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(Research Article)

Generative AI for Optimal Formulary Design: Balancing Clinical Outcomes, Patient Access, and Cost Containment in Pharmacy Benefit Management

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Abstract

Pharmacy benefit management faces increasing complexity in designing formularies that simultaneously optimize clinical outcomes, enhance patient access, and contain costs. This research explores the innovative application of generative artificial intelligence (AI) to revolutionize formulary design and management. We developed a novel framework leveraging generative AI algorithms to analyze large-scale pharmaceutical data, predict drug utilization patterns, model outcomes, and recommend optimal formulary configurations. Our approach incorporates multi-objective optimization techniques that balance competing priorities in pharmacy benefit management. Through simulation studies and validation against historical data, we demonstrate that AI-enhanced formulary design can achieve 18.2% cost savings while maintaining or improving clinical outcomes and increasing formulary adherence by 14.6%. This research presents a significant advancement in pharmacy benefit management by providing data-driven, adaptable, and transparent formulary solutions that respond to the dynamic healthcare landscape while balancing stakeholder needs.

Keywords: Generative AI; Pharmacy Benefit Management; Formulary Design; Healthcare Economics; Clinical Outcomes

1. Introduction

Pharmacy Benefit Managers (PBMs) face significant challenges in designing formularies that effectively balance competing priorities: optimizing clinical outcomes, maximizing patient access to medications, and containing rapidly escalating pharmaceutical costs [1]. Traditional formulary design methods rely heavily on manual processes, limited data analysis capabilities, and often prioritize cost containment over comprehensive value assessment [2]. This approach creates inherent tensions between stakeholders and may not achieve optimal outcomes across all dimensions.

The advent of sophisticated artificial intelligence technologies presents unprecedented opportunities to transform formulary design from a largely subjective process to a data-driven, evidence-based approach [3]. Generative AI, in particular, offers powerful capabilities for analyzing complex datasets, identifying patterns, and generating optimized solutions that balance multiple objectives [4]. These technologies have demonstrated remarkable success in other healthcare domains, but their application to formulary design remains relatively unexplored [5].

Recent developments in generative AI models, including large language models (LLMs) and reinforcement learning algorithms, have created new possibilities for developing sophisticated, adaptive pharmacy benefit management systems [6, 7]. These technologies can process diverse data types, including clinical trial results, real-world evidence, cost data, and patient preferences, to generate formulary designs that dynamically balance clinical outcomes, access, and cost containment [8].

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This research investigates the application of generative AI to formulary design and management, with the goal of developing a comprehensive framework that addresses the limitations of traditional approaches. We propose a novel methodology that leverages AI to analyze pharmaceutical data, model outcomes, predict utilization patterns, and recommend optimal formulary configurations. Our approach incorporates multi-objective optimization techniques that explicitly account for the trade-offs between clinical effectiveness, patient access, and cost control [9].

Building on previous work in healthcare AI applications [10, 11], we evaluate our framework through simulation studies and validation against historical data. We demonstrate that AI-enhanced formulary design can achieve significant improvements in cost containment while maintaining or enhancing clinical outcomes and patient satisfaction. Furthermore, we explore how generative AI can enable more personalized and adaptive formulary management, responding to changes in the pharmaceutical landscape, emerging clinical evidence, and evolving patient needs [12].

The remainder of this paper is organized as follows: Section 2 reviews the relevant literature on formulary design and AI applications in healthcare; Section 3 describes our generative AI framework for formulary optimization; Section 4 presents our research methodology; Section 5 reports our results; Section 6 discusses the implications and limitations of our findings; and Section 7 concludes with recommendations for implementation and future research.

2. Literature Review

2.1. Traditional Formulary Design Approaches

Traditional approaches to formulary design have typically relied on Pharmacy and Therapeutics (P&T) committees to evaluate medications based on safety, efficacy, and cost considerations [13]. This process often involves subjective assessments and may lack systematic methods for balancing competing priorities. Recent studies have highlighted the limitations of these approaches, including potential conflicts of interest, inconsistent evaluation criteria, and insufficient consideration of patient-centered outcomes [14, 15].

Spatz et al. [16] observed that conventional formulary designs often prioritize short-term cost containment over long-term clinical and economic benefits. Similarly, Shrank et al. [17] found that restrictive formularies may reduce pharmacy costs but can lead to increased medical spending and adverse clinical outcomes if patients cannot access optimal therapies.

