting [65], or on mapping the institutional uptake of HPR within regulatory and reimbursement frameworks [66]. A review that traces the coherent intellectual lineage from economic choice theory through methodological development to institutional implementation, and that situates these dimensions as interdependent rather than parallel strands, has not been provided.

4.4. Limitations

As a narrative review, this approach reflects a purposive selection of literature based on conceptual relevance and influence. The focus on key theoretical, methodological, and institutional contributions may limit the inclusion of all relevant publications. Narrative reviews are further susceptible to selection bias and reduced reproducibility compared to systematic approaches [15,16]. To partially mitigate these limitations, explicit inclusion and exclusion criteria were defined, and the search process was complemented by citation tracking to capture seminal works not retrieved through database searches. However, this approach enables a structured synthesis of the most influential developments in the field and supports a coherent interpretation of its evolution across disciplinary and regulatory contexts.

5. Conclusion

By tracing the development from discrete choice theory to contemporary DCE-based applications in healthcare, this article suggests that HPR represents a coherent extension of established economic and econometric principles.

In healthcare systems characterized by uncertainty, institutional constraints, and heterogeneous patient values, HPR provides a structured framework for quantifying trade-offs and integrating PPI alongside clinical and economic evidence. The growing recognition of patient preference evidence within regulatory and HTA contexts points to a broader transformation in regulatory science toward more transparent and patient-centered benefit–risk evaluation.

The future institutionalization of HPR will depend on sustained methodological rigor, transparent reporting, and alignment with regulatory decision frameworks. If these conditions are met, PPI has the potential to become a systematically embedded component of healthcare decision-making across jurisdictions.

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The author declares no conflicts of interest.

Declaration of Generative AI and AI-Assisted Technologies

During the preparation of this work, the author used ChatGPT to support language refinement and improve readability. Following the use of this tool, the author reviewed and edited the content as needed and takes full responsibility for the final version of the publication.

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