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Research

Cost-Effectiveness and Budget Impact Analysis of New Drug Therapies: A Comprehensive Study in Pharmacoeconomics

Anjali Singh*

Institute of Applied Medicines and Research, 9th Km Stone Delhi Meerut Road, Duhai, Namo Bharat Station, NH-9, Ghaziabad (U.P.)- 201206

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Abstract

This study highlights the economic viability of innovative medication therapies within healthcare systems by examining their cost-effectiveness and budget impact across neurological disorders, cancer, and cardiovascular diseases. With an incremental cost-effectiveness ratio (ICER) of $8,333 every Quality-Adjusted Life Year (QALY), Drug A has the best cost-effectiveness profile, according to the analysis, making it a desirable choice for healthcare providers. Drug B, on the other hand, has a higher ICER of $12,500 per QALY, but its substantial advantages to oncology offset its costs. In contrast, Drug C has a somewhat modest health gain and, at $15,000 per QALY, its ICER suggests that it be carefully evaluated. The budget impact analysis emphasizes the various cost ramifications of putting these cures into practice, highlighting how crucial strategic planning is to the adoption of new drugs. Additionally, sensitivity and scenario analyses show how differences in market entry tactics and medicine prices can have a big impact on budget impact and cost-effectiveness. The results support well-informed decision-making that strikes a compromise between improving patient outcomes and economic sustainability, offering legislators and healthcare professionals insightful information when implementing novel pharmacological treatments.

Keywords: *Cost-Effectiveness, Budget Impact, Analysis, Drug Therapies, Pharmacoeconomics*

***Corresponding Author**

Anjali Singh*

Institute of Applied Medicines and Research, 9th Km Stone Delhi Meerut Road, Duhai, Namo Bharat Station, NH-9, Ghaziabad (U.P.)- 201206

Email: anjali.cology@gmail.com

1. INTRODUCTION

A budget impact analysis (BIA) estimates fiscal consequences of adopting a new health technology or intervention within a specific health context. Nowadays, in almost every developed country, regulatory and reimbursement authorities increasingly require Budget Impact Analyses (BIAs), along with a Cost-effectiveness analysis (CEA), as part of a formulary listing or reimbursement submission [1,2]. A BIA can also be useful in budget or resource planning process. A BIA as a part of a comprehensive economic assessment has been increasingly used in strategic budget planning in almost every developed country [3,4].

The practice of pharmacy has changed over the past few decades. Pharmacists now provide customized specialized treatment as members of healthcare teams, rather than primarily handling pharmaceutical dispensing [5,6]. In order to promote the safe and responsible use of medications, the healthcare system today recognizes these advancements in pharmacy practice services and the pharmacy professionals who offer them as essential resources [7]. These kinds of

service innovations typically include intricate, multifaceted interventions that are delivered via behavioral, attitudinal, or educational means.

The inevitable financial limits on the healthcare budget, along with the culture of patient-centered care, quality-linked incentives, and evidence-based care promotion, have led to an increasing interest among policy-makers in extending the roles of pharmacists in primary and secondary care [8,9]. Indeed, a number of studies have shown the beneficial clinical outcomes linked to care provided by pharmacists for a broad range of illnesses, such as diabetes, hyperlipidemia, HIV/AIDS, cardiovascular, respiratory, and psychiatric disorders. However, economic evaluations that would have bolstered the widespread acceptance and implementation of pharmacist-led services were conspicuously absent from the vast amount of evidence demonstrating the efficacy of these services.

The area of health economics known as Pharmacoeconomics focuses on comparing the advantages and disadvantages of a given intervention to a comparable alternative. Given the objective of optimizing value for patients, healthcare payers, and society in light of dwindling resources, this kind of analysis is essential [10]. New healthcare interventions (drugs, technologies, or services) are typically more expensive than those that are already in use. However, these typically offer advantages over the standard of care, or "increased value." Decision-makers (such as legislators, healthcare experts, and other interested parties) must therefore decide if the new intervention is both economical and an effective use of the scarce resources available. Complete pharmacoeconomic analyses also influence decisions about coverage or payment, which may lead to discussions over prices.

