



Navigating Healthcare Economics: Optimizing Therapeutic Efficacy and Cost with Pharmacoeconomics

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Citation Rania I., Moumita R., Sudipto M. Navigating Healthcare Economics: Optimizing Therapeutic Efficacy and Cost with Pharmacoeconomics. Journal of Pharmacoeconomics and Pharmaceutical Management. 2025; 11(1):5-13.

Running Title Navigating Healthcare Economics

Article Type Review Article

Article info:

Received: 29.01.2025

Revised: 15.03.2025

Accepted: 25.03.2025

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Publisher

Tehran University of Medical
Sciences

ABSTRACT

Background: In today's healthcare landscape, escalating costs underscore the pressing need for pharmacoeconomic evaluations, particularly in low- and middle-income countries (LMICs) where medication expenses can dominate healthcare budgets. Pharmacoeconomics, a multidisciplinary field, scrutinizes the costs and benefits of healthcare interventions, offering vital insights for optimizing value within resource constraints.

Methods: This article provides an overview of pharmacoeconomics, tracing its historical development, methodologies, and diverse applications in healthcare decision-making. Despite its significance, obstacles persist in the widespread adoption of pharmacoeconomic studies, including limited funding, expertise shortages, and data deficiencies. Addressing these challenges is paramount to harnessing the full potential of pharmacoeconomics in informing resource allocation and enhancing healthcare efficiency and sustainability worldwide.

Results: As healthcare payers increasingly prioritize cost-effectiveness, the demand for pharmacoeconomic evaluations continues to grow, highlighting the urgent need for overcoming barriers to implementation. By embracing pharmacoeconomic principles, stakeholders can navigate complex healthcare landscapes, optimize patient outcomes, and promote equitable and efficient resource allocation. Ultimately, integrating pharmacoeconomics into healthcare decision-making processes holds promise for fostering a more resilient, effective, and patient-centered healthcare system for all.

Keywords: Pharmacoeconomics, Direct costs, Indirect costs, Intangible costs, Cost-utility analysis (CUA), Cost-effectiveness analysis (CEA), Average cost-effectiveness ratio (ACER), Incremental cost-effectiveness ratio (ICER), Disability-adjusted life year, Health-related quality of life (HRQOL)



Introduction

Healthcare payers globally are increasingly prioritizing pharmacoeconomic analyses due to the growing significance of pharmaceutical therapy-related costs. In certain low- and middle-income countries (LMICs), medication expenses can constitute as much as 70% of the overall healthcare expenditure.¹ Growing attention has been placed on evaluating the value and feasibility of allocating resources to different healthcare treatments and programs through pharmacoeconomic assessments, particularly in LMICs, due to constraints on healthcare resources. The increasing utilization of pharmacoeconomic research is creating a demand for skilled professionals capable of analyzing and comprehending research outcomes and applying them in practical settings, particularly in low- and middle-income countries where resource limitations and other challenges are prevalent [1].

Pharmacoeconomics, a subfield of health economics, calculates the advantages and disadvantages of a given intervention in relation to a comparable substitute. A relatively new interdisciplinary field that combines the ideas of economics, medicine, and pharmacy is called Pharmacoeconomics. It delves into the societal implications and ramifications of various forms

History of the emergence of Pharmacoeconomics

The first textbook on health economics was published in 1973, marking the beginning of Pharmacoeconomics in the 1970s. Within this subject, McGhan, Rowland and Bootman from the University of Minnesota later introduced the ideas of cost-effectiveness and cost-benefit analysis in 1978. Bootman et al. published an early pharmaceutical research study in 1979 by taking advantage of complex pharmacokinetic methods. In order to clarify the results of adjusting aminoglycoside dosages for specific badly burned patients with gram-negative septicemia, the article used cost-benefit analysis. An academic program that focused on the use of the cost-benefit and the cost-effectiveness analysis in medical care was introduced by the Ohio State University College of Pharmacy in 1983. The program's goal was to give participants a thorough understanding of these approaches, with a focus on how they may be used to administer pharmacological

