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AI-Optimized Formulary Designs Addressing Social Determinants of Health

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Abstract: Formulary design the way payers, PBMs, and health systems choose which drugs to cover and the terms under which they cover them has recently been recognized as a contributor to both pharmacoequity and health equity. While the social determinants of health (SDoHs) like socioeconomic status, neighbourhood deprivation, housing, transportation, and access barriers all play a major role in health outcomes as well as access to and use of medications. This paper presents a conceptual and methodological framework to meet the challenges of integrating artificial intelligence (AI) with formulary design in consideration of the social determinants of health, to improve formulary design in order to reduce inequities in coverage policies, access pathways, and benefit designs. And summarize the literature on social determinants of health and formulary policy, providing a checklist of major AI methods machine learning, predictive analytics, optimization, and decision support before presenting a multi-phase framework: (1) data aggregation and SDoH construction, (2) predictive analytics of medication access/outcome by SDoH strata, (3) formulary optimization with equity constraints, and (4) execution and evaluation. also provide examples of hypothetical cases (ex. diabetes medications, newly introduced biologics) and identify some operational, ethical, legal, and methodological challenges. And provide suggestions for future work and discuss what changes to policy and practice would stem from it.

Keywords- *Formulary design; social determinants of health; AI; pharmacoequity; health equity; predictive modelling; benefit design*

1. Introduction

The design of pharmaceutical formularies has always placed its focus on three main components. This includes the clinical efficacy and safety of the medication, the cost of the medication, and the various techniques of utilization and cost containment such as tiering, prior authorization, and step therapy. These factors have always determined the decisions made concerning the formularies for the most important and basic priority of covers for patients, which is affordability and effectiveness of medications. The main objective of the last approaches looks for the most basic covering. However, recent approaches take for granted the most basic covering approaches, while consistent coverage is available. However, recent approaches take for granted the most basic covering approaches while ignoring the overarching coverage and complexity of the challenges confronting healthcare systems. These challenges are mainly ensuring equity for healthcare systems. Coverage equity is often lacking even for policies that have been proven to work. Most disparities continue to marginalize certain groups of people by geo-economic, socio-racial, and ethnic divides, and are often compounded by structural inequities that remain unaccounted for in the ways formularies are designed.

According to public health and policy studies, the concept of soci Determinants of Health (SDoH) have taken off rapidly over the years. SDoH refers to education, income, housing, employment, and healthcare accessibility. These socio economic conditions influence the health outcome of an individual and the healthcare consumption. Historically, health and services access is inequitable to disadvantaged groups. Given the extent SDoH affect health outcomes, it is no longer reasonable to consider only cost control when designing formulary and access pathways. If equity in healthcare delivery is the goal, the SDoH must

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also be taken into account. The gap between healthcare effectiveness and equitable access has more refined formulary designs. These designs address SDoH and the inequitable access to needed care and medicines.

Artificial intelligence has the potential to create new ways of structuring formularies using more efficient, fair, and innovative ways. AI has the ability to comb through large databases, even ones with SDoH, to create models that can predict medication access and medication outcomes based on population segments. These models can shed light on social factors that affect a patient's ability to adhere to a medication, the success of a medication, and the overall use of healthcare systems. Furthermore, AI can be used for the formulation of algorithms to create a formulary structure that incorporates a focus on equity. For example, formulary benefit designs can be used to eliminate barriers to access for higher resource and lower resource patient groups, reducing the inequities in access to necessary medication and healthcare that are experienced by the most disadvantaged groups in a population.

This paper explores the potential of AI (Artificial Intelligence) in optimally designed AI-Driven Radial Formulary systems focusing on appraising the social determinants of health and advancing pharmacoequity. The integration of AI into the formulation of plans ought to enable health systems to strategically and proactively respond to socially determined inequities in health so that all systems attain cross-sectional functional equity in the health outcomes of the entire population. This paper presents evidence of the relationship between SDoH and inequities in the accessibility of medications and formulary policy. It highlights the AI methodologies to bridge the inequities and proposes an AI-optimally designed formulary system. It presents illustrative examples and discusses the system implementation barriers and proposed solutions. Finally, the paper presents potential avenues for policy formulation and research.