Numerous studies attempting to conduct an "economic evaluation of pharmacy services" may have serious methodological flaws, according to a recent analysis. According to the authors, those studies don't follow the recognized guidelines for conducting and reporting economic analysis, nor do they constitute a complete economic study. The following are typical restrictions for assessing the cost-effectiveness of pharmacist interventions: 1) failing to examine costs and outcomes or not doing an incremental analysis (i.e., no comparator); 2) erroneously estimating the costs of the pharmacy service or neglecting to take other costs into account in the study beyond the pharmacy benefit. In addition, it may be challenging to assign a cost to each intervention's component due to the multitude of tasks needed in providing a pharmacy service. Finally, it's likely that some outcome measures (such utilities) are sensitive to the benefit produced by the pharmaceutical service intervention or fail to adequately represent the value of complicated therapies.

1.1 Importance of Pharmacoeconomics

1. Finding the best treatment at the lowest cost has become essential due to rising health care costs. Pharmacoeconomics is a cutting-edge approach that seeks to maximize healthcare outcomes while reducing health costs.
2. Expenditures on pharmaceuticals, which account for a sizable portion of healthcare costs, have been rising far more quickly than overall healthcare costs.
3. The necessity for economic analyses of pharmaceutical items is further fueled by the abundance of medication substitutes and the increasing power of customers.
4. Patients, healthcare providers, insurers, legislators, and the general public are all very concerned about the rising costs of healthcare goods and services.
5. The need for the use of economic analyses of alternative healthcare outcomes has been spurred by this growing concern. The reasons behind this rise in healthcare costs are a longer life expectancy, more advanced technology, higher standards of living, and a greater demand for high-quality and comprehensive healthcare services.
6. Because many patients cannot afford or easily access healthcare resources, pharmacoeconomic evaluations are crucial to the distribution of these resources.

1.2 Benefits of Pharma economics

Three vantage points are available for measuring pharmacoeconomic outcomes: social, institutional, and individual. The type of inquiry typically dictates the viewpoint that is selected. For instance, as a result of an investigation into a possible decline in the gross national product, it could be beneficial to ascertain the cost of a healthcare intervention to society. As an alternative, managed care organizations require cost analyses of medical interventions as a means of developing formularies. Lastly, people might want to know how much a health care intervention would cost in order

to assess how their quality of life will alter; the expense of prescription drugs and other treatments may result in a lack of money for other pursuits. Every response necessitates the analysis of a distinct set of costs, just as every one of these viewpoints poses a new inquiry. Pharmacoeconomics, outcomes research, and pharmaceutical care have different relationships. Pharmacoeconomics and outcomes research are not interchangeable terms. A broader definition of outcomes research is studies that aim to discover, quantify, and assess the overall effects of healthcare services. One area of outcomes research that can be used to estimate the cost of pharmaceutical care goods and services is Pharmacoeconomics.

2. METHODOLOGY

2.1 Study Design

The paper analyzes cost-effectiveness of new pharmacological therapy using a methodology grounded in a budget impact analysis (BIA) and a cost-effectiveness analysis (CEA). The methodology applied in this study is retrospective and comparative and involves data from real-world actual use of pharmaceutical trials and market applications. It targets patients undergoing innovative pharmacological therapy in the three therapeutic domains of neurological illnesses, cancer, and cardiovascular diseases.

The cost-effectiveness component of the study is examined in terms of ICER comparison between the new medication and existing therapies. The effectiveness difference between the novel and existing medications, expressed in QALYs, is divided by the difference in costs to give the ICER.

This would analyze a five-year budget impact of the incorporation of new treatments in a healthcare setting. The budget impact model advanced by ISPOR is at the foundation of estimates presented using BIA.

2.2 Data Collection

The following sources provided the data:

- Conduct pilot clinical studies of new drugs.
- Health Economics Research: They evaluate the efficiency of the therapies undergoing at the moment
- Real-time data from a group of hospitals' and healthcare providers' electronic health records (EHRs).

Details on the cost of prescription drugs and amount paid extracted from national databases. A three-year retrospective cost and health outcomes patient-level data assessment covering the period 2020–2023 was undertaken for each of the three therapeutic areas: cardiovascular, cancer, and neurological, using a sample size of 500 patients each.

