# Revolutionizing Patient Access: Development of Value-Based Pricing Models for Biopharmaceuticals in Emerging Markets

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# Introduction to Biopharmaceuticals and Value-Based Based Pricing

Biopharmaceuticals have revolutionized treatment for chronic and life-threatening conditions, yet their high costs pose significant access challenges, access challenges, especially in emerging markets where out-of-pocket expenses are prevalent. Traditional pricing often fails to reflect true therapeutic reflect true therapeutic value, driving global interest in Value-Based Pricing (VBP), which links drug price to actual health outcomes.

With India's growing prominence in biosimilar manufacturing, there's an urgent need to explore how VBP can improve affordability, accessibility, and accessibility, and sustainability within the Indian healthcare system and similar low- and middle-income countries (LMICs).

# Study Aim and Objectives

## 1 Evaluate VBP Feasibility and Design

Assess VBP models for improving patient access to biopharmaceuticals in emerging markets, focusing on stakeholder stakeholder readiness, systemic barriers, and policy recommendations.

## 2 Assess Awareness and Understanding

Determine current awareness and understanding of VBP among healthcare stakeholders in emerging markets.

## 3 Identify Barriers and Enablers

Pinpoint major obstacles and facilitators for VBP implementation in implementation in India and other LMICs.

## 4 Evaluate Stakeholder Perceptions

Analyze perceptions regarding the feasibility, benefits, and limitations of outcome-based drug pricing models.

## 5 Analyze Framework Applicability

Examine the applicability of VBP frameworks for high-cost therapies, particularly biologics and biosimilars.

## 6 Propose Strategic Roadmap

Develop a context-specific roadmap for piloting and scaling VBP scaling VBP models in the Indian healthcare system.

# Why Value-Based Pricing Matters

### Aligns Price with with Performance Performance

Ensures drug costs reflect reflect actual patient outcomes, fostering fair fair value exchange.

### Improves Access in Resource-Limited Settings

Promotes affordability, making crucial therapies available to more patients.

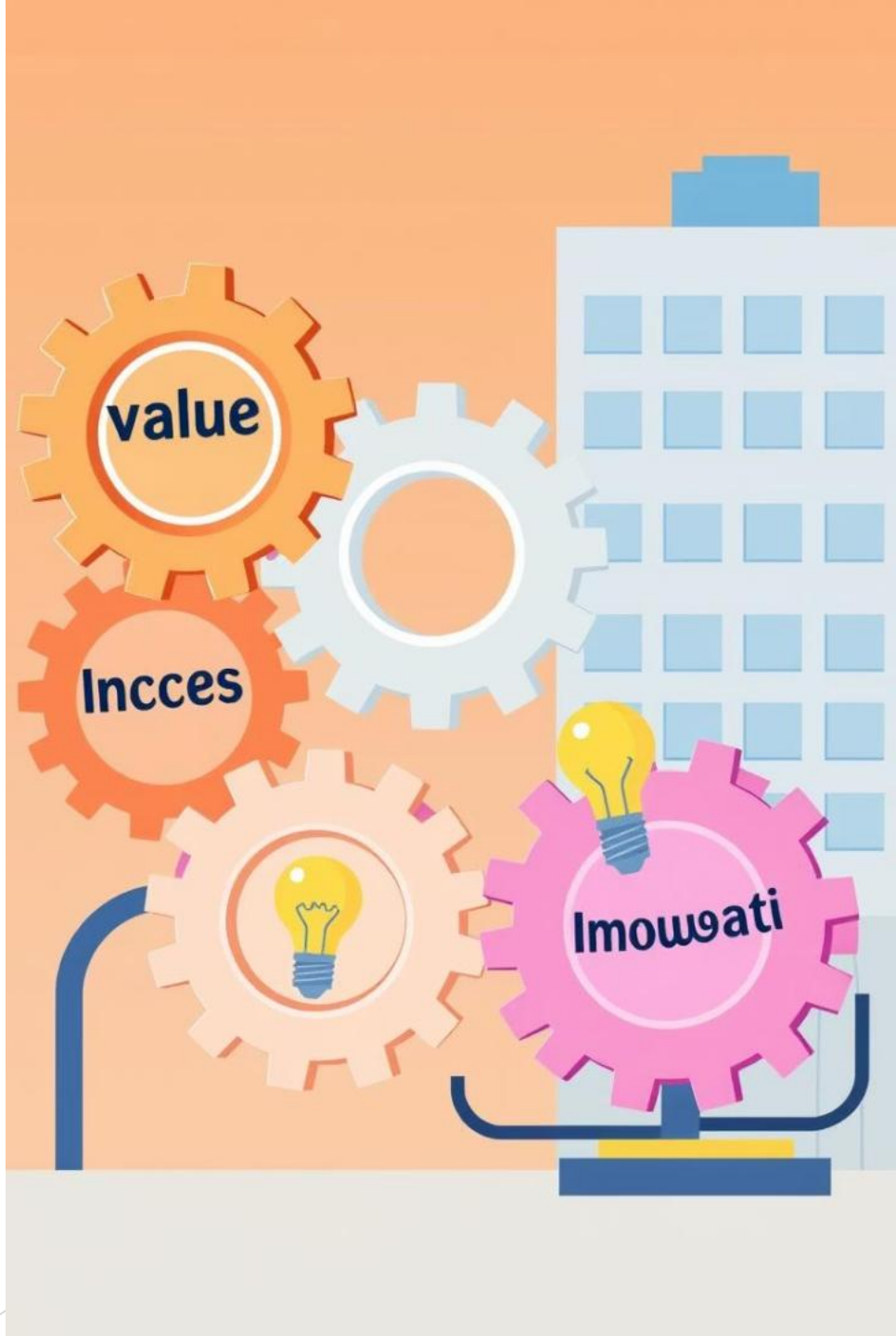
### Drives Innovation

Encourages pharmaceutical companies to focus on outcomes rather than just just marketing.

### Supports Health Health System Efficiency

Optimizes resource allocation by investing in in treatments that deliver deliver proven results.

VBP also fosters accountability across the healthcare value chain and encourages the robust use of real-world of real-world data and Health Economics and Outcomes Research (HEOR), leading to more evidence-based evidence-based decision-making and sustainable healthcare systems.