Literature review

Social determinants of health and medication access

A solid collection of literature focusing on social determinants of health (SDoH) states that there are uncountable factors that affect health outcomes and health service usage. In addition to clinical care, some factors that need to be taken into consideration are social, economical, and environmental living conditions (SDoH) [1]. Some SDoH factors are education, income, housing, neighborhood, and social support [2]. Research shows that people from more deprived and disadvantaged neighborhoods have lower rates of therapy initiation, and medication adherence and have worse outcomes compared to more privileged people [3]. These inequities are often aligned with socioeconomic gradients. Even though inequities are often taken for granted, health gaps are closing thanks to civil(rights) motivated policies and social investments [4]. In regards to access to medication and the use of pharmacies, literature examining SDoH factors has not been extensive, but it is evident that the social and structural factors SDoH embraces need to be considered in the design of formularies to improve access to medications and health outcomes [5].

Formulary design and pharmacoequity

The design of a formulary, which is the determination of what drugs, and under what conditions, payers, health systems, and pharmacy benefit managers cover and at what cost, has, until recently, primarily been concerned with three areas: clinical efficacy and safety of medications; cost of medications; and various measures of utilization/cost containment (tiering, prior authorization, step therapy, etc.) [6]. However, a growing body of literature has illustrated the shortcomings of this traditional approach, suggesting that formulary design must incorporate at a minimum access inequity. Pharmacoequity means that patients, regardless of race, class, or resource availability, should be able to access the highest quality evidence-based therapy [7]. Numerous reviews have suggested that equity should be considered with respect to three fundamental components of formulary design: clinical criteria, processes and burdens of prescription/prescriber demand, and patient access policies like cost sharing and dispensing flexibility [8]. Despite increased attention on these topics, many formulary decision processes still utilize a “one size fits all” approach and do not incorporate the social determinants of health (SDoH) that influence access to care [9]. This highlights the need for developing more flexible and structured approaches to incorporate SDoH into formulary management and improving pharmacoequity [10].

AI in Healthcare and Decision Support

While discussing formulary design, a growing number of literature analyzes how AI can be used in healthcare, focusing on predictive modelling, decision support, and personalized better outcomes [11]. AI has the ability to improve clinical decision making and patient outcomes in healthcare by predicting outcomes with high accuracy from large patient datasets, modeling complex relationships that are impossible for human clinicians to discern. For example, applications of AI include diagnostic decision support, patient data analytics, and clinical decision support [12]. However, some researchers warn that AI has the potential to create or amplify existing inequities in health, especially when the data set used to train the algorithms is non-representative, or when the algorithms operate without assumptions of social variables like income and access to health care [13]. AI systems that operate without explicit consideration of social justice are likely to reinforce the very stereotypes and biases that sustain inequitable health outcomes. The literature on AI in healthcare, therefore, has placed a premium on the equitable design of healthcare AI systems to avoid widening existing gaps in health outcomes.

Integrating AI, SDoH, and Formulary Design: Emerging Evidence and Gaps

Reviewing the literature on SDoH, formulary design, and AI illuminates a passionate but comparatively neglected frontier. The literature on SDoH and its relevance to the healthcare delivery system is extensive, but the intersection of AI and formulary management with SDoH is virtually absent. There is work on value-based formulary design, and on the application of AI in healthcare, but this work does not demonstrably address the full incorporation of SDoH in the modeling of decision-making processes. [14]. The most recent scholarship in formulary policy proposes that AI be utilized to refine the design and benefit structure of a formulary; however, this remains a developing concept. Similarly, SDoH is largely absent in the literature around AI and clinical decision support systems, particularly in relation to access to medications and formulary design. It is this in this gap that the most pertinent research is situated; the intersection of SDoH, the design of a formulary, and the application of predictive analytics [15].