of pharmacotherapy⁵. This type of study plays an essential role because it takes into account the goal of maximizing value for patients, healthcare payers, and society, especially when resources are limited. Typically, novel healthcare interventions such as drugs, medical devices, or services tend to be more expensive than existing ones. In contrast to the standard of care, they typically provide more advantages or value. Decision-makers, including legislators, healthcare professionals, and other stakeholders, must thus assess whether these innovative approaches are both financially viable and constitute an effective use of scarce resources³.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is a multidisciplinary organization with a wide range of stakeholders dedicated to promoting scientific excellence in outcomes research and health economics⁷. ISPOR defines pharmacoeconomics as "the field of study that evaluates the behavior of individuals, firms, and markets relevant to the use of pharmaceutical products, services, and programs, and which frequently focuses on the costs (inputs) and consequences (outcomes) of that use" [4].

care⁵. Ray Townsend first used the word "Pharmacoeconomics" at a 1986 Toronto pharmacists' conference. "A description and evaluation of the cost of the drug therapy with an impact on healthcare systems and society" was the initial definition of Pharmacoeconomics. Townsend and his colleagues then revised the term, defining Pharmacoeconomics as "cost and quality of life related to the use of a novel pharmacotherapy"⁵.

Main elements of economic evaluations

The following lists the main definitions and inputs that must be taken into account when performing a pharmacoeconomic evaluation. The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement can be summed up as follows.

- Economic evaluation: In order to provide a decision framework, the comparative assessment of a minimum two health treatments entails assessing the costs and effects of various technologies within a

particular population. The two primary parts of the analysis are usually "costs" and "outcomes."

- Target population- The group of patients or particular subgroups that the health intervention is anticipated to benefit.
- Comparators- The interventions that are being compared in the economic analysis could include medications, vaccinations, treatments, or services.
- Setting- The environment or situation in which the act of intervention is carried out.
- Perspective- Various perspectives from which health benefits and costs can be evaluated include those of the patient, healthcare provider, payer (such as insurance companies or government agencies), and society at large.
- Time horizon- The time frame used in an economic investigation to calculate costs and outcomes (benefits/consequences).
- Opportunity cost- The advantage that might have been gained from a choice that is not chosen is included in this.
- Costs- This pertains to the economic analysis's financial component, which includes intangible costs as well as both direct and indirect medical and non-medical expenses.
- Outcomes- The outcomes, often known as "benefits" or "repercussions," are the expected medical or humanistic outcomes of an intervention.
- Willingness to pay (WTP)- It is the procedure whereby people are asked to

indicate the highest amount of money they are prepared to spend in order to receive an particular advantage from an intervention or service.

- Discounting- Discounting is the term for the technique used to account for people's preferred time. The majority of people have an advantage of time preference, meaning they would rather incur expenses later rather than sooner and receive rewards sooner rather than later. Discounting takes into account people's preferences for time and converts future expenditures and benefits to their present value.
- Modelling- Decision analysis, which can be applied via modeling approaches like decision analysis or simulation models, is frequently used in economic evaluations.
- Sensitivity analysis- One technique for accounting for uncertainty in the results of economic evaluations is sensitivity analysis. The following are the four main categories of sensitivity analyses:
 - One-way simple sensitivity analysis
 - Multiway sensitivity analysis
 - Threshold sensitivity analysis
 - Probabilistic sensitivity analysis [3].

Costs for economic evaluations

Any cost analysis is thought to begin with the identification of various expenses (i.e., monetary results). Typically, these expenses are divided into three categories: direct, indirect, and intangible (Figure 1).

