**How Precision HEOR provides evidence-based guidance on how to improve care?**

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**Author Note**

Geetanjali Gupta is a graduate student in Northeastern University's Health Informatics program. This literature review is part of the program's capstone project. The paper expresses the author's views, which may or may not reflect those of Northeastern University. There are no conflicts of interest to disclose for the author. Correspondence about this article should be sent to the author via email at [gupta.g@northeastern.edu](mailto:gupta.g@northeastern.edu)

**Abstract**

Health Economics is a field in health that is highly essential in the evolution of health informatics, and it has to be studied and assessed in depth in order to design strategies to advance the value of health care delivery and the application of evidence-based techniques for cost-effective utilization of restricted health system resources in terms of patient outcomes. Such health economics tools can be used for evaluating the impacts of healthcare interventions and Precision Medicine and can be combined to extract the cost and results of a new treatment or a new drug, results derived from big data in order to make healthcare decisions suited to precise patient clusters or individuals (Chen et al., 2016). "Health Economics Outcomes Research (HEOR)," which combines these two concepts, is one such notion for healthcare decision-making.

Keywords: HEOR; big data; precision health economics; precision medicine

**Background**

About Health Economics Outcomes Research (HEOR)

HEOR establishes and evaluates the relationship between treatment and actual outcomes and renders evidence-based recommendations for better care. To assess the health outcomes of interventions, HEOR incorporates clinical outcomes, clinical trial-data, financial considerations, and quantifiable measures such as quality of life and satisfaction from patient surveys or electronic health records along with many other relevant attributes. Pharmaceutical companies, insurance companies, and many healthcare entities use HEOR to better recognize how healthcare providers prescribe medications and how these medications perform in the real world (Definitive Healthcare, n.d.). Similarly, a medical device manufacturer must conduct a systematic review of all available information on the outcome and cost implications allied with the use of a particular type of medical device for its approval by adopting comparative clinical benefit assessment, as requested by Health Technology Assessment (HTA) (Angelis et al., 2018).

Why is HEOR necessary, and what factors are contributing to the increased need to demonstrate value? The reasons and examples mentioned above are real-world experiences that are ultimately used to improve patient care at a low cost. HEOR offers almost precise knowledge for making healthcare coverage and access decisions, including healthcare-related investment decisions, key stakeholders' behaviors, and measuring quality by stipulating and evaluating a range of economics and outcomes data in health and health care, demonstrating how specific governing attributes alternatives impact outcomes and influence stakeholders (*Definitive Healthcare*, n.d.). This all adds up to more value in healthcare. Growing populations and rising healthcare spending; increased availability of new medicines, treatment options, and patient expectations; and pressure on public funding are all contributing to an increased need for value demonstration. However, no regular practice for integrating HEOR into process of making decisions exists, and the existing applications of HEOR by healthcare payers is still unknown to some extent.

**About Precision Medicine**

Precision medicine, according to Jameson and Longo, is defined as "treatments tailored to the needs of individual patients based on genetic, biomarker, phenotypic, or psychosocial characteristics that distinguish a given patient from other patients with similar clinical presentations" (Jameson & Longo, 2015, p.1). Precision Medicine is a medical model that is built on a patient's genetic matter or other molecular or cellular analysis, with healthcare decisions, practices, treatments, or products being designed to a subset of patients.

**HEOR + Precision Medicine and its importance**

Precision HEOR is a big data-driven healthcare decision-making tool that uses a combination of costs and outcomes to help determine and propose treatment processes with the highest likelihood of quality of life and treatment success for highly specific patient subgroups or individuals, using a variety of methodologies and Machine Learning techniques such as recursive partitioning to predict and test possible outcomes (“Recursive partitioning is a [statistical](https://en.wikipedia.org/wiki/Statistics) method for [multivariable analysis](https://en.wikipedia.org/wiki/Multivariable_analysis). Recursive partitioning creates a [decision tree](https://en.wikipedia.org/wiki/Decision_tree_learning) that strives to correctly classify members of the population by splitting it into sub-populations based on several dichotomous [independent variables](https://en.wikipedia.org/wiki/Independent_variable)”) (Recursive partitioning. (n.d). In Wikipedia).

Another goal of precision HEOR is to increase the feasibility of precision medicine by adapting and assisting in the allocation of healthcare resources by integrating clinical value and economic assessment using well-defined clinical and healthcare utilization phenotypes to augment the cost-effectiveness of health care intervention use (Chen et al., 2016). This review is going to explore this concept, based on the discussions on the present and upcoming responsibilities of HEOR in health sector process of making decisions, big data and predictive analytics, and several other key HEOR frameworks.