The intersection among SDoH, AI, and formulary designing present multiple solutions to ensure equitable healthcare access, enabling patients to receive the medication they most need, despite their social situations.

3. Artificial Intelligence Methods for Formulary Design

This part of the paper describes some of the AI and computational tools needed to inform and enhance formulary with SDoH data. These tools can help accelerate equity in access and address inequity in access. They enable the formulation of benefit designs to be data driven and more equitable.

3.1 Data Integration and Feature Engineering

To take full advantage of AI in formulary design, more than clinical or administrative medication data need to be integrated. This clinical data need to be SDoH data such as socioeconomic status, neighbourhood deprivation, housing stability, food insecurity, transportation, and education. These data are contextual factors that help to explain health and health outcome disparities. For example, data on neighbourhood deprivation and housing vacancy can help explain some of the environmental barriers to care and barriers to medication access. Data on transportation and the food environment can explain barriers to medication adherence.

As of now, can now merge patient-level clinical records with an example of SDoH datasets which are publicly accessible. One example of this strategy is the creation of ontologies such as SDoHO (Social Determinants of Health Ontology), which organizes and systematizes the assimilation of various social and environmental datasets into a digestible form for artificial intelligence models. Such ontologies can assist in the embedding of SDoH into advanced analytic models and formulary decision making, so as to address patient needs in a more customized and just manner in differing social situations.

Feature engieering helps to transform raw data to useful inputs to be used by AI models. A form of feature engineering is building composite indexes like deprivation scores that combine multiple SDoH factors into a singular value. This allows the model to capture the total amount of social disadvantage a patient or community is experiencing. Another form is spatial linkage where patient addresses are mapped to pertinent neighbourhood variables like crime, public transport accessibility, and healthcare service proximity. Lastly, AI can analyze

unstructured data like social risk mentions found in electronic health records or patient notes. NLP allows the AI to obtain valuable pieces of information needed in formulating certain health plans.

3.2 Predictive Modelling

Predictive analytics ML models like gradient boosting and random forests are highly effective and adaptable for forecasting various patient outcomes and are highly usable for predicting elements of formulary design like the probability of starting a medication, medication adherence, medication persistence, and key clinical outcomes like controlling diabetes, or rates of hospitalization. Incorporating SDoH into the models helps understand the role that social factors like medication access and medication adherence. Predictive models might include the understanding that patients from lower income or those with inadequate transportation.

It can be noted that models like these can also help pinpoint high social vulnerability, and other at-risk subgroups that are likely to face barriers along the way and understand the impact of SDoH on the pathways to medications. This helps formulary decision makers appreciate the confluence of social disadvantage and medical need and helps in the implementation of tailored solutions. For example, the model could show that some clinically effective but expensive medications are less likely to be prescribed to patients from underserved populations even though they have other barriers such as high out-of-pocket costs, transportation issues, or low health literacy. These barriers can be explored using predictive modeling and the results can help formulary managers develop more equitable coverage solutions in order to close the gaps.

3.3 Optimization and Decision Support

AI can optimize formulary designs, based on earlier modeling, once predictive models have been developed. Implementation of integer programming, multi objective programming, and constrained optimisation techniques tries to balance multiple objectives (access equity, cost containment, and clinical outcomes) simultaneously. For example, an optimisation model can formulate an objective to ensure that no significant disparity in access rates exists between low resource and high resource patient subgroups, while the overall cost of medications in the health system, is minimized.

AI optimization models work best when it comes to making policies concerning tiering medications and setting cost sharing and prior authorisation rules. Decisions support systems can use predictive analytics to run simulations to look at possible outcomes from various changes in a formulary. For instance, what will be the impact, in terms of access, changes in medication adherence, cost of the medication, and equity, if prior authorisation is not required for a medication that is critical for patients who have a high SDoH risk, or if cost sharing is eliminated for certain vulnerable patients? AI powered optimisation helps formulary decision makers understand the impact a policy change has to make data driven, equitable, and balanced decisions.