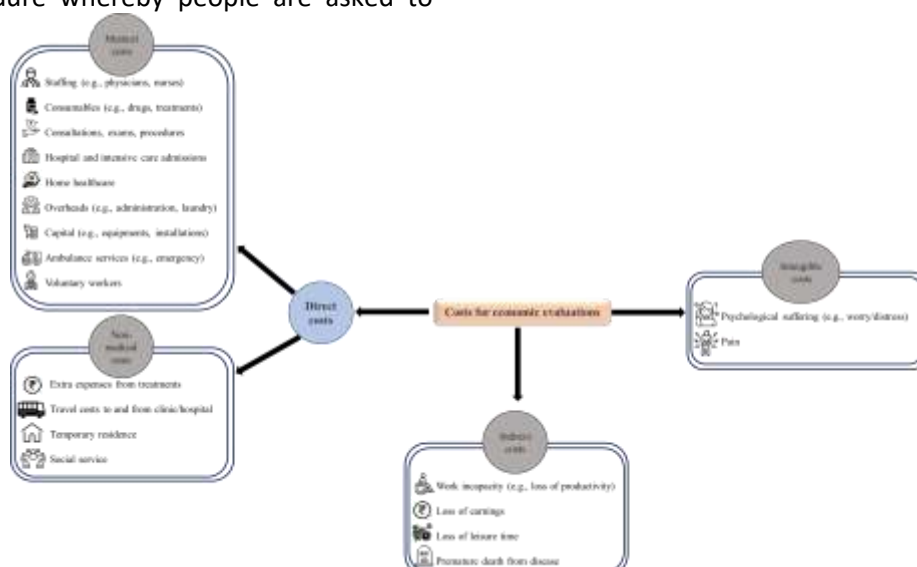


Figure 1. Costs for economic evaluation

- Direct costs pertain to expenses directly allocated to healthcare services, specifically those associated with the treatment of the patient. Depending on whether they entail specific healthcare services (direct medical) or any additional connected expenses (direct non-medical), these costs can be further divided into medical and non-medical categories.
- Indirect costs allude to the monetary effects that patients, their family, or society as a whole endure, such as lost wages or decreased productivity brought on by the patient's illness.
- Intangible costs are associated with the extent of ailments endured as a result of illness or healthcare intervention [3].

The cost can be estimated in following ways:

- Cost / unit
- Cost / treatment
- Cost / person

- Cost / person / year
- Cost / case prevented
- Cost / life saved
- Cost / DALY (disability-adjusted life year)

Outcome or benefit is the second most vital component as far as pharmacoeconomics is concerned. The expected benefits can be expressed as:

“Natural” units: e.g. years of life saved, events prevented (such as, peptic ulcers healed, surgeries avoided, strokes prevented, etc.)

“Utility” units: Utility is a measure of contentment or well-being. Utility places emphasis on assessing the overall quality of a state of wellness rather than just quantity. Direct measuring techniques like time trade-off or conventional gambles can be used to obtain utility estimates. They can also be based on the opinions of experts or the body of existing material. Evaluations of the quality of life in different illness states are commonly used to derive these estimations [8].

Methods

Comparing the expenses, clinical results, and humanistic effects of various therapy modalities is the goal of pharmacoeconomic research. The evaluation methods described are often useful in demonstrating the financial consequences of novel treatments, which increases their adoption by administrators, healthcare practitioners, and the general public. Pharmacoeconomic analysis techniques include:

Cost-of-illness analysis (COI): The goal of COI analysis is to evaluate the financial impact of a disease or condition, including treatment expenses, on a particular population or geographic area. This assessment method, which involves calculating both direct and indirect costs related to a certain ailment, is often referred to as a burden of illness. It is possible to determine the relative worth of a therapy or preventative strategy by precisely defining both the direct and indirect costs related to a disease. The potential value of executing a prevention plan on a national level, for example, might be revealed by deducting the cost of the strategy from the total societal cost of a certain disease. While this analysis can

aid in prioritizing between different diseases, it alone may not be adequate for informing efficient allocation of healthcare resources for coverage and reimbursement decisions, especially regarding the therapeutic options available to alleviate this burden. In such scenarios, budget-impact analysis (BIA) is preferred, as it also considers the affordability aspect, which is crucial for short-term economic planning purposes [8,10].

Budget-impact analysis (BIA): BIA determines how integrating or implementing a new technology or intervention would impact a certain healthcare budget. This method assesses how affordable a healthcare intervention is in a given context as opposed to not being there. Typically conducted from the payer's viewpoint, the BIA takes into consideration the population size and operates within a short-term timeframe, typically spanning 3 to 5 years. The primary outcome generated by this analysis is the cost [6].

Cost-minimization analysis (CMA): CMA aims to elucidate the least costly alternative among two or more therapeutic interventions. Therapeutic equivalence, i.e., equivalent safety and efficacy

profile of these interventions, is either presumed or demonstrated. The author conducting the study must reference the evidence on equivalence, which should have been established prior to the CMA. The expenditures can be identified, measured, and contrasted in financial terms (dollars) when the results' equivalency has been confirmed. CMA only highlights a program's or treatment's "cost-saving" features in comparison to others. When examining multiple therapeutically comparable medications or different dosage regimes for the same medication, CMA is a useful tool. Given the rise in generic competition in the pharmaceutical market, the use of this method has become more prevalent and its application may continue to grow [8,10].