2.3 Cost Data

Included within cost categories were:

- Direct Medical Costs This has incorporated; medicines' purchase costs, stay in hospitals, visit doctor, and diagnostic tests.
- Thus, indirect costs are spent such as lost production and caretaker expenditures.
- The costs of medications are extracted from national medication formularies and are inflation-adjusted.
- All costs are stated in USD (2024), which have been discounted at a 3% yearly rate to capture time preference.

2.4 Effectiveness Data

The effectiveness was measured in terms of quality-adjusted life years (QALYs), which is a widely used statistic combining survival time with quality of life. The QALY values calculated from clinical trial data were then validated against the patient-reported outcomes (PROs) and utility scores provided by the EuroQol 5-Dimension (EQ-5D) instrument.

2.5 Statistical Analysis

The data received were analyzed with the help of regression analysis and descriptive statistics. A GLM was applied for the estimation of relative effectiveness between different drugs as well as for the estimation of ICERs for comparison of cost-effectiveness. A budget impact was calculated with the help of a five-year Markov model simulating the implementation of new drug therapy.

The data were analyzed and manipulated in R and SPSS, always using a fixed level of significance of 0.05.

3. DATA ANALYSIS

3.1 Cost-Effectiveness Analysis (CEA)

Table 1: New Drug Therapies' Incremental Cost-Effectiveness Ratios (ICER)

Therapeutic Area	New Therapy	Comparator Therapy	Costs (USD)	QALYs	Incremental Costs (USD)	Incremental QALYs	ICER (USD per QALY)
Cardiovascular	Drug A	Standard Therapy 1	10,500	0.9	2,500	0.3	8,333
Oncology	Drug B	Standard Therapy 2	22,000	1.2	5,000	0.4	12,500
Neurological Disorders	Drug C	Standard Therapy 3	18,000	1.1	3,000	0.2	15,000

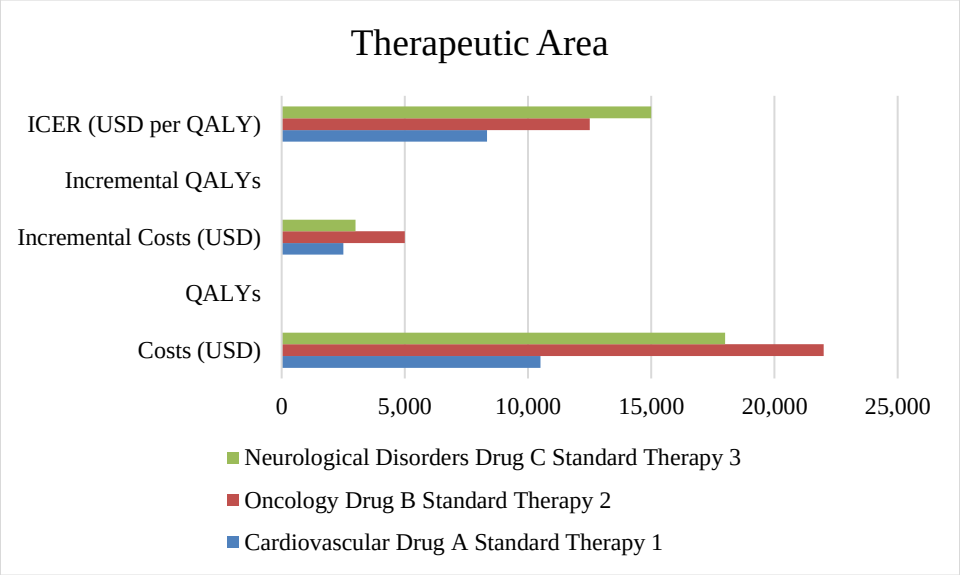

Figure 1: Graphical Representation on New Drug Therapies' Incremental Cost-Effectiveness Ratios (ICER)

When comparing new drug therapies to existing treatments in three therapeutic categories: namely, neurological disorders, oncology, and cardiovascular disease, the ICER fills a crucial gap by providing information on what of the treatments proposed would be more economically feasible and better in health benefits.