3.4 Monitoring and Adaptive Learning

After implementing an AI-optimized formulary design, it is important to monitor its effect and make adjustments over time. Access, adherence, clinical outcome, cost, and equity trends should be monitored against pre-determined target (KPIs). AI models and frameworks should incorporate active monitoring and reporting systems enabling formulary managers to discover disparities in access, adherence, and outcome metrics. These systems can detect the presence of certain subgroups (e.g. high SDoH risk) facing barriers to policy-responsive changes, enabling prompt action.

Also, new data can have reinforcement learning and adaptive algorithms fine-tune formulary parameters. These AI systems can learn from past outcomes and modify formulary decisions as new social and clinical evidence is available and as population needs change. For example, if new evidence comes to light stating that specific medications are far more advantageous to underserved populations, the AI system could automatically change formulary recommendations to include those therapies, thus enhancing access and outcomes for high risk patients. The adaptive nature of AI allows formulary systems to remain highly responsive to new developments so that coverage policies continue to be effective and equitable.

4. Proposed Framework: AI-Optimised Formulary Design for SDoH

This section outlines the first comprehensive four-stage framework dealing with pharmaceutical formularies sensitive to the social determinants of health (SDoH) and augmented with artificial

intelligence (AI). This framework seeks to design formularies that enhance clinical effectiveness and cost-efficiency while simultaneously addressing and alleviating the barriers to access and inequitable outcomes for dispensed medications for vulnerable patients.

Collection of Data and SDoH profiling

The first stage of the proposed framework is the collection and unification of multi-source data that builds the basis for the later stages. This stage should consider the collection of data from various sources such as clinical and medication claims data, pharmacy claims, pharmacy utilization and socio-demographic and geospatial neighborhood data. The integration of these various data types is needed for the comprehensive assessment of patients and their access to care. For instance, integration of geospatial information, e.g., neighborhood deprivation index, housing vacancy rate, and access to public transit can help illustrate social determinants that affect medication access and adherence, as well as disparity, inequity, and inequitable access to medications in certain communities.

Once the data is gathered, the next step is the development and verification of certain SDoH characteristics. These characteristics are important for modelling, and they include things like neighbourhood deprivation (ex. income inequality and lower education levels), housing instability (e. g. frequent moves or evictions), and loss of transportation (e.g. unavailable public transit services), and surrogates for health literacy (ex. health information deficit). Positive confirmation of these characteristics ensures that they are social adversities that might constrain patients' ability to access and stepwise medication adherence.

After this, populations are stratified based on their SDoH risk segments and patients are assigned to categories of high, medium, and low SDoH challenge. This stratification enables deeper understanding of the social risks that are influencing medication outcomes and ensures that these SDoH profiles are corresponding with the medication access and clinical outcomes. This step is important to ensure that social factors are accommodated before the derived risk modelling or the optimum formulary is designed.

Predictive Modelling of Access & Outcomes

Once able to identify SDoH and stratify patients into populations, also can begin developing predictive models. These models will focus on estimating metrics such as medication initiation, adherence, persistence, and clinical effectiveness, with the focus being on SDoH stratification. For example, a predictive model could be built to estimate the likelihood of medication initiation based on factors like formulary coverage, prior authorisation, cost-sharing, and the SDoH features identified in Stage 1. By modelling the SDoH features, and can estimate whether patients of various SDoH strata are more or less likely to initiate a prescribed medication.