**Problem Statement**

The intricacy of day-to-day healthcare decision-making is escalating. Precision medicine has enabled the development of novel treatments with curative potential. However, the emergence of new innovative therapies is complicating the value-determination process for patients, payers, and healthcare budget planners. These treatment options, combined with the WHO's encouragement for increased access to healthcare services and the growing emphasis on healthcare equity and outcomes, present a difficult combination of issues for decision makers (Orsini, 2020). In the midst of all this, there is increasing demand to provide high-quality, cost-effective, patient-centered health care.

**Data Generation For HEOR**

The data gathered can come from various sources, including medical records, insurance databases, patient questionnaires, and the majority of it is currently quantitative. The Agency for Healthcare Research and Quality (AHRQ) monitors health outcomes research through the Healthcare Cost and Utilization Project (HCUP) and therefore the Medical Expenditure Panel Survey (MEPS), as part of its efforts to enhance patient safety, reduce medical errors, and identify and address gaps in healthcare quality. In the United States, HEOR data could also be obtained primarily from pharmaceutical companies within the variety of dossiers in the Academy of Managed Care Pharmacy (AMCP) format. Furthermore, pharmaceutical companies gather humanistic, clinical, and economic real-world data all through the life cycle of a therapy during clinical trials (Harvard T.H. Chan School of Public Health, n.d.).

Patient Reported Outcomes (PRO) data is an important supplement to clinical evidence in demonstrating the worth of a treatment, especially for interventions developed to treat chronic, disabling conditions where the goal isn't necessarily to cure but rather to alleviate symptoms, facilitate function, or improve quality of life, because it has been established that patient input is a critical factor when assessing the economic, social, and ethical implications of the treatment (Brogan et al., 2017).

**Health Economics and Outcomes Research Methods**

There are certain established types and frameworks for economic evaluations in healthcare. Determining which method to use necessitates weighing potential uses in resource-allocation decision-making against its information and computational complexity requirements. These methods are (Ignjatovic, 2016) –

1. Cost of illness (COI) studies – COI studies compute the overall economic impact of a specific disease, including both direct and indirect costs. The cost per patient or cost per population may be reflected in the results. Annual total costs per Alzheimer's patient, for example, range from $2500 to $50000 (Jo, 2014).
2. Cost-Benefit Analysis (CBA) – CBA measures the price of outcomes so that the value of an intervention can be weighed against the value of its effect. For example, a $4000 per year drug can save $10,000 in annual hospitalization costs (Satpathy & Bansal, 1982).
3. Cost-Effectiveness Analysis (CEA) – CEA compares the cost per outcome of two or more interventions. In comparison to a willingness-to-pay threshold, the ICER indicates whether the simpler therapy is simply too costly or saves money. For example, a $4000-per-year drug that prevents two more acute asthma attacks per year than a $1000-per-year drug that stops one asthma attack was deemed too expensive (Jakubiak-Lasocka and Jakubczyk, 2014).
4. Cost-Utility Analysis (CUA) – The cost per QALY (Quality-adjusted Life Year) is the parameter of interest in CUA. The QALY represents the utility/value of potential outcomes and enables value comparisons across indications. A cytotoxic drug that costs $4000 per year and increases survival by 3 months, for example, has a higher cost per QALY than a $1000 per year drug to stop asthma attacks which results in a gain in 0.5 QALYs (Jakubiak-Lasocka and Jakubczyk, 2014).
5. Budget-Impact Analysis (BIA) – BIA develops a model that incorporates intervention uptake and thus the size of a disease population to calculate the online cumulative cost of treatment with and without a specific intervention. A $4000-per-year drug, for example, would add a marginal cost of $250,000 to the state's healthcare budget each year (Sullivan et al., 2014).

**How Precision HEOR data provides evidence-based guidance to improve healthcare?**

The techniques used in fiscal evaluations can differ subjected to the services and population framework, as well as the attributes and understanding of the product. *Ex-post* or *after the fact* economic evaluations are most used in health program evaluation, using experiential methods applied to cost and outcome data mined from trials or other research designs accustomed to evaluating initiatives being tested in specific populations and settings. *Ex-ante*, economic evaluations can be used to update option appraisal and pre-implementation management by utilizing existing evidence and modeling to simulate the prices and outcomes of alternatives, such as population rescale or geographical spread of methods and strategies for improvement and evidence uptake (Roberts et al., 2019). Depending on the use case, different attributes are used to interpret HEOR analysis correctly. When evaluating a new drug based on cost and effect, entities such as current drug market share, efficacy, head-to-head comparative data, net ingredient cost, outcomes data, drug differentiation, safety, and drug superiority can all be considered. The manufacturer's ability to drive market share, customer programs, manufacturer relationships, rebates, and the manufacturer's size are the factors considered.