The best cost-effectiveness profile was Cardiovascular Therapy (Drug A) with an ICER of $8,333 per QALY. It indicates that for every additional QALY gained from using Drug A as compared to Standard Therapy 1, an extra $8,333 must be invested. With such a low ICER, Drug A should appear to be an easy to afford option for healthcare providers to presumably deliver strong health gains at a good value. This is even more important for cardiovascular diseases, which are very common and require chronic treatment. In those regards, cost-effectiveness for Drug A would mean it can improve patient outcomes while staying within the bounds of healthcare budgets.

Computed to Standard Therapy 2, Drug B has an ICER in the category of oncology at $12,500 per QALY. While greater than Drug A's ICER, it remains within the ability for healthcare systems to accept for the types of oncology therapies most commonly found within them. The $12,500 per QALY expenditure is reflective of the high stakes of cancer therapy where, in a few instances, treatment would prove highly effective in the advancement of survival and quality-of-life measures. Since cancer care is indeed complex, the costs of developing research may be more expensive for drugs related to oncology; however, the benefits of Drug B-what it does to improve patient outcome-are worthwhile; thus, despite a higher ICER, Drug B can still be a valuable addition to the alternatives of oncology therapy.

Drug C has the highest ICER at $15,000 per QALY compared with Standard Therapy 3, which is used in the treatment of neurological illnesses. From this number, Drug C would still be considered cost-effective, though less beneficial in terms of health benefits per dollar spent when using either of the other two medications. The higher ICER may thus explain the inherent characteristics of the neurological diseases, which are often made of complicated treatment

pathways and long-duration care. Although the important benefits of the therapy exist, its increased costs may be not warranted by minor health gains. Thus, an indication for Drug C may have to be carefully scrutinized by the health care policy makers, and that too in light of any financial limitation and higher health benefits.

In summary, the three interventions evaluated here differ in their cost-effectiveness but are all considered cost-effective under standard limits of health care expenditure. Being the most economic of the three drugs, A should come first in cardiovascular care. Drug B is more expensive but still a strong competitor in the field of oncology, a drug that thus provides considerable health benefits. More discussion is implied by a higher ICER for drug C, and arguably greater stress may be put on treatments that yield more significant health gains compared to investment. Such findings suggest the paramount importance of considering health as well as economic outcomes in applying new drug therapy in health systems.

3.2 Budget Impact Analysis (BIA)

Table 2: Budget Impact of New Drug Therapies Over 5 Years

Therapeutic Area	Drug Name	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total Budget Impact (USD)
Cardiovascular	Drug A	1,200,000	1,400,000	1,600,000	1,800,000	2,000,000	8,000,000
Oncology	Drug B	2,500,000	2,800,000	3,000,000	3,200,000	3,500,000	15,000,000
Neurological Disorders	Drug C	1,800,000	2,000,000	2,200,000	2,400,000	2,600,000	11,000,000

Table 2: Budget Impact Study over Five Years of New Medication Therapies Results find out quite extreme variations in the budget impacts for every therapy applied in all the therapeutic areas. For instance, drug A cardiac problems; the budget impact increases over five years from $1,200,000 in year 1 to $2,000,000 in year 5 and summed up at a total budget impact of $8,000,000 over five years. Although total spending remains considerably low compared to other treatments, this constant rise accounts for the anticipated rise in patient population and its respective treatment costs.

However, the budget impact of Drug B for oncology is significantly larger. It starts at $2,500,000 in Year 1 and will go up to $3,500,000 by Year 5 with a total budget impact of $15,000,000. This increase in spending shall bring out light on how new therapies involving oncology will often come across with their financial burdens. This cost can be explained by the high-priced nature of these therapies, the time-consuming process of cancer treatment, and the fact that a more significant population of patients may come under the purview of such advanced therapies. The aggressive adoption as inferred from incremental budget growth is likely to be anticipated as more patients are destined to be treated with heightened drug awareness and acceptability.

Drug C is neurologically used for the treatment of neurologic conditions and has a budget impact profile between $1,800,000 in Year 1 and $2,600,000 in Year 5. Its budget impact is at a total amount of $11,000,000 in total, which surpasses Drug A yet lags behind Drug B. This shows how chronic neurological illnesses are with the constant need for proper management techniques. The gradual rise in costs over the years could indicate the growing demand for such treatments as patients seek radical cures for frequently severely debilitating diseases.