In addition to medication initiation, the models also estimate the likelihood of patients with those prescriptions filling their prescriptions, staying on those medications (persistence), and staying on those medications (persistence) over time. For example, patients with SDoH risk in the high range may have more access barriers associated with reduced adherence, such as cost-sharing and transportation barriers. The model is able to estimate the extent of and predict the adverse effect of these challenges on clinical outcome attainment, such as control over the disease (HbA1c for diabetes) or the rate of hospitalizations. Having these estimates made the exclusion of some patient groups from plan formularies easier and more rapid. With the estimates from the model, the people designing formularies were able to know which patient groups were most socially disadvantaged and likely to have clinically adverse outcomes and target those patients for their clinical interventions.

Also, the models are able to measure current formulary designs and their impact on other SDoH differentials and gaps both on the access side and outcome side. This measurement is the first step towards understanding how formulary policies may have differential negative impact on low-resource SDoH population and is one of the most important data needed for step (process) to be efficient in the next step.

Formulary Optimisation Under Equity Constraints

Using predictive modeling; the next step involves optimizing the formulary design to address inequities of access and outcomes of medications. The objective is to design formulary structures to achieve criticisms of cost minimization and inequities of access and adherence of high- and low-SDoH groups. This step requires setting specific criteria and determining specific decision variables.

The objectives can be to achieve cost minimization of medications and cost of downstream health care (hospitalization complications) while keeping inequities of access and adherence of high SDoH and Low SDoH groups to an equitable constrained target. Decision variables for this step include the selection of medications to be added on the formulary; tiering of medications; cost-sharing levels; prior authorization requirements; targeted subsidies to high SDoH risk groups; and inclusion of the formulary.

When incorporating these decision variables into the optimisation process, these factors also include the additional factors such as budgeting, clinical guidelines, safety, policy, equity. For instance, one might be if the access gap for high-SDoH and low-SDoH patients could not be over a certain degree, thereby allowing the formulary design to prioritise equity over cost containment.

With these parameters established, optimised algorithms can be used for a multi aim design of the formulary. In addition, changes to the formulary rules can be used to predict "what if" scenario analyses. For example, the evaluation of opening cost-sharing for patients in high-SDoH neighbourhoods or removing prior authorisation for certain high-impact interventions can be used to predict changes to access, clinical and equity outcomes.

Implementation, Tracking, and Adaptive Continuous Improvement

The final part of the framework is implementation, tracking, and adaptive continuous improvement of the design of the formulary. After the ideal formulary has been developed, it needs to be installed into the healthcare system, and its effects need to be tracked. There needs to be tracking of key performance indicators (KPIs) such as initiation and adherence rates, clinical outcome metrics (e.g. HbA1c levels for diabetes), and cost trends. There also needs to be monitoring of equity metrics such as the degree of difference in access and outcomes for high SDoH versus low SDoH populations.

In the model, equity was the left variable, and remaining equity gaps. If equity gaps were to remain above the tolerable threshold, there were allowed to be modifications of the decision variables, such as additional decreases of cost sharing for certain high-risk groups, looser prior authorization for essential medications, or additional outreach and education for the targeted high-risk groups.

Also, adaptive learning algorithms allow the system to frequently change predictive models as new data comes in to continuously improve formulary decision making in real time. This adaption in real time helps ensure that the formulary is fair, accessible, and effective, especially as new data comes in or there are changes to the social and health system. For example, the AI system is able to adjust and reformulate new therapies when there are changes to patient behaviors or patterns in social determinants of health.

5. Illustrative Case Examples

The proposed AI optimized formulary framework aims to improve the equity of medication access and health outcomes for vulnerable populations affected by social determinants of health.

5.1. Diabetes Therapy Example

A payer in charge of a population with type 2 diabetes discovers that customers living in severely deprived areas are 25% less likely to start high-value therapies, such as SGLT2i, and GLP1a, due to high costs, transportation issues, and health literacy barriers. Within the AI optimized formulary framework, a number of changes are suggested: lowering cost sharing, removing prior authorizations, and offering pharmacy delivery. Predictive modeling estimates that these interventions would generate a 35% increase in therapy initiation for patients with SDoH tier 1 affecting the initiation gap to be less than 10%. Furthermore, downstream modeling estimates fewer complications, lower hospitalization costs, and increased equity, making the formulary more cost-effective. Improving the healthcare access for these vulnerable population increases the health equity outcomes of the formulary.