HEOR is an important component of real-world evidence (RWE). RWE is defined as “the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD” (*Framework for FDA’s Real-World Evidence Program*, 2018). Real World Data (RWD) which is defined as “data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources” differs from data generated in structured and controlled clinical trials. We need to quantify disease burden, treatment patterns, costs, patient preferences, utilities, and other outcomes using primary and secondary data for generating RWE. For instance, if a patient has renal disease, a physician may prescribe a pain reliever at a low dose, which is contrary to the inclusion criteria in clinical trials. This treatment can generate some data, and other clinicians have prescribed the same low-dose drug, generating even more data (Liu et al., 2016).

This data derived from various resources can be used to generate Real-World Insights (RWI) by applying appropriate scientific and/or generated commercial analysis, and it can be stored in the form of tables and graphical representations. The main component of conducting HEOR analysis is the insights generated from RWD with the intention of supporting a claim or belief to produce Real-World Evidence (RWE) for multiple stakeholders. If the RWE trial results are positive, it can benefit all of the stakeholders involved. It can assist the patient in reducing side effects, the physician in optimizing his treatment plan, and payers in managing costs by optimizing dosage and validating reimbursement (Liu et al., 2016).

Analysis based on various factors from the observation data can be done using Machine Learning (ML) models like regression trees for analyzing prescribing patterns; clustering algorithms for cost prediction; data visualization tools; statistics using regression analysis and co-variance etc.; and simulation modelling. Health economic analyses, often referred to as cost-effectiveness analyses, are used to determine fair pricing for various healthcare products and services. A cost-effectiveness analysis provides a consistent method for evaluating value. Several organizations have issued *value frameworks* in recent years. Value frameworks are tools and approaches for measuring the value of medications, treatments, and other health technologies that use clinical, real-world, and unpublished evidence, as well as patient-reported outcomes and economic modeling, as appropriate (*AMCP.Org*, 2019).

The costs and benefits of (new) medical technologies are assessed using value frameworks. Benefit attributes include symptom reduction, improved functioning, quality of life, and life expectancy, while considering potential toxicity and side effects associated with the use of the medical technologies in question (Cohen, 2021). Many of the existing frameworks for assessing value are drug-specific (and to a lesser extent on medical devices) (Clearfield et al., 2021). However, most health-care dollars are spent on physician and hospital services.

**Machine Learning Models in HEOR implementation**

Machine Learning has become a vital tool for growth assessments and cost-effectiveness analysis and evaluating the complex interactions between healthcare interventions and outcomes by integrating available evidence. When combined with medical expertise from a medical professional, machine learning solutions can deliver meaningful insights into accelerating clinical work-flow and augmenting positive interventions and resource allocation. Few conceptual models and frameworks used in P-HEOR implementation are (Chen et al., 2020) -

1. Decision analysis and simulation model - In the absence of direct evidence, a decision analysis and simulation model is used to quantify uncertainty and elucidate the benefits and risks of therapies.
2. Trial-based economic evaluation- Direct valuations of therapies' effect on healthcare economic burden and clinical outcomes are performed.
3. Cost-effectiveness analysis - CEA in which informed decisions about treatment options and reimbursement are made

**HEOR in Pharmaceutical company**

For a replacement drug to successfully launch within the market, pharmaceutical companies must secure payer reimbursement through a process that combines clinical, economic, and health outcomes data analysis. These companies must also demonstrate improved patient outcomes that justify the upper tag in comparison to established RWE therapies. Many decision makers within the pharmaceutical market in the United States use HEOR evidence while coming up with formulary ("A formulary is a list of generic and brand name prescription drugs covered by an individual's health plan at the lowest possible cost" (Ivory, 2020)) and coverage choices, and this use is predicted to cultivate in the future (Shah & Nidhi, 2021).

Health economics is the study of the costs of therapies that drug and device manufacturers present to health-care systems and payers. Pharmacoeconomic studies aim to establish, measure, and compare the financial value of a specific treatment associated to the health benefits it provides to patients. Payer organizations rely on this information to determine whether a specific treatment will provide the same or better health outcomes at a lower cost than existing treatments. Outcomes research, on the other hand, helps to determine, measure, and evaluate the patient's final results of the treatment or service received. Not all outcomes are clinical or economic in nature (Hoomans & Severens, 2014). For example, quality of life – or the attempt to measure a patient’s health status or satisfaction with the healthcare services provided – are often included in outcomes research. Including quality-of-life measures makes the health outcomes component of the analysis more interpretive (Medical Affairs Essentials: The Value of HEOR Teams | ACMA, n.d.).

Another case study for HEOR analysis is estimating the price of a medical device introduced by an organization in market after FDA approval. This company anticipates that this device should be covered by insurance so as to produce easy accessibility to patients in need of a much better treatment that this device can provide. To be covered, the device company must provide substantial real-world evidence that this device is less expensive than current standard care. The company requires deidentified, real-world patient data from claims and EHR, because the technology and health expertise to integrate, sort, and analyze that data. This standard of care, like all surgical care, has the potential for complications. The company needs to quantify the cost of all the complications. If the newly approved device could avoid or minimize complications and associated costs, the device company would have the evidence to differentiate their solution. The primary step within the process is to compile the list of complication codes collected from the physicians and hospitals. Second step would be to identify the patients who have undergone the surgical procedure during the decided period and associated diagnosis and procedure codes (Optum resources, n.d.).

The medical team will then cross reference the codes and determine which of them pointed to complications post procedure. this data will help in to work out the medical and pharmacy cost related to those complications, observing key variables at 90 days, 1 year and three years post procedure. This analysis will generate a report for the medical device company to form an in-depth report for convincing the insurance companies that how this device is crucial for the improved healthcare outcomes because it causes less complications and hence reduce the prices for handling those complications (Optum resources, n.d.).

For brand success, evidence generation across commercial functions such as Medical Affairs for scientific community messaging, market access and reimbursement for pricing and access functions, and Products Lifecycle Management (PLCM) for brand value management is becoming increasingly important (Shah & Nidhi, 2021). Pharmaceutical companies must line up with the shifting healthcare landscape and the value agendas of stakeholders. The unilateral value framework and evidence-producing process of a pharmaceutical company must be transformed into a reiterative analytic model that focuses on immediate business strategy questions while providing feedback and support to long-term evidence-generation strategies.

The transformation would necessitate an assessment of underlying organizational capabilities, as well as the rewriting of value frameworks across the commercial range using HEOR. Despite the fact that the mainstream of insurance companies and arbitrators in the United States considers HEOR evidence when creating drug formulary and coverage decisions, actual formulary drug allocations show that the lowest-priced branded drugs costs are rarely included in a preferred tier in the list, highlighting the importance of cost in the drug formulary decision (Holtorf et al., 2012).

**Challenges in implementation of HEOR Analysis**

The application of medical big data for financial evaluations of precision medicine renders practical and methodological challenges. The existence of bias and contradiction in observational studies, the mismanagement of clinical miscoding and missing data, the scarcity of accessible health state utility values (used to calculate quality-adjusted life years [QALYs]) for population subgroups of concern, and an absence of strong indication on willingness-to-pay thresholds and reimbursement are major complications (Chen et al., 2020). Because of lack of standardization, more of quantitative data and fewer of qualitative data is getting used for HEOR for rational processes which isn't sufficient to get detailed and logically appropriate reason behind the variations (Holtorf et al., 2012).

There may be numerous attributes and factors for providing precise details for affecting the expansion of the Health Economics & Outcomes market by Country and Individual Segments that has to be identified and to be implemented concisely globally. There is lack of analysis and studying of the micro-markets in terms of their contributions to the worldwide Health Economics & Outcomes market, their prospects, and individual growth trends. There is a lack of study estimating which precision patient subcategories can benefit from a specific cost-effective clinical therapy program, or other challenges in implementing ML models for P-HEOR (Chen et al., 2020).

**Conclusion**

In the field of health economics and outcomes research (HEOR), health informatics is critical in the use of data to explore and analyze interventions, systems, and processes that affect patient health outcomes in real-life and abstract situations (Peeples, 2022). Also, P-HEOR has developed a lot since its inception in health economics evolution in terms of identifying resources to improve healthcare quality and services with the scope of improvement in terms of allocation of key resources to the specific population subgroups and utilizing right implementation science. To categorize patient cohorts with different risk-benefit profiles in terms of both clinical and economic outcomes, a conceptual P-HEOR framework that holds the potential of precisely assessing the worth of a selected therapy processes in heterogeneous subgroups using RWE must be developed, supported by ML optimization (Hughes et al., 2019).

Currently, the utilization of HEOR for policy-making across various healthcare systems is case-based and prioritized and thus HEOR must begin incorporating patient learnings about their clinical journeys so policymakers can better understand all of the prices and benefits that are relevant to an economic evaluation and using indirect treatment comparison methods to judge clinical and economic outcomes of competing interventions for evidence synthesis (Chen et al., 2020). With this understanding, any policies or rulings that are implemented can better characterize the patient's point of view.

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