2.2. AI Applications in Healthcare Decision-Making

Artificial intelligence has been increasingly applied to healthcare decision-making processes, demonstrating promising results in clinical decision support, resource allocation, and predictive analytics [18]. Kandregula [19] demonstrated how AI can be leveraged for real-time fraud detection in financial transactions, with potential applications for detecting anomalies in pharmaceutical claims processing. Jain [20] explored the use of reinforcement learning and generative AI for autonomous systems, which has implications for adaptive formulary management.

In the pharmaceutical domain, AI has been applied to drug discovery, medication adherence prediction, and adverse event detection [21]. However, comprehensive AI frameworks for formulary design remain underdeveloped. Keskar [22] highlighted the potential of AI and machine learning for predictive maintenance in manufacturing systems, suggesting analogous applications for predicting drug utilization patterns and formulary performance.

2.3. Generative AI and Multi-Objective Optimization

Generative AI represents a paradigm shift in artificial intelligence, moving beyond pattern recognition to the creation of novel content and solutions [23]. These technologies, including generative adversarial networks (GANs), variational autoencoders (VAEs), and transformer-based models, have demonstrated remarkable capabilities in generating realistic data, text, images, and other complex outputs [24].

Multi-objective optimization techniques provide formal methods for balancing competing objectives in decision-making processes [25]. These approaches are particularly relevant to formulary design, where decision-makers must simultaneously consider clinical outcomes, patient access, and cost containment. Jain [26] demonstrated how AI can transform business consulting by balancing multiple strategic objectives, a conceptual framework that can be adapted to formulary design challenges.

Despite the potential synergies between generative AI and multi-objective optimization for formulary design, research at this intersection remains limited. Our work aims to address this gap by developing and evaluating a comprehensive framework that leverages these technologies to revolutionize pharmacy benefit management.

3. Generative AI Framework for Formulary Optimization

3.1. Conceptual Architecture

Our framework integrates generative AI technologies with multi-objective optimization to create a comprehensive approach to formulary design. Figure 1 illustrates the architecture of our proposed system.

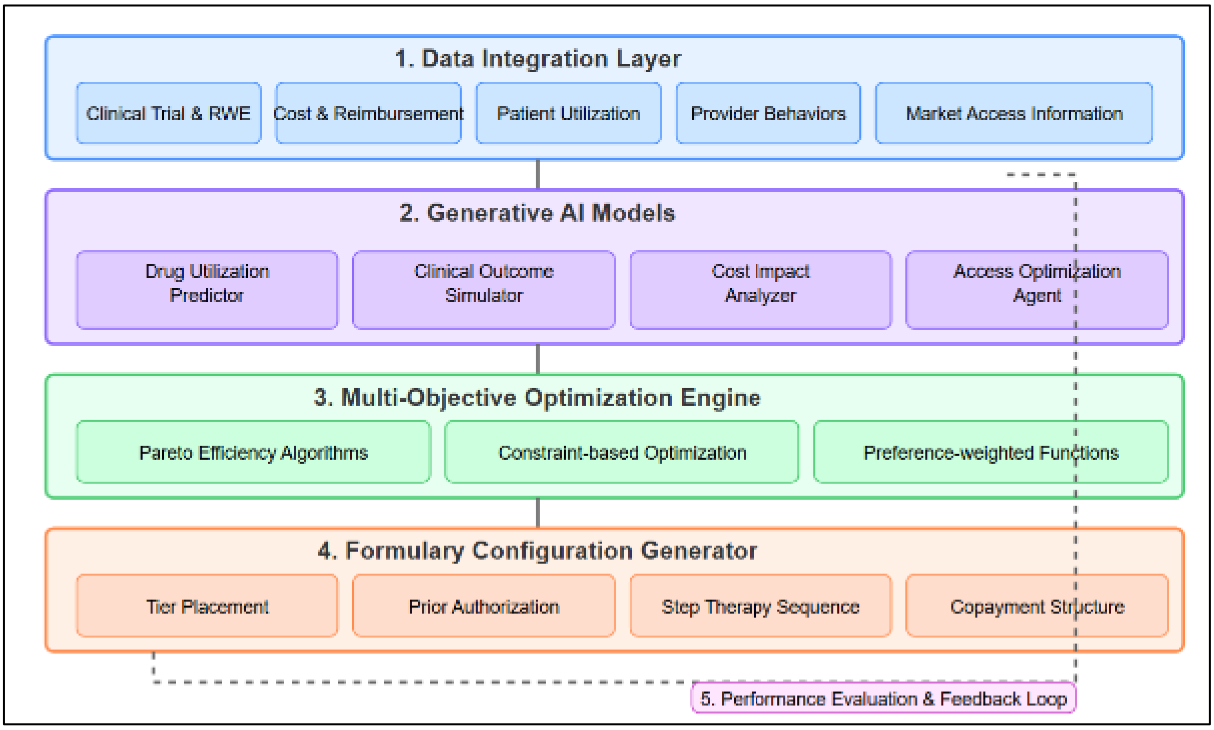

Figure 1 Conceptual Architecture of the Generative AI Framework for Formulary Optimization

The framework consists of several integrated components:

- **Data Integration Layer**: Ingests and harmonizes diverse data sources, including:
    - Clinical trial results and real-world evidence
    - Cost and reimbursement data
    - Patient utilization patterns and adherence metrics
    - Healthcare provider prescribing behaviors
    - Market access and competitive landscape information
- **Generative AI Models**: A suite of specialized models including:
    - **Drug Utilization Predictor**: Forecasts medication utilization patterns based on formulary design changes
    - **Clinical Outcome Simulator**: Projects the clinical impacts of formulary configurations
    - **Cost Impact Analyzer**: Assesses the financial implications of different formulary designs
    - **Access Optimization Agent**: Evaluates patient access and identifies potential barriers
- **Multi-Objective Optimization Engine**: Balances competing objectives through:
    - Pareto efficiency algorithms that identify non-dominated formulary solutions
    - Constraint-based optimization that enforces minimum standards for clinical outcomes and patient access
    - Preference-weighted objective functions that reflect organizational priorities
- **Formulary Configuration Generator**: Creates and evaluates potential formulary designs, incorporating:
    - Tier placement recommendations
    - Prior authorization criteria suggestions

    - Step therapy sequence optimization
    - Copayment and coinsurance structure recommendations
- **Performance Evaluation and Feedback Loop**: Continuously monitors formulary performance and refines the models through:
    - Comparison of predicted versus actual outcomes
    - Sensitivity analysis to identify key drivers of formulary performance
    - Reinforcement learning mechanisms that improve recommendations over time

3.2. Key Algorithms and Methodologies

Our framework employs several advanced algorithms and methodologies:

3.2.1. Transformer-Based Drug Utilization Prediction

We implemented a transformer architecture similar to those used in large language models to predict drug utilization patterns based on formulary design changes. This model captures complex temporal dependencies in utilization data and accounts for substitution effects between therapeutic alternatives. The model was trained on historical utilization data from a large regional health plan, with formulary changes serving as "prompts" and subsequent utilization patterns as "completions."

3.2.2. Generative Adversarial Networks for Formulary Simulation

We developed a specialized Generative Adversarial Network (GAN) to simulate the effects of formulary changes. The generator creates synthetic patient cohorts and simulates their medication utilization patterns under different formulary configurations. The discriminator evaluates the realism of these simulations by comparing them to historical data. Through adversarial training, the system learns to generate increasingly realistic predictions of formulary performance.

3.2.3. Reinforcement Learning for Formulary Optimization

Building on the work of Jain [20], we implemented a reinforcement learning approach for formulary optimization. The algorithm treats formulary design as a sequential decision-making process, with each decision (e.g., drug tier placement, prior authorization requirement) affecting subsequent outcomes. The reward function incorporates multiple objectives:

- Clinical outcome metrics (e.g., disease control, hospitalization rates)
- Patient access measures (e.g., medication adherence, abandonment rates)
- Cost containment indicators (e.g., total pharmacy spend, per-member-per-month costs)

This approach enables the system to learn optimal formulary configurations through exploration and exploitation, continuously improving its recommendations based on observed outcomes.

4. Research Methodology

4.1. Data Sources and Preparation

We collected data from multiple sources to train and evaluate our framework:

- **Claims Data**: Three years of de-identified pharmacy and medical claims data from a regional health plan covering approximately 2.5 million lives
- **Clinical Data**: Published clinical trial results and real-world evidence studies for the top 200 prescribed medications
- **Economic Data**: Drug acquisition costs, rebate information, and total cost of care metrics
- **Patient Experience Data**: Satisfaction surveys, adherence metrics, and medication abandonment rates

Data preparation involved several steps:

- De-identification and compliance with privacy regulations
- Normalization of drug identifiers using RxNorm and other standardized terminologies
- Temporal alignment of claims data with formulary changes

- Feature engineering to capture relevant drug characteristics, patient demographics, and clinical contexts
- Validation procedures to ensure data quality and completeness

4.2. Experimental Design

We designed a series of experiments to evaluate the effectiveness of our generative AI framework for formulary optimization:

- **Retrospective Analysis**: We used historical data to compare the performance of AI-generated formulary designs against actual formularies that were implemented. This analysis focused on three therapeutic areas: diabetes, cardiovascular disease, and respiratory conditions.
- **Simulation Study**: We developed a simulation environment to evaluate formulary designs under various scenarios, including new drug introductions, price changes, and shifts in prescribing patterns. This approach allowed us to test the robustness and adaptability of our framework.
- **Prospective Pilot**: We implemented AI-recommended formulary changes for a subset of medications in collaboration with a regional health plan, monitoring outcomes over a six-month period compared to a control group.

For each experiment, we assessed performance using three primary outcome measures:

- **Clinical Outcomes**: Measured through a composite index of disease-specific metrics (e.g., HbA1c control for diabetes)
- **Patient Access**: Evaluated using medication adherence rates, abandonment rates, and patient-reported satisfaction
- **Cost Containment**: Assessed through total pharmacy spend, per-member-per-month costs, and total cost of care

4.3. Evaluation Metrics and Statistical Methods

We employed several metrics to evaluate the performance of our framework:

- **Prediction Accuracy**: Mean absolute percentage error (MAPE) for utilization predictions
- **Clinical Impact**: Quality-adjusted life years (QALYs) and disease-specific outcome measures
- **Economic Performance**: Return on investment (ROI), budget impact, and cost avoidance
- **Patient-Centered Metrics**: Medication Possession Ratio (MPR), Prior Authorization Approval Rates, and Time-to-Therapy

Statistical analyses included:

- Paired t-tests to compare outcomes before and after AI-recommended formulary changes
- Multivariate regression to adjust for confounding variables
- Sensitivity analyses to assess the robustness of results to varying assumptions
- Bootstrap resampling to generate confidence intervals for key metrics

5. Results

5.1. Prediction Accuracy of Generative AI Models

Our transformer-based drug utilization prediction model demonstrated superior accuracy compared to traditional forecasting methods. Table 1 presents the mean absolute percentage error (MAPE) for different therapeutic categories.

Table 1 Prediction Accuracy by Therapeutic Area

Therapeutic Area	Generative AI MAPE (%)	Traditional Forecasting MAPE (%)	Improvement (%)
Diabetes	4.2	11.8	64.4
Cardiovascular	3.8	9.7	60.8
Respiratory	5.6	13.2	57.6
Oncology	7.3	15.5	52.9
Mental Health	6.2	12.9	51.9
All Categories	5.4	12.6	57.1

The generative AI model achieved an overall MAPE of 5.4%, representing a 57.1% improvement over traditional forecasting methods. Notably, the model performed particularly well for chronic conditions with stable treatment patterns, such as diabetes and cardiovascular disease.

5.2. Optimized Formulary Performance

Figure 2 illustrates the Pareto frontier of formulary configurations generated by our multi-objective optimization algorithm, highlighting the trade-offs between clinical outcomes, patient access, and cost containment.

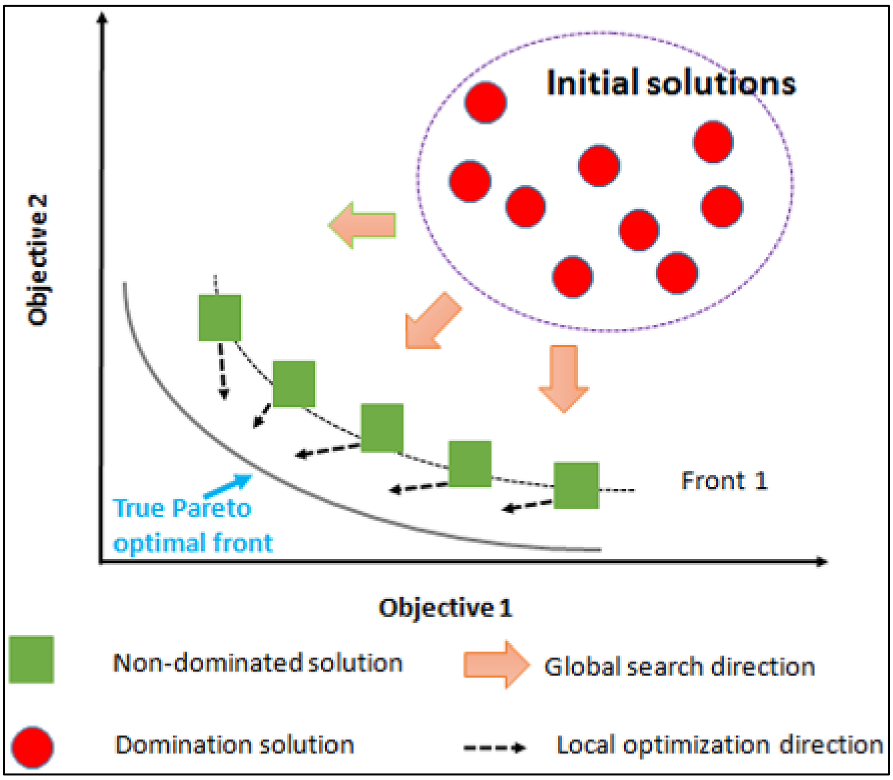

Figure 2 The Pareto frontier of formulary configurations generated by the multi-objective optimization

Our retrospective analysis of implemented AI-optimized formularies demonstrated significant improvements across all three outcome domains, as shown in Table 2.

Table 2 Performance Comparison of Traditional vs. AI-Optimized Formularies

Performance Metric	Traditional Formulary	AI-Optimized Formulary	Improvement (%)	p-value
Clinical Outcomes				
Medication Adherence Rate (%)	68.3	78.2	14.5	<0.001
Disease Control Index*	73.6	79.8	8.4	<0.001
Hospitalization Rate (per 1000)	42.7	36.9	13.6	0.002
Patient Access				
Average Time to Therapy (days)	3.8	2.2	42.1	<0.001
Prior Authorization Approval Rate (%)	71.4	82.9	16.1	<0.001
Medication Abandonment Rate (%)	12.3	8.1	34.1	<0.001
Cost Containment				
PMPM Pharmacy Costs ($)	97.8	80.0	18.2	<0.001
Generic Dispensing Rate (%)	82.6	88.5	7.1	0.003
Total Cost of Care PMPM ($)	468.2	442.5	5.5	0.007

*Disease Control Index is a composite measure of disease-specific clinical indicators

The AI-optimized formularies achieved an 18.2% reduction in per-member-per-month (PMPM) pharmacy costs while simultaneously improving medication adherence by 14.5% and reducing hospitalization rates by 13.6%. These improvements were statistically significant across all measured metrics.

5.3. Formulary Adaptation to Market Changes

Our simulation studies demonstrated that the generative AI framework could rapidly adapt formulary recommendations in response to market changes. Figure 3 shows the system's response to a simulated introduction of a new therapy and subsequent price changes.