# Traditional Pricing Models and Their Limitations

| Pricing Model | Description | Limitations |
|---|---|---|
| **Cost-Plus Pricing** | Drug price = Production cost + fixed markup (e.g., 10-30%) 10-30%) | Ignores patient outcomes, discourages efficiency |
| **External Reference Pricing (ERP)** | Based on average drug prices in other countries (e.g., UK, (e.g., UK, US) | Doesn't reflect local affordability or health priorities |
| **Internal Reference Pricing (IRP)** | Price based on similar drugs within the same country | Not suitable for novel or breakthrough drugs |
| **Flat/Uniform Pricing** | One price across all market segments or geographies | No flexibility for different income levels or health outcomes |
| **Regulated/Controlled Pricing** | Government fixes prices (e.g., India's DPCO for essential drugs) | Can lead to product withdrawal or stifle innovation |
| **Tiered Pricing** | Prices differ by region or income level | Often lacks transparency; may not improve real access |

These traditional models, while offering some benefits in specific contexts, often fall short in addressing the complexities of biopharmaceutical pricing, particularly regarding true therapeutic value and equitable patient access in diverse global markets.

# Research Methodology

### Study Type

An exploratory study combining primary quantitative research with a comprehensive secondary literature review to gain a holistic understanding of VBP models.

### Study Population

A targeted sample size of 57 participants, comprising healthcare professionals, pharmaceutical industry professionals, and academic researchers, offering diverse perspectives.

### Sampling Technique

Purposive sampling (n = 57)

### Data Collection Tools

. Structured questionnaire via Google Forms

# Barriers to VBP Adoption in India

- Lack of Health Technology Assessment (HTA) Infrastructure
- Insufficient Real-World Data (RWD)
- Weak Digital Health Systems
- Regulatory & Legal Ambiguity
- Stakeholder Misalignment
- Low HEOR Capacity
- Reimbursement & Insurance Gaps

# The Role of HEOR in VBP of Biosimilars

## What is HEOR?

Health Economics and Outcomes Research (HEOR) provides real-world evidence on:

- Cost-effectiveness
- Clinical Outcomes
- Quality of life

## Why it matters?

- Adds credibility to the brand messaging
- Helps influence payers, doctors, patients
- Use in marketing
- Show real-world benefits
- Support value-based care models

HEOR is indispensable for Value-Based Pricing as it provides the necessary evidence to demonstrate the true value of biopharmaceuticals, particularly biosimilars, influencing key stakeholders and supporting a shift towards outcome-focused healthcare.

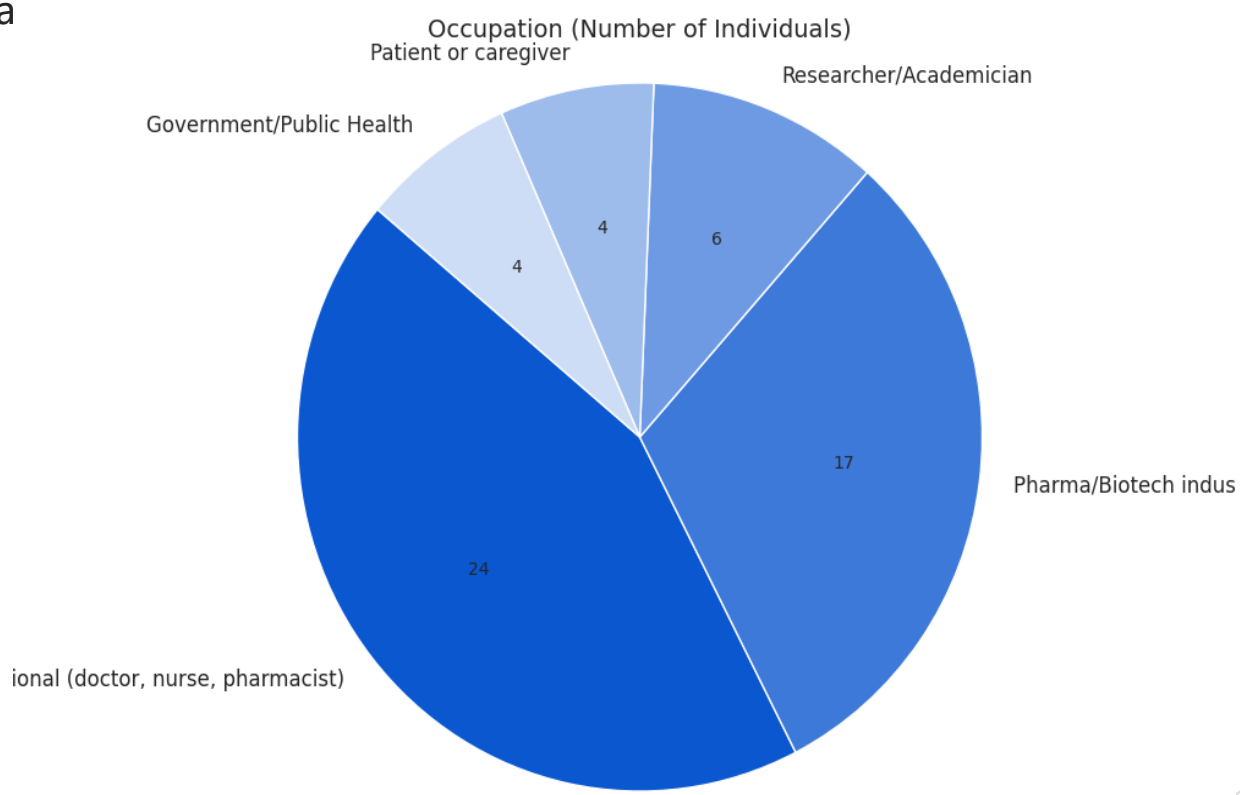
# Study Results and Key Findings

- The study gathered insights from **57 respondents** across the healthcare healthcare ecosystem, including providers, policymakers, pharma professionals, professionals, and researchers.
- The findings reflect the **current awareness, readiness, and perceived perceived challenges** surrounding the implementation of Value-Based Pricing Based Pricing (VBP) in India and similar emerging markets.
- Responses were analyzed using descriptive statistics, focusing on key key indicators like stakeholder knowledge, digital infrastructure, data availability, data availability, trust in VBP models, and expected health outcomes