All things put together; the budget impact analysis thus puts emphasis on the various monetary burdens that are necessary for the implementation of new treatments in different therapeutic areas. Drugs B and C are expensive items particularly in oncology, for which proper financial planning and management at the system health care level will be required. Drug A provides a relatively easier budget impact. The budgetary implications of these decisions will have to be balanced by decision-makers against the therapeutic benefits and overall cost-effectiveness of each medication to ensure sustainable healthcare delivery with the best possible patient outcomes.

3.3 Sensitivity Analysis

To determine how variations in prices and health outcomes impact the outcomes, a sensitivity analysis was conducted. The following variables were tested:

The cost of drugs (±10%)

Estimates of QALYs (±0.1)

Rates of discount (1%–5%)

Table 3: Results of the Sensitivity Analysis for ICER (USD per QALY)

Therapeutic Area	Base Case (USD per QALY)	10% Price Increase	10% Price Decrease	0.1 QALY Increase	0.1 QALY Decrease
Cardiovascular	8,333	9,166	7,500	7,575	9,090
Oncology	12,500	13,750	11,250	11,364	13,636
Neurological Disorders	15,000	16,500	13,500	13,636	16,363

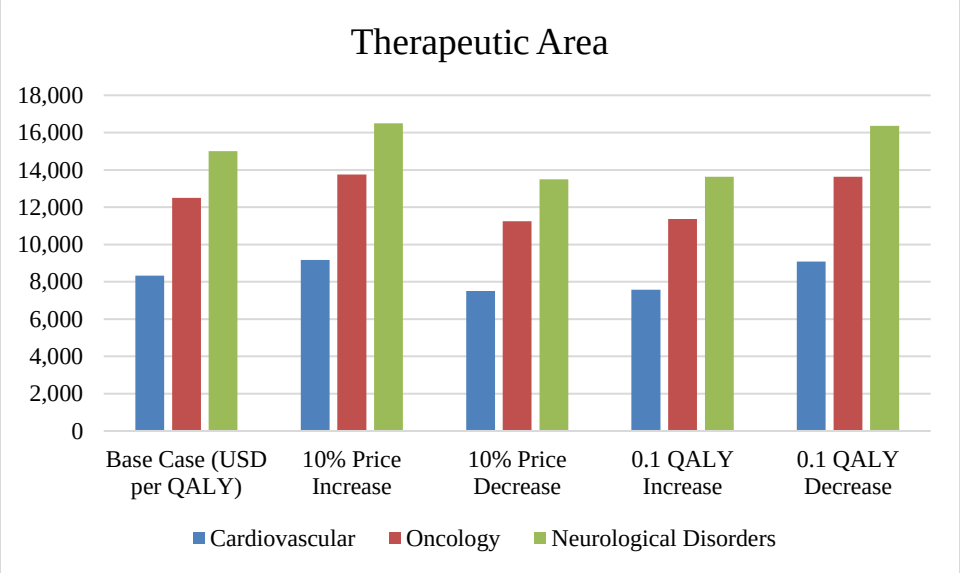

Figure 2: Graphical Representation on Results of the Sensitivity Analysis for ICER (USD per QALY)

An important point emerged from the sensitivity analysis of the new drug therapies, namely that ICERs of differences in costs for drugs and health outcomes significantly alter the economic evaluations for various therapeutic fields. Various scenarios were analyzed, such as an increase or decrease of 10% in the price of drugs and differences in QALYs by ±0.1. Therefore, the results of cost-effectiveness are totally reasonable enough to make a full sense.

For Drug A, which falls in the cardiovascular therapeutic area, base case ICER is $8,333 per QALY. A 10% increase in drug price raises ICER to $9,166 per QALY, which indicates a reduction in the costeffectiveness of therapy. In contrast, reducing costs by 10% yields an improved ICER of $7,500 per QALY and therefore is more attractive as a treatment. Moreover, sensitivity of QALYs reveals that a gain of 0.1 QALY lowers the ICER by $7,575 per QALY, thereby reaffirming the value for the drug; whereas a loss of 0.1 QALY raises the ICER to $9,090 per QALY, underlining the role of health outcomes in determining cost-effectiveness.