Cost-benefit analysis (CBA): CBA is a method for assessing and contrasting the costs and advantages of a specific program or course of treatment. It entails weighing the program's advantages against the expenses associated with running it. It is a technique used to determine which solutions are best for benefits, labor efficiency, time, and cost savings, allowing for well-informed decision-making and the adoption of best practices. CBA serves two primary objectives:

- Assessing the feasibility and justification of an investment or decision.
- Offering a framework for project comparison by weighing the anticipated total costs against the anticipated total benefits to ascertain the degree to which benefits outweigh costs.

The relationship between these costs and benefits is quantified through a benefit-to-cost ratio. The program or treatment option with the highest net benefit, or the highest benefit-to-cost (B:C) ratio, would be chosen by a clinical decision maker.

- A B:C ratio > 1 indicates that program or treatment efficacy is demonstrated when the advantages of the program or alternative treatment exceed the disadvantages.
- A B:C ratio $= 1$ indicates that the program's or treatment alternative's benefits and the cost of providing it are equivalent.

- A B:C ratio < 1 suggests that the program or treatment lacks economic benefit, with costs surpassing benefits.

Cost-utility analysis (CUA): CUA is a kind of economic analysis that evaluates the health benefits and comparative costs, measured in quality-adjusted life-years (QALYs), of various treatment strategies. It helps to identify the most cost-effective therapeutic option for a particular ailment⁶. This method integrates patient preferences for a particular therapy and their health-related quality of life (HRQOL). Cost is estimated in monetary units like rupees, dollar, etc., whereas the therapeutic outcome is evaluated based on patient-weighted utilities in contrast to physical measures. QALY, frequently employed in CUA, integrates morbidity and mortality information to assess health status. The result is expressed as a ratio of cost to quality of life of patient. This method is used to assess treatment alternatives that range from measures that largely reduce morbidity instead of mortality (e.g., healthcare management of arthritis) to life-extending medications with substantial adverse effects (e.g., cancer chemotherapy). It is particularly relevant while assessing HRQOL as the primary health outcome. Compared to other economic evaluation approaches, CUA is seldomly used owing to challenges in standardizing utility measurements, complexities in comparing QALYs across diverse patient populations, and difficulties in quantifying patient preferences.

Cost-effectiveness analysis (CEA): Globally, CEA has a widespread application for economic evaluation of different therapeutic strategies. ISPOR states that it entails comparing therapies according to their quantitative non-monetary health outcomes and costs stated in monetary units. Lowering mortality or morbidity, cases avoided, days gained without signs, patients enhanced, or life years gained are some examples of these health units.

In contrast to BIA, CEA typically adopts a long-term perspective, drawing on data from clinical studies and employing prediction tools to anticipate future outcomes.

The results of CEA are expressed either as an average cost-effectiveness ratio (ACER) or as an incremental cost-effectiveness ratio (ICER).

The ACER ratio, which represents the dollar cost per certain clinical outcome achieved regardless

of comparators, is calculated by dividing the overall cost of a therapy by its clinical outcome.

$ACER = (\text{Health care cost}) / (\text{Clinical outcome})$

This enables the clinician to identify the cost-effective therapy with least cost per outcome gained.

Clinical effectiveness is frequently achieved at a higher cost. When comparing one treatment option to the next best option, incremental CEA helps determine the additional cost and effectiveness attained. It analyzes the increased cost incurred by a particular therapy over another with the greater benefit or outcome it gives, rather than contrasting the ACERs of every treatment choice.

$ICER = (\text{Health care cost of drug A} - \text{Health care cost of drug B}) / (\text{Effect of drug A} - \text{Effect of drug B})$

This formula determines the additional expense required to produce the additional impact that switching from medicine A to drug B produces.

Application of Pharmacoeconomics

Pharmacoeconomics is increasingly pivotal in clinical practice, aiding in informed clinical and policy decision-making. Nowadays, pharmacists provide services to improve patient access to medical care, optimize health outcomes, and encourage better medication use.