# Survey responses

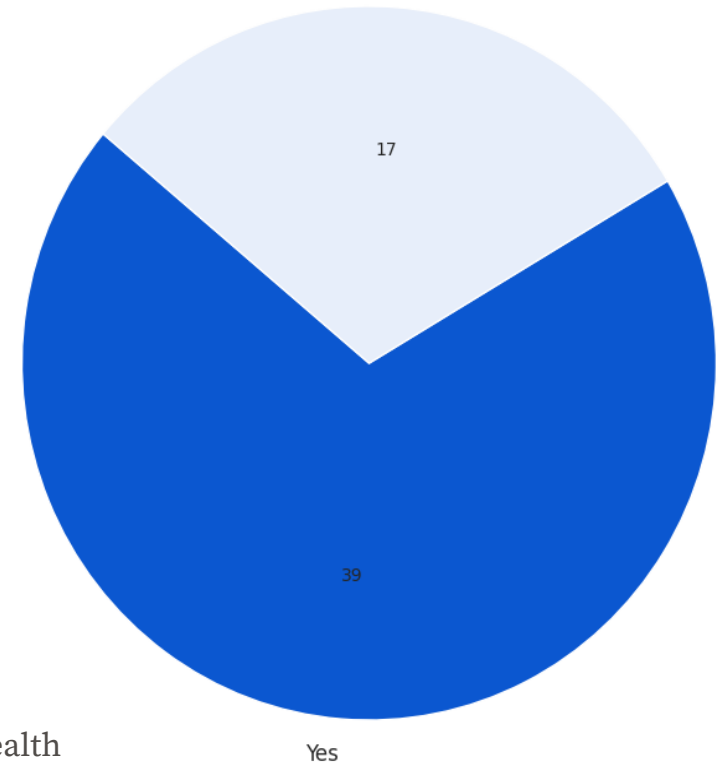
# Occupation

- Healthcare professional (doctor, nurse, pharmacist)
- Pharma/Biotech industry professional
- Government/Public Health
- Private Insurance professiona
- Researcher/Academician
- Patient or caregiver



## Do you currently have health insurance coverage?

- Yes
- No




70%

With Insurance

30%

Without Insurance

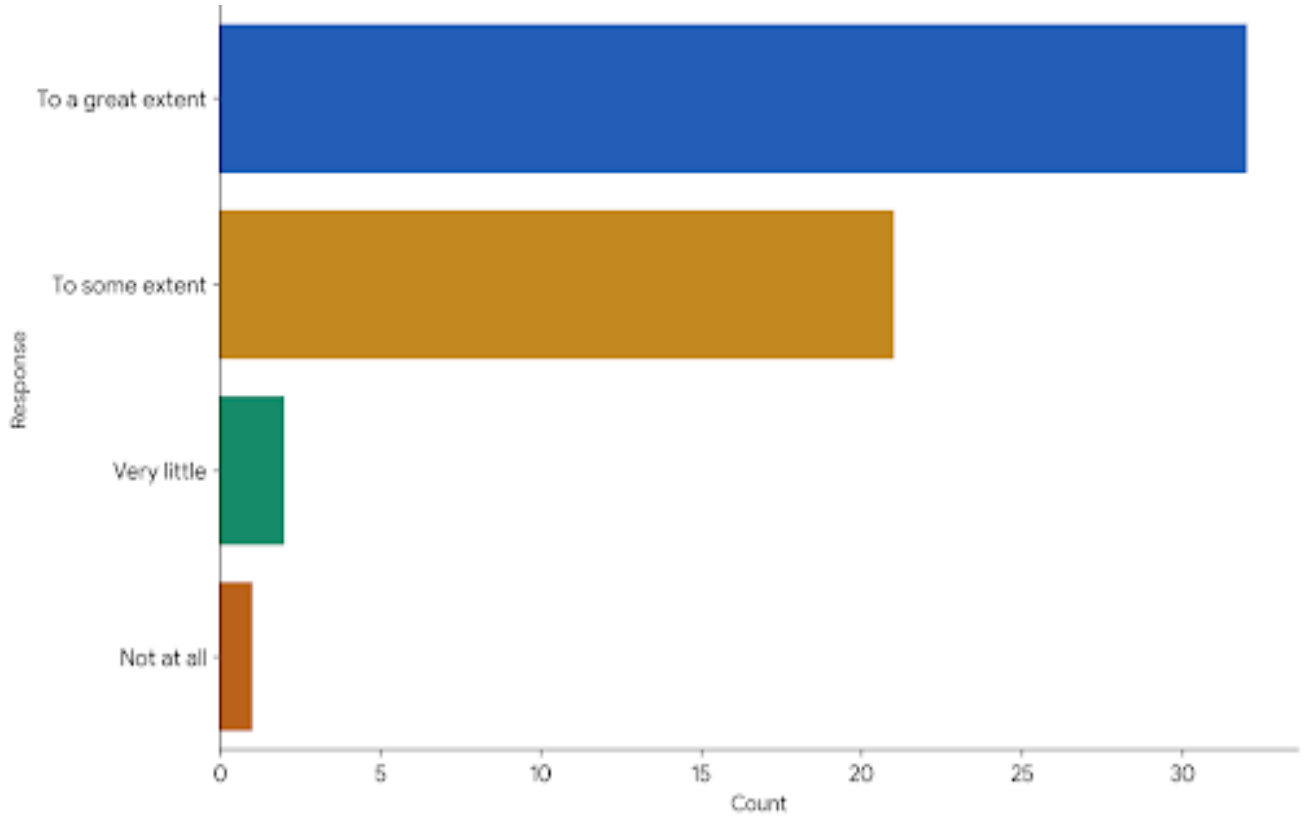
A significant majority of our survey respondents indicate they currently possess some form of health insurance coverage. This highlights the growing awareness and adoption of insurance as a crucial aspect of healthcare planning in India.

However, a considerable portion still lacks health insurance, underscoring the urgent need for broader coverage initiatives and affordable options to protect vulnerable populations from catastrophic health expenditures.

The presence or absence of health insurance profoundly impacts access to advanced therapies, especially high-cost biopharmaceuticals. This data points to a dual challenge: ensuring VBP models integrate seamlessly with existing insurance frameworks, and expanding coverage to those currently outside the safety net.

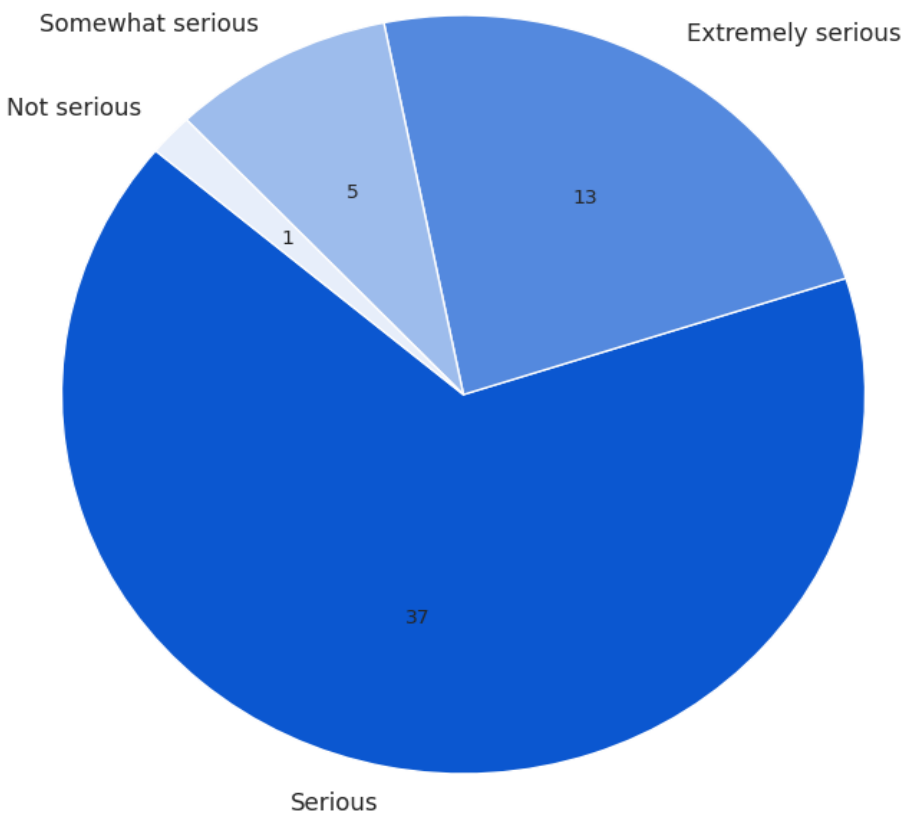
## To what extent do you believe drug pricing impacts access to biopharmaceuticals in India?

- To a great extent
- To some extent
- Very little
- Not at all
- Not sure



## How serious is the affordability issue for patients needing innovative biopharmaceuticals in India?

- Extremely serious
- Serious
- Somewhat serious
- Not serious
- Not sure

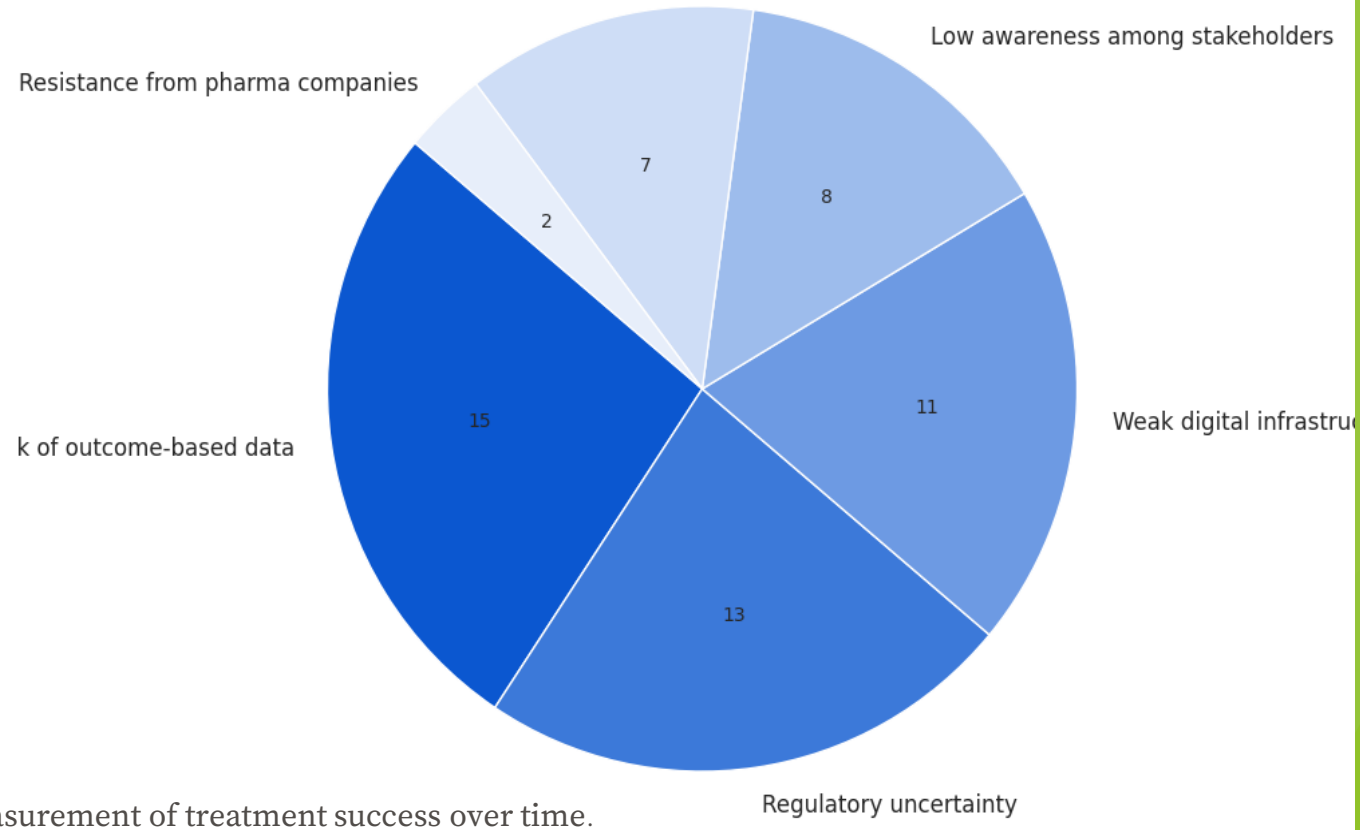



❑The perceived affordability issue for innovative biopharmaceuticals in India is largely seen as a critical concern by stakeholders. A combined 80% view it as "extremely serious" or "serious," indicating a widespread understanding of the financial burden placed on patients and the healthcare system.

❑This perception underscores the urgent need for strategies like VBP to mitigate costs and enhance access to these essential, often life-saving, treatments. Addressing this challenge requires collaborative efforts from all sectors involved in healthcare delivery.

## What are the biggest challenges India faces in adopting value-based pricing models?

- Lack of outcome-based data
- Weak digital infrastructure
- Regulatory uncertainty
- Low awareness among stakeholders
- Resistance from pharma companies
- Difficulty measuring treatment success




### ❑ Lack of Outcome-Based Data

A significant hurdle is the scarcity of robust, real-world data on patient outcomes, which is crucial for determining the true value of a therapy.

### ❑ Weak Digital Infrastructure

Inadequate digital health infrastructure hampers effective tracking and measurement of treatment success over time.

### ❑ Regulatory Uncertainty

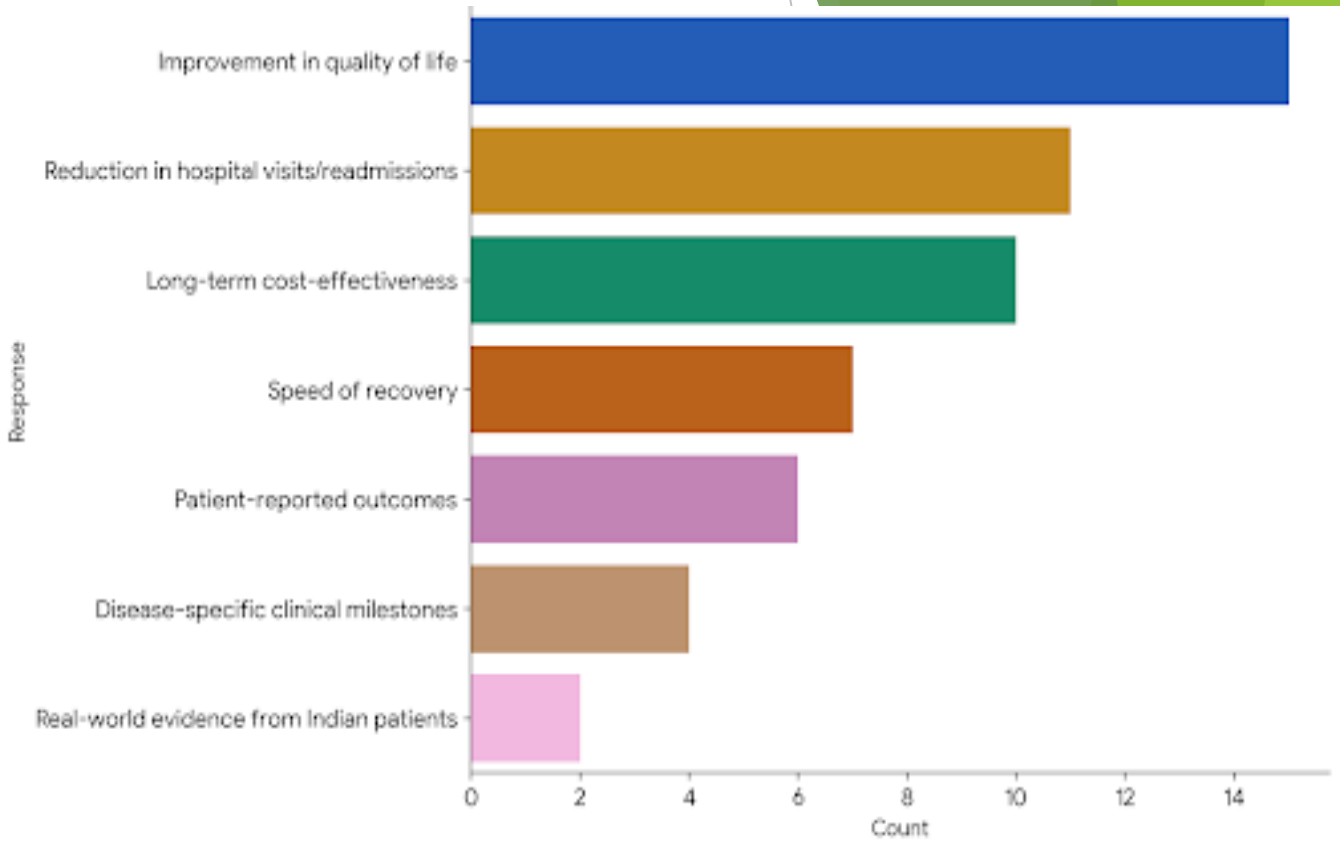
The absence of clear regulatory guidelines for VBP models creates ambiguity for both payers and manufacturers.

### ❑ Resistance from Pharma Companies

Some pharmaceutical companies may be hesitant to adopt VBP due to concerns about revenue predictability and data sharing.

# Which outcomes should be prioritized in a value-based contract in the Indian context?

- Improvement in quality of life
- Reduction in hospital visits/readmissions
- Disease-specific clinical milestones
- Long-term cost-effectiveness
- Patient-reported outcomes
- Speed of recovery
- Real-world evidence from Indian patients




**Patient-Centric Outcomes**

- Improvement in quality of life (QoL)
- Patient-reported outcomes (PROs)
- Speed of recovery and return to normalcy

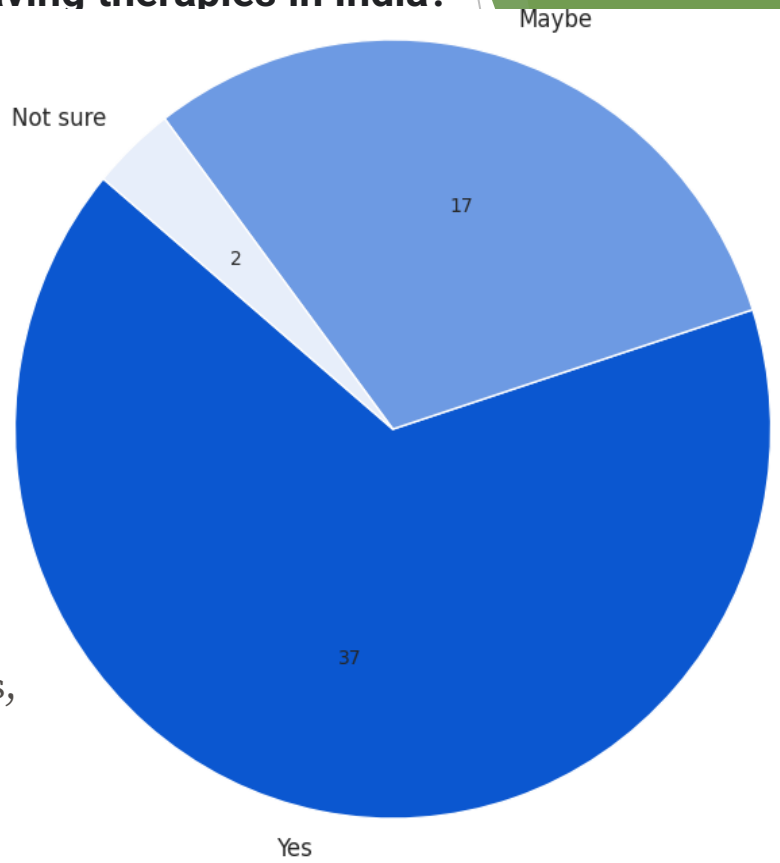
**Clinical & Economic Outcomes**

- Reduction in hospital visits/readmissions
- Disease-specific clinical milestones
- Long-term cost-effectiveness
- Real-world evidence from Indian patients

Prioritizing outcomes that directly impact a patient's daily life and well-being is crucial for VBP models in India. This includes subjective measures that reflect how patients feel and function, offering a holistic view of treatment success beyond clinical markers.

## Do you think value-based pricing could help improve access to costly, life-saving therapies in India?

- Yes
- Maybe
- Not sure




### Yes

A significant majority of stakeholders believe VBP could positively impact access to costly, life-saving therapies in India.

### Maybe

A considerable portion holds a cautious optimism, suggesting that while potential exists, successful implementation hinges on various factors.

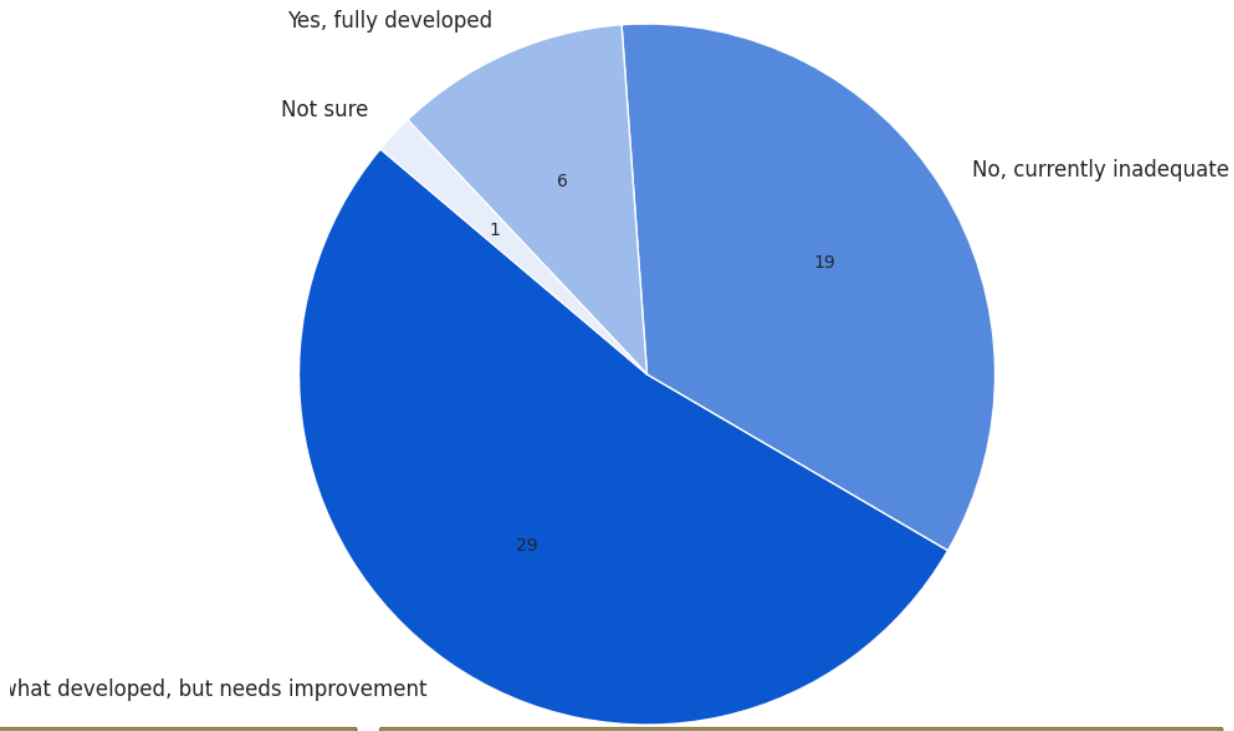
### Not Sure

A smaller group remains uncertain, highlighting the need for more education and pilot programs to demonstrate VBP's effectiveness.

The general sentiment among healthcare professionals and industry stakeholders is that VBP holds promise for improving access to high-cost treatments. By linking payment to actual patient outcomes, VBP models can incentivise pharmaceutical companies to focus on delivering tangible value, potentially making these therapies more affordable and accessible within the Indian healthcare system.

## Do you believe India currently has the digital infrastructure (like electronic health records, outcome tracking) required to implement value-based pricing models?

- Yes, fully developed
- Somewhat developed, but needs improvement
- No, currently inadequate
- Not sure




**Somewhat Developed**

The majority view India's digital health infrastructure as "somewhat developed," indicating a foundation exists but significant improvements are needed for VBP implementation. This includes upgrading electronic health records (EHRs) and establishing interoperable systems for comprehensive outcome tracking.

**Inadequate**

A considerable segment believes the current infrastructure is "inadequate," pointing to gaps in data collection, sharing, and analytical capabilities crucial for sophisticated VBP models. Investment in robust IT systems and data governance is essential.

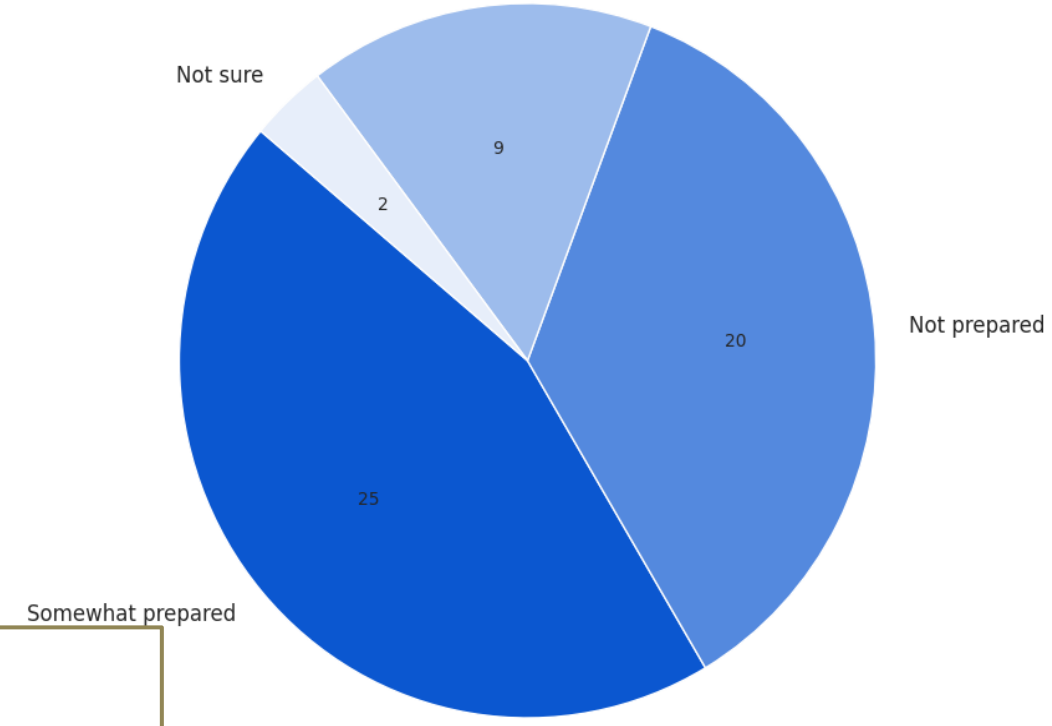
**Fully Developed / Not Sure**

Only a small fraction considers it "fully developed," while others are "not sure," reflecting varying levels of awareness and regional disparities in digital health adoption across India.

**While India has made strides in digital healthcare, a concerted effort is required to strengthen its digital infrastructure to fully support VBP models. This includes standardizing data collection, ensuring secure data exchange, and developing analytical tools that can effectively measure real-world outcomes and inform pricing adjustments.**

# How prepared are Indian pharmaceutical companies to participate in value-based pricing contracts?

- Very prepared
- Somewhat prepared
- Not prepared
- Not sure




**Somewhat Prepared**

The majority of stakeholders perceive Indian pharmaceutical companies as "somewhat prepared" for VBP contracts. This suggests that while there's an understanding of the concept, further internal restructuring, data collection capabilities, and strategic shifts are needed.

**Not Prepared**

A notable portion believes they are "not prepared," indicating a potential lack of readiness in terms of internal data infrastructure, analytical capabilities, and strategic alignment with outcome-based reimbursement models.

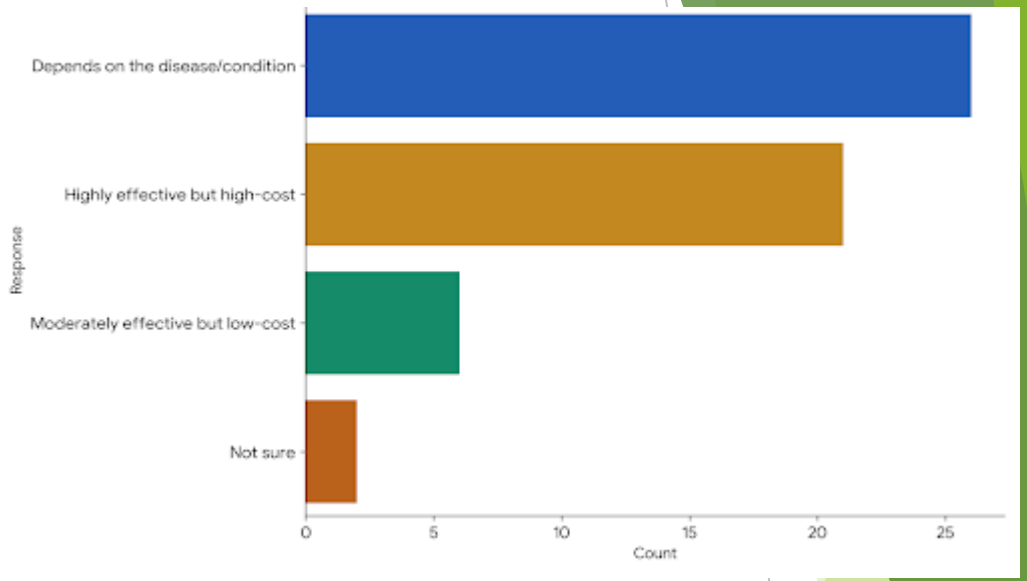
**Very Prepared / Not Sure**

Only a minority feel they are "very prepared" or are "not sure," highlighting the mixed readiness levels and the need for comprehensive industry engagement and capacity building initiatives.

Indian pharmaceutical companies will need to invest in data analytics, real-world evidence generation, and new business models to successfully engage in VBP. This transition requires a shift from traditional volume-based sales to a focus on patient outcomes and shared risk with payers.

## Would you prefer a moderately effective but low-cost treatment, or highly effective but high-cost treatment under a VBP model

- Moderately effective but low-cost
- Highly effective but high cost
- Depends on the disease/condition
- Not sure




### ❑ Depends on the Disease/Condition

A significant number of respondents indicate their preference is highly dependent on the s
disease or condition. This nuanced view acknowledges that for life-threatening or debilita
higher efficacy might be prioritised, even at a greater cost.

### ❑ Highly Effective, High-Cost

Many stakeholders would opt for a highly effective, albeit high-cost, treatment under a VBP model. This reflects a belief in the long-term value and improved patient outcomes that breakthrough therapies can offer, especially when linked to performance-based pricing.

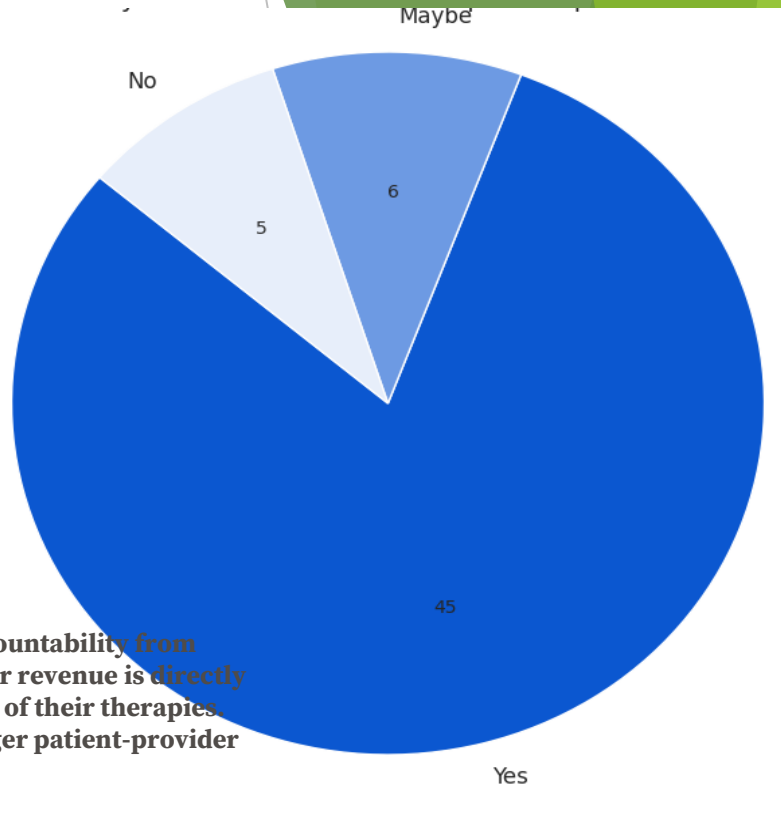
### ❑ Moderately Effective, Low-Cost

A smaller but notable group prefers moderately effective, low-cost options, particularly in the context of India's cost-sensitive healthcare environment and for less severe conditions where incremental benefits may not justify significantly higher expenses.

**This varied preference highlights the complexities of healthcare decision-making in India. VBP models must be flexible enough to accommodate different clinical scenarios and patient needs, ensuring that both cost-effectiveness and optimal outcomes are considered.**

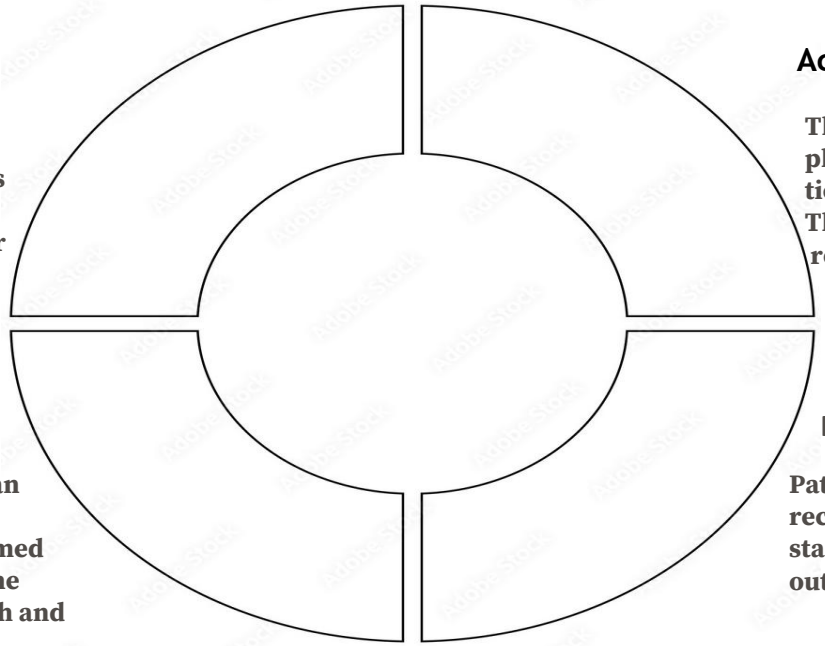
# As a patient or caregiver, would you be more likely to trust a medicine if its price depended on actual performance?

- Yes
- No
- Maybe




### Increased Trust

**Patients and caregivers are more likely to trust a medicine if its price is contingent on actual performance. This model instils confidence that they are paying for demonstrated results, rather than just the product itself.**



### Accountability

**The VBP model fosters greater accountability from pharmaceutical companies, as their revenue is directly tied to the real-world effectiveness of their therapies. This transparency can build stronger patient-provider relationships.**

### Patient Empowerment

**By focusing on outcomes, VBP models can empower patients and caregivers with more informed choices, knowing that the cost reflects the therapy's tangible benefits to their health and quality of life.**

### Fairness and Value

**Patients perceive VBP as a fairer system, ensuring they receive value for their investment. It aligns the interests of all stakeholders towards achieving the best possible patient outcomes.**

# Recommendation

## Policy Recommendations

- **Establish Health Technology Assessment (HTA) Bodies**

**Institutionalize HTA to evaluate cost-effectiveness and guide drug pricing decisions.**

- **Invest in Digital Health Infrastructure**

**Strengthen EMR systems and outcome tracking tools to enable real-world data collection.**

- **Create Legal Frameworks for Risk-Sharing**

**Develop policies that support performance-based reimbursement models.**

- **Promote HEOR Studies**

**Encourage pharma and academia to generate evidence on both patient and caregiver outcomes.**

- **Align Stakeholders**

**Facilitate collaboration among pharma, payers, providers, and regulators to co-create pilot models.**

- **Pilot VBP Models in High-Burden Therapeutic Areas**

**Start with oncology, diabetes, and immunology for proof of concept.**

# Conclusion

- **VBP is a transformative model that links drug cost to measurable outcomes.**
- **Strong theoretical support exists among stakeholders, but infrastructure gaps persist.**
- **To move forward, India must build HTA capacity, promote HEOR, and digitize data systems. systems.**
- **Caregiver roles and real-world impacts should be included in pricing decisions.**
- **With leadership in biosimilars and digital health ambition, India is well-positioned to lead VBP VBP implementation among emerging markets.**

Thank you!!!!