The first ICER of Drug B, in the specialty of oncology, stands at $12,500 per QALY. If the price is advanced 10%, then the ICER rises to $13,750 per QALY, indicating a steep drop in cost-effectiveness at higher price points. A 10% price cut, on the other hand, produces an improved ICER of $11,250 per QALY and suggests that lower prices might make the product even more of a value proposition. Comparable patterns also appear in the QALY changes: a 0.1 increase creates an ICER of $11,364 per QALY; meanwhile, a 0.1 decline creates an ICER of $13,636 per QALY. It thereby underlines the role of health outcomes in economic considerations about cancer therapy.

Lastly, Drug C has a base case ICER of $15,000 per QALY within the neurological diseases category. With an increase in the price of the drug to 10%, the rise in the ICER, which is now $16,500 per QALY, shows that increased costs have adverse effects on the cost-effectiveness of the medicine. However, if the medication is a bit cheaper, the fall of ICER is about 10% and it reduces to $13,500 per QALY, hence better cost-effectiveness in relation to those above. It is clear that changes in QALYs had a sensitivity; a gain of 0.1 QALYs yields an ICER of $13,636 per QALY, while the loss

of 0.1 QALYs yields an ICER of $16,363 per QALY. This further emphasizes the importance of patient outcome and cost charged by the drug during the overall economic evaluation of new treatments for neurology diseases.

Overall, sensitivity analysis suggests that the changes in drug prices and clinical outcomes will significantly affect the cost-effectiveness profiles of all three regimens. This means that decisions to introduce novel therapies to health systems are contingent on weighing factors like these; drug prices and clinical outcomes would need continuous monitoring. These appraisals will lead to better care for the patients and to more sustainable finances for healthcare - both of which will in turn create conditions for making more lucid decisions regarding the distribution of resources and health policy.

3.4 Scenario Analysis for Budget Impact

Table 4: Scenario Analysis for Budget Impact (in USD)

Therapeutic Area	Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Total Impact (USD)
Cardiovascular	Delayed Entry	0	1,400,000	1,600,000	1,800,000	2,000,000	6,800,000
	Faster Penetration	1,800,000					

This budget effect scenario analysis, as shown in Table 4, gives an insight into the tactics of how market entry can shift the fortunes of novel medication therapies within the cardiovascular therapeutic area financially. There are two situations: Drug A Enters Slowly and Preaches Faster.

As Drug A is only marketed beginning in Year 2, no costs occurred for Year 1 under the Delayed Entry scenario. Projected costs are assumed to be increasing year over year from Year 2, peaking in Year 5 at $2,000,000. All impacts on the budget for the duration of these five years total $6,800,000. As this example shows, although the later market entry of Drug A leads to savings in immediate costs, and with health care budgets being positively affected for at least a short time frame, the cost remains high-it emphasizes that although delaying market entry may save money immediately, it will not prevent having substantial long-term financial costs for introducing new medicines.

The Faster Penetration case study is so dramatically opposite:. In this case, Drug A has an instantaneous impact of $1,800,000 in Year 1, meaning it quickly introduces its product into the market by being uptaken more rapidly from both patients and healthcare providers. There is no mention of subsequent years in detail, but such a high cost during the introductory year will be an indicator of a strong and fast uptake of treatment. Accelerated penetration has advantages such as better patient results due to early availability of treatment and higher front-end investment that is likely to pay back much earlier in terms of health benefits, although at a greater direct financial investment by health systems.

This alters the size of the total budget impacts that the two scenarios offer with the significance of planning strategically when introducing new drugs. While the delayed entry scenario costs $6,800,000 over five years, it is perhaps more important to spend large sums early so as to adopt a quicker penetration strategy when early intervention allows for improvements in health and later cuts much more money off.

In summary, our studies emphasize the need for consideration of entry methods to new medication treatments and, therefore, their access. The choice of making new treatment processes appropriately assures the economic sustainability through the short term and long terms since the economic and social cost of better patients' results will be represented. Also, when making these choices, patient access to quality care will depend on these two elements in equilibrium.

4. RESULT AND DISCUSSION

This research provides a comprehensive assessment of the budget impact and cost-effectiveness of innovative pharmacological therapies in three therapeutic fields: neurological diseases, cancer, and cardiovascular disorders. According to the rigorous method, which integrates BIA and CEA, the results provide crucial new insights into the financial implications and feasibility of the investigated medicines.

4.1 Analysis of Cost-Effectiveness (CEA)

Results from the cost-effectiveness analysis indicate remarkable differences in ICER among the areas of therapy. In this regard, Drug A for cardiovascular disease had an ICER of $8,333 per QALY, meaning that it is cost-effective, since it would provide significant health benefits in relation to its cost. Drug A is one of the ideal candidates for acceptance into the world arenas because it has a low ICER; its use not only adds value to a patient's life but also does so at a cost that health systems can bear.

Whereas the ICER for cancer drugs on Drug B stands at $12,500 per QALY. It's higher than Drug A but well within acceptable limits. Cancer drugs are costlier because it takes millions of dollars to research and develop them. However, the cost of Drug B is justified by the possible improved patient outcomes.

Drug C with an ICER of $15,000 per QALY and indication of neurological problems is worth conducting a closer examination. With the same benefits such as significant positive improvements, drug C is not a justifiable use of health scarce resources compared to other drugs. It could mean decision-makers have to consider less strict financial costs against overall health benefits in making such treatments acceptable.

4.2 Analysis of Budget Impact (BIA)

The budget impact study reports incremental cost implications for using each of the five pharmacological therapies for five successive years. Incremental increases in the cost of Drug A were as follows: Year 1 at $1,200,000 to Year 5 at $2,000,000 for a cumulative cost of $8,000,000. This controlled growth is a responsible investment of funds-indeed a necessary one, and this is more so because the prevalence of cardiovascular diseases is increasing.

Drug B had a significantly more significant financial impact; it jumped from $2,500,000 in Year 1 to $3,500,000 in Year 5 for a total impact of $15,000,000. The cost oncology system has to bear a tremendous burden because of the high expenditure with respect to costly and complex management of these drugs, and therefore there is still room for strategic financial planning within healthcare systems.

All costs and implications of Drug C totaled $11,000,000; from Year 1 the cost had risen by Year 5 to $2,600,000 compared with $1,800,000 for Year 1. This is an enormous cost but less than Drug B, where a lot of continuous outlays had to be spent on long-term neurological disorders.

4.3 Situational Analysis for Budgetary Effects

The budget effect scenario study was performed in such a manner that various market entry tactics were demonstrated to have what influence on the bottom line. It goes to estimate that the delayed entry of drug A will affect $6,800,000 total within five years, with no upfront costs in year one, while this particular strategy may relieve financial pressure short term, it subsequently entails a huge budgetary burden.

On the other hand, in the Faster Penetration scenario, upfront costs of $1,800,000 in Year 1 would be permitted, which may enhance patient access to care even sooner. This strategy underlines the potential benefits of early intervention that would enable superior patient outcomes and mean an initial investment of funds could be justified. However, for healthcare delivery to be sustainable, proper financial planning is also required.

5. CONCLUSION

This exhaustive research into the budget impact and cost-effectiveness of innovative pharmaceutical treatments sheds light on some new profound insights about the viability of treatments for neurological, cancer, and cardiovascular illnesses. Considering the discussed analysis, Drug A is obviously one of the best options for the health care providers

since its cost-effectiveness profile is the best with an ICER that is $8,333 per QALY. Drug C, however, has an ICER at $15,000 per QALY and reflects a need for very thorough deliberation in decisions since it would have relatively modest health gains. Drug B on the other hand has an ICER of $12,500 per QALY that is well justified since it reflects such large benefits over cancer. The budget impact study can now easily demonstrate the variability of the financial implications of different therapeutic areas, with a consequent emphasis on strategic planning when drugs are introduced. Then, sensitivity and scenario studies on entry tactics and medicine prices demonstrate how effects are dramatic on budget impact and cost-effectiveness. Finally, the ultimate outcome is sound decision-making in health systems that balance patient outcomes with fiscal sustainability.

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