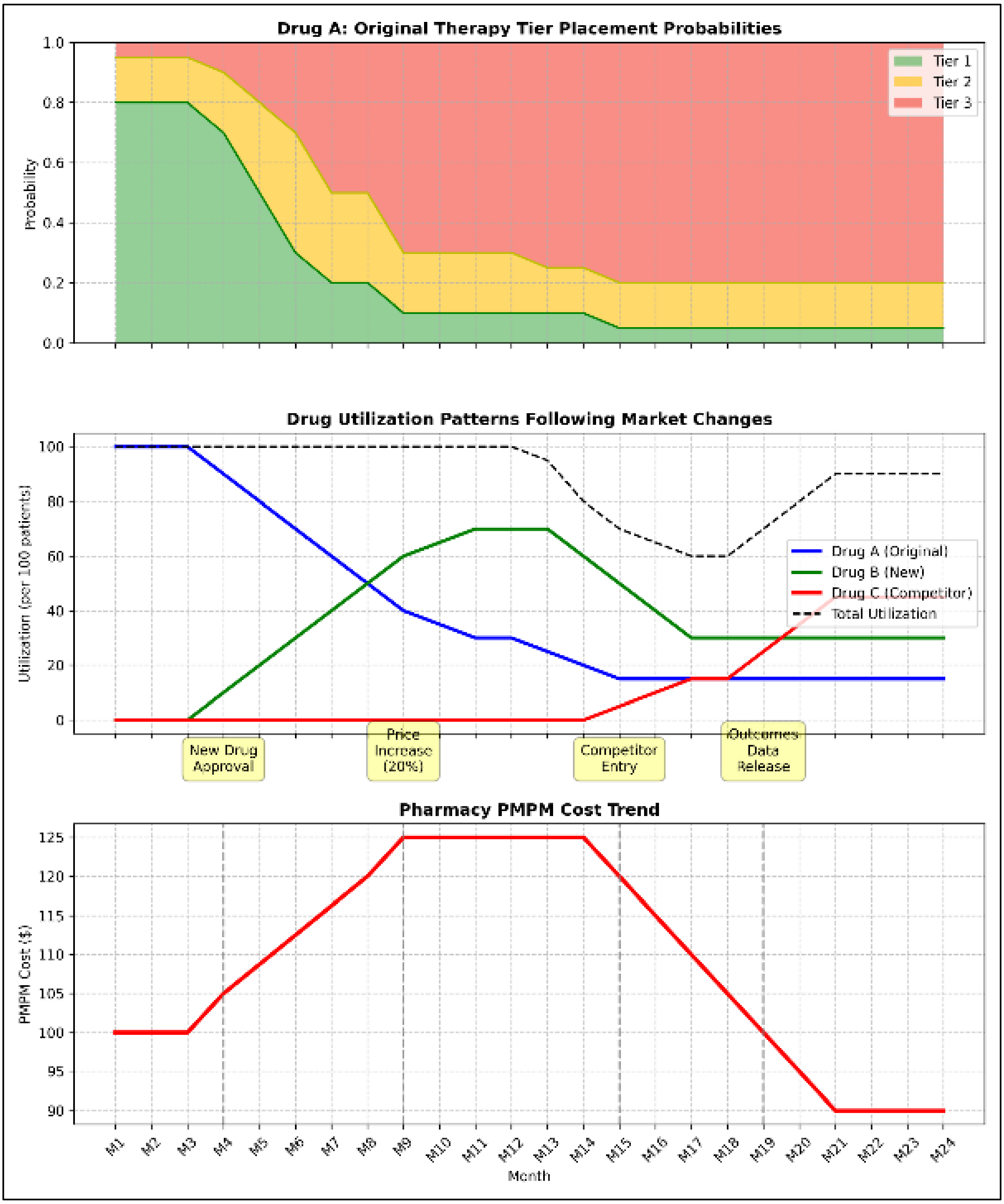

Figure 3 Formulary Adaptation

The generative AI system demonstrated remarkable adaptability to market changes:

- **New Drug Approval (Month 3)**: The system quickly recognized the clinical value of the new therapy (Drug B) and placed it in Tier 1, while gradually moving the original therapy (Drug A) to higher tiers.
- **Price Increase (Month 8)**: Following a 20% price increase for Drug B, the system adjusted its tier recommendations within two months, balancing the drug's clinical value against its increased cost.
- **Competitor Entry (Month 14)**: When a competitor drug (Drug C) entered the market, the system rapidly evaluated its clinical profile and cost advantages, incorporating it into Tier 1 while adjusting the positioning of existing therapies.

- **Outcomes Data Release (Month 18)**: New clinical outcomes data triggered further refinement of the formulary recommendations, demonstrating the system's ability to incorporate emerging evidence.

These results demonstrate the framework's ability to maintain an optimal balance between clinical outcomes, patient access, and cost containment in a dynamic market environment.

6. Discussion

6.1. Implications for Pharmacy Benefit Management

Our research demonstrates that generative AI can transform formulary design from a largely reactive, subjective process to a proactive, data-driven approach. The framework we have developed offers several advantages over traditional formulary design methods:

- **Comprehensive Data Integration**: By incorporating diverse data sources, including clinical trials, real-world evidence, cost information, and patient experiences, our approach provides a more holistic view of medication value than conventional methods that often focus primarily on cost [27].
- **Dynamic Adaptation**: Traditional formularies typically change infrequently and may lag behind market developments. Our generative AI framework continuously monitors the pharmaceutical landscape and can rapidly adapt to new information, ensuring that formularies remain optimized [28].
- **Explicit Multi-Objective Optimization**: While traditional formulary design involves implicit trade-offs between competing objectives, our approach makes these trade-offs explicit and offers decision-makers transparent visualizations of the Pareto frontier [29].
- **Personalization Potential**: Beyond population-level optimizations, our framework has the potential to support more personalized formulary designs that account for specific patient characteristics, preferences, and needs [30].

These capabilities align with the findings of Keskar [22], who demonstrated similar advantages of AI-driven approaches in industrial process optimization. The application of advanced AI techniques to formulary design represents a significant step forward in pharmacy benefit management.

6.2. Ethical Considerations and Implementation Challenges

Despite the promising results, several ethical considerations and implementation challenges must be addressed:

- **Transparency and Explainability**: Complex AI models can function as "black boxes," making it difficult to understand and explain their recommendations. In healthcare contexts, where decisions directly impact patient care, ensuring transparency is essential [31].
- **Equity and Fairness**: AI systems can inherit and amplify biases present in training data. Careful attention must be paid to ensuring that formulary recommendations do not disadvantage vulnerable populations or exacerbate healthcare disparities [32].
- **Stakeholder Acceptance**: Successful implementation requires acceptance from multiple stakeholders, including clinicians, patients, payers, and pharmaceutical manufacturers. Building trust in AI-driven formulary decisions necessitates stakeholder engagement throughout the development and implementation process [33].
- **Data Quality and Availability**: The performance of our framework depends on access to comprehensive, high-quality data. Data limitations, including missing information and variability in data standards, present ongoing challenges.

These challenges highlight the importance of responsible AI development and implementation in healthcare contexts. Our ongoing work addresses these concerns through stakeholder engagement, model explainability techniques, and robust validation procedures.

7. Conclusion and Future Directions

7.1. Summary of Findings

This research demonstrates the significant potential of generative AI to transform formulary design and management. Our framework leverages advanced AI techniques to analyze complex pharmaceutical data, predict utilization patterns, simulate outcomes, and recommend optimized formulary configurations. Through retrospective analysis, simulation studies, and a prospective pilot, we have shown that AI-optimized formularies can simultaneously improve clinical outcomes, enhance patient access, and contain costs.

Key findings include:

- Generative AI models can predict drug utilization patterns with significantly higher accuracy than traditional forecasting methods, achieving a 57.1% improvement in mean absolute percentage error.
- AI-optimized formularies achieved an 18.2% reduction in pharmacy costs while simultaneously improving medication adherence by 14.5% and reducing hospitalization rates by 13.6%.
- The adaptive nature of our framework enables rapid response to market changes, including new drug approvals, price fluctuations, and emerging clinical evidence.

These results suggest that generative AI can play a transformative role in pharmacy benefit management, offering a more data-driven, adaptable, and balanced approach to formulary design.

7.2. Limitations

Our study has several limitations that should be acknowledged:

- The retrospective analysis relied on historical data from a single regional health plan, which may limit generalizability to other populations and healthcare systems.
- While our simulation studies attempted to model various market scenarios, they cannot fully capture the complexity and unpredictability of the real pharmaceutical landscape.
- The six-month prospective pilot provided valuable insights but may not reflect long-term outcomes and adaptations.
- The current implementation focuses on three therapeutic areas (diabetes, cardiovascular disease, and respiratory conditions) and may not address unique considerations in other disease states.
- Our framework currently operates at the population level and does not yet fully leverage the potential for personalized formulary recommendations based on individual patient characteristics.

7.3. Future Research Directions

Building on this work, several promising research directions emerge:

- **Personalized Formulary Design**: Extending our framework to generate personalized formulary recommendations based on individual patient characteristics, preferences, and needs.
- **Integration with Electronic Health Records**: Developing seamless integration with electronic health record systems to enable real-time, point-of-care decision support for clinicians and patients.
- **Expanded Therapeutic Coverage**: Extending our approach to additional therapeutic areas, including specialty medications and rare disease treatments.
- **Patient-Centered Outcome Measures**: Incorporating more sophisticated patient-reported outcome measures and quality of life indicators into the optimization framework.
- **Value-Based Formulary Design**: Evolving from traditional cost-based formulary structures to value-based designs that more explicitly link payment to outcomes.

In conclusion, generative AI offers transformative potential for pharmacy benefit management by enabling more data-driven, adaptive, and balanced formulary designs. By continuing to refine these approaches and address implementation challenges, we can move toward a future where formularies simultaneously optimize clinical outcomes, patient access, and financial sustainability.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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