5.2 Targeted Example of Noval Biologic Therapy

A costly biologic therapy for a rare disease among low-income communities and the underserved will require formulary optimisation which will involve lowering tiering and cost sharing for patients with high SDoH and automating prior authorisation. These changes will improve therapy access due to budgetary constraints. Predictive modelling will suggest that more high SDoH patients will achieve access to the biologic with greater clinical outcomes

and improved long-term health outcomes due to less complications and hospitalisations. This will strengthen the case for continued sustained equitable access to high-cost biologic therapy.

6. Results and Discussions

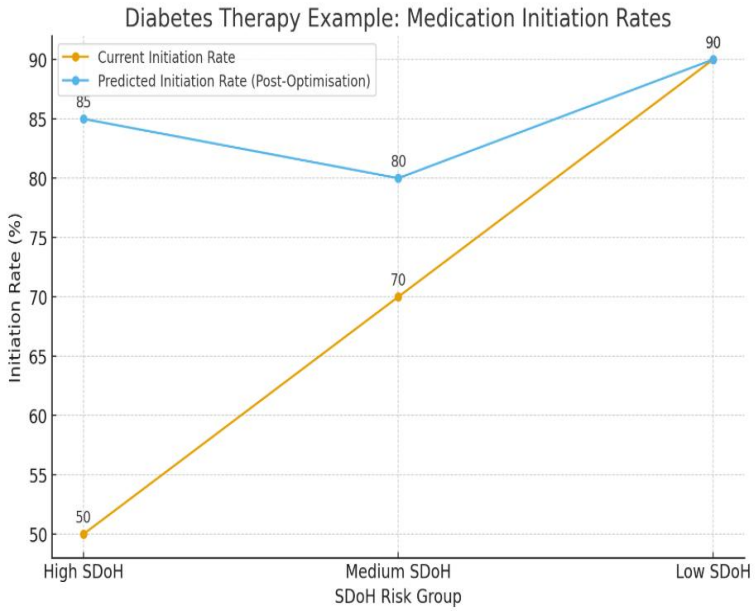
The results of the implementation of the proposed AI driven formulary design framework are presented for two prototype cases; namely, diabetes management and novel biologic treatments for rare diseases. The optimisation results are then followed by a discussion of the changes that are SDoH-aware, particularly pertaining to the initiation of and adherence to medications and the subsequent long term outcomes of the downturn of the healthcare costs for the patients.

Diabetes Management Therapy Case

The AI driven formulary framework was applied to a population of patients with type 2 diabetes, focusing on value therapeutic agents SGLT2 and GLP1 receptor agonists but also SGLT2 inhibitors (SGLT2i). The objective was to close the gaps pertaining to the initiation of medications across the lower and upper deprivation neighbourhoods.

Table 1: Predictive Modelling Results for Medication Initiation and Adherence

SDoH Risk Group	Current Initiation Rate	Predicted Initiation Rate (Post-Optimisation)	Change in Initiation Rate	Predicted Adherence Rate (Post-Optimisation)	Change in Adherence Rate
High SDoH	50%	85%	+35%	60%	+10%
Medium SDoH	70%	80%	+10%	75%	+5%
Low SDoH	90%	90%	0%	90%	0%



• High SDoH: Predictive modelling indicates a 35% initiation rate increase among these patients if the formulary is optimised and is able to eliminate cost sharing, prior authorisation, and offer home delivery, moving the gap to be within 10%. There is also a predicted improvement of 10% in adherence.

• Medium and Low SDoH: Modelling also predicts slight increases in initiation and adherence in the medium SDoH group, 10%. There are negligible changes in the low SDoH group, and no significant change overall.