The role of Pharmacoeconomics is vital across the pharmaceutical industry's spectrum, from research and development to marketing. Several nations mandate pharmacoeconomic assessments during the licensing phase. Hospital pharmacists frequently employ pharmacoeconomics to guide formulary decisions and optimize medication usage for enhanced cost-effectiveness and benefits.

Knowledge of health economics alongside political acumen is imperative for comprehending resource allocation and expenditure within contemporary healthcare systems. Pharmacists, leveraging their specialized understanding of medication, play a pivotal role in utilizing pharmacoeconomic analysis to shape expenditure and resource allocation concerning medicines.

Hence, employing the most effective operational methods to minimize costs and optimize benefits is progressively vital. Pharmacoeconomics forms a crucial component of the toolkit available to pharmacists,

empowering them to enhance the efficiency of their hospital operations.

Need for pharmacoeconomic studies

The rising costs within healthcare underscore the importance of integrating pharmacoeconomic evaluations. By adjusting drug prices to levels that ensure patient accessibility, this discipline, a subset of health economics, has swiftly demonstrated its necessity and significance through tangible benefits. Numerous facets of the health care system, including hospitals, companies, national administration, and both the public and private biopharmaceutical sectors, are in need of it.

The following points underscore the necessity of pharmacoeconomics in the healthcare system⁴:

- **Cost-effective Treatment:** Pharmacoeconomics aids in identifying and implementing cost-effective treatment options, ensuring optimal allocation of healthcare resources.
- **Budget Optimization:** It helps in optimizing healthcare budgets by assessing the value and cost-effectiveness of various pharmaceutical interventions.
- **Policy Decision Making:** Pharmacoeconomic evaluations provide valuable insights for policymakers in making informed decisions regarding drug pricing, reimbursement, and formulary management. It assists Pharmacy and Therapeutics (P&Ts) Committees in making informed decisions regarding formulary management.
- **Resource Allocation:** With healthcare resources being finite, pharmacoeconomics helps in prioritizing resource allocation to maximize health outcomes.
- **Enhanced Patient Access:** By identifying cost-effective interventions, pharmacoeconomics facilitates improved access to essential medications for patients.
- **Assistance in Clinical Practice:** It assists in promoting good prescription practices, enabling physicians to prescribe medications that are both beneficial

and cost-effective, ultimately benefiting patients. Cost-analysis studies can optimize medication prescribing by considering factors like Efficacy, Suitability, Price, and Safety (ESPS).

- **Quality Improvement:** It promotes quality improvement initiatives by encouraging the use of efficient and economically viable healthcare interventions.
- **Healthcare Sustainability:** Pharmacoeconomics contributes to the sustainability of healthcare systems by ensuring that resources are utilized judiciously to achieve optimal health outcomes.
- **Pharmaceutical Industry:** Pharmacoeconomics is essential in directing research and development endeavors in the pharmaceutical industry towards creating economically feasible and clinically efficient medications.
- **Patient-Centric Care:** By considering both clinical and economic outcomes, pharmacoeconomics promotes patient-centric care that focuses on maximizing patient health benefits while minimizing costs.
- **Health Insurance:** Additionally, at the level of private medical systems, it aids in designing health insurance benefits and determining treatment cost coverage.
- **Continuous Evaluation:** It facilitates continuous evaluation and monitoring of healthcare interventions to assess their long-term cost-effectiveness and impact on patient outcomes.

Barriers to Pharmacoeconomic Studies

The continuous increase in pharmaceutical spending emphasizes the need for more sophisticated pharmacoeconomic analyses to improve healthcare outcomes and more effectively distribute resources¹. Despite Pharmacoeconomics' many advantages and importance, this branch of health economics faces several difficulties in practice. Acceptability and accessibility are two examples of pharmacoeconomic challenges and obstacles. The suitability of using cost-analysis

techniques and methods to evaluate results in light of scarce resources and the significance of pharmacoeconomic application are examples of acceptability factors. Cost concerns, a lack of specialists, the accessibility of resources of excellent quality, and insufficient data for formulary choice-making are further difficulties. Inadequate record-keeping procedures and inadequate time and attention given to the review process are major factors associated with hospitals. Barriers to the implementation of pharmacoeconomics in various Middle Eastern countries include^{3,4}:

Absence of a National Body to Govern Pharmacoeconomics- Monitoring the effectiveness of drugs and costs requires the presence of a national regulatory authority that supervises assessment studies and health economics. **Drug pharmacoeconomic evaluation** is governed worldwide by the International Society for Pharmacoeconomics and Outcome Research (ISPOR). However, the absence of such bodies in some countries hampers effective policy implementation, creating leadership and accountability gaps.

Insufficient Equilibrium between Treatment Efficacy and Cost-Effectiveness among Healthcare Providers- Assessing the value of medications in relation to their therapeutic benefits is crucial. The lack of balance between drug effectiveness and cost presents a challenge, as it leads to the overprescription of expensive drugs.

Lack of Local and National Registries with Patient Data and Pharmacoeconomic Records- The lack of a well-functioning healthcare system contributes to the challenge of implementing pharmacoeconomics, stemming from the absence of comprehensive registries at local and national levels. These registries are crucial for documenting medication costs, therapeutic effectiveness, quality of life data, and health resource utilization.

Insufficient Funding for Pharmacoeconomic Evaluation- Insufficient funding allocated by developing country governments to healthcare, particularly for pharmacoeconomics, poses a significant barrier to conducting such studies. Limited budgetary resources hinder pharmaceutical experts from conducting analyses and cost comparisons of medications

and therapies, impacting effective health economic evaluation in low-income countries.

Inadequate Availability of High-Quality Pharmacoeconomic Data- Insufficient high-quality data poses a significant obstacle to implementation, hindering experts' ability to conduct thorough evaluation studies.

Inadequate Pharmacoeconomic Workshops- Healthcare professionals and stakeholders lack awareness and understanding of cost analysis techniques. It is crucial for pharmacoeconomic specialists to conduct workshops to educate them about the significance of this aspect of health economics.

Inadequate Pharmacoeconomic Evaluation Experts- Despite increasing awareness of pharmacoeconomics, several countries lack specialists capable of conducting quality evaluations and raising awareness of its importance. These experts are essential for informed decision-making in formulary management and drug therapy, as well as for conducting workshops and educating healthcare professionals and students about its benefits.

Insufficient Involvement of Patients in Decision-Making Process- In pharmacoeconomics, decisions occur at multiple levels: national, local, and patient-specific. Unfortunately, patient input is often overlooked at the

individual level, despite its potential to enhance decision-making and policy formulation for better implementation of pharmacoeconomic studies.

Lack of Efficient Formulary Management- Efficient utilization of pharmacoeconomics hinges on effective formulary management, as the two concepts are intricately linked and pivotal to each other's advancement. Ensuring the safety, efficacy, and cost-effectiveness of drugs in hospital formularies before inclusion underscores the importance of formulary data in driving efficient pharmacoeconomic implementation.

Insufficient Public Awareness Regarding the Significance of Pharmacoeconomics- For pharmacoeconomics to have a meaningful impact on healthcare systems, it is essential for researchers, students, decision makers, and healthcare practitioners to fully understand its significance. The effectiveness of pharmacoeconomics in evaluating healthcare costs, patient outcomes, and medication quality of life relies heavily on awareness about medication costs and economic aspects of pharmaceuticals. Insufficient awareness hinders the successful implementation of pharmacoeconomic studies and their influence on economic policy making.

Conclusion

In conclusion, pharmacoeconomics stands as a critical tool in navigating the complexities of healthcare resource allocation. As healthcare payers increasingly prioritize cost-effectiveness, the demand for pharmacoeconomic evaluations continues to grow. However, significant barriers hinder its widespread implementation, necessitating concerted efforts to address funding gaps, enhance expertise, and improve data accessibility. Overcoming these challenges

is essential for leveraging pharmacoeconomics to its fullest potential in driving informed decision-making, optimizing patient outcomes, and promoting healthcare sustainability. Embracing pharmacoeconomic principles can pave the way for a more efficient, equitable, and cost-effective healthcare system, benefiting patients, healthcare providers, and society at large.

Acknowledgement

Department of Pharmaceutical Technology, JIS University and Department of Pharmaceutical

Sciences, Jharkhand Rai University are kindly acknowledged.

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