Table 2: Downstream Modelling Results on Clinical Outcomes

SDoH Risk Group	Current Hospitalisation Rate	Predicted Hospitalisation Rate (Post-Optimisation)	Change in Hospitalisation Rate	Predicted Complications Rate (Post-Optimisation)	Change in Complications Rate
High SDoH	15%	10%	-5%	20%	-10%
Medium SDoH	10%	9%	-1%	15%	-5%
Low SDoH	5%	5%	0%	10%	0%

• High SDoH: Studies suggest that optimisations may predict 5% of hospitalisations for the disease to be avoided, and 10% of complications to be avoided, due tobetter and earlier initiation of therapy and close follow up.

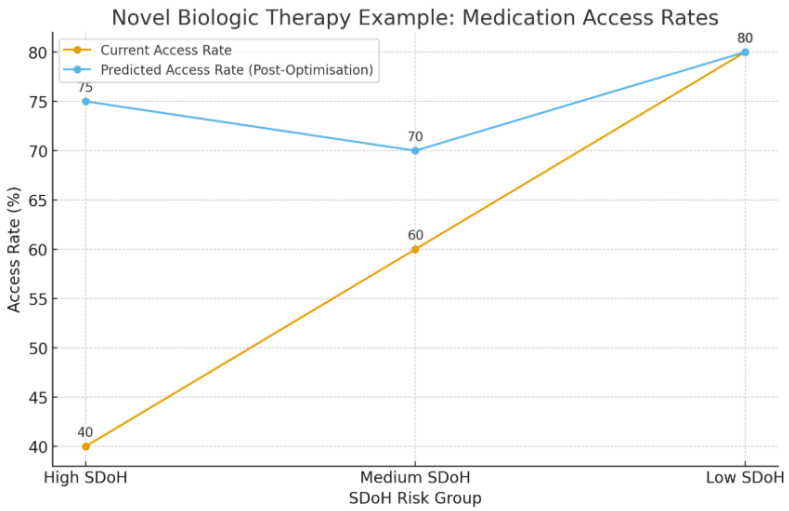
• Medium and Low SDoH: The hospitalisations and complications for SDoH Medium and Low patients demonstrate some further reduced hospitalisations and complications, representing smaller amelioration of medication access and adherence.

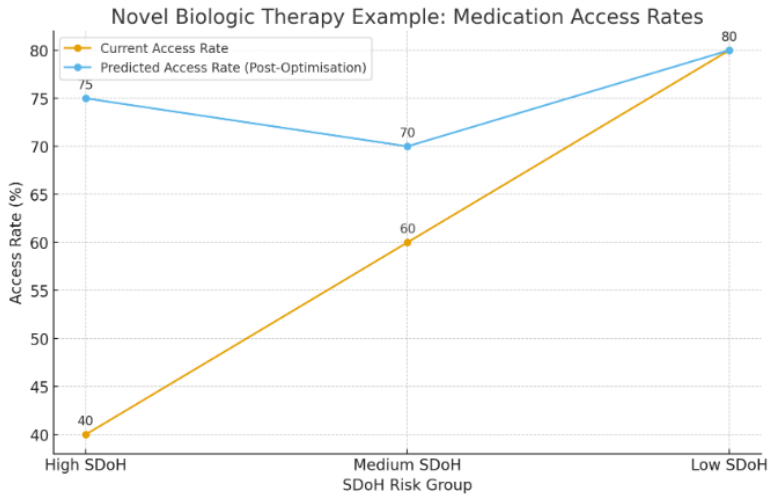
Biologic Therapy Example

In the second case, the focus was on optimising the formulary for a costly biologic therapy for a rare disease that is disproportionately found in underprivileged communities, with the primary objective of enhancing access for patients with high SDoH.

Table 3: Predictive Modelling Results for Medication Access and Adherence (Novel Biologic)

SDoH Risk Group	Current Access Rate	Predicted Access Rate (Post-Optimisation)	Change in Access Rate	Predicted Adherence Rate (Post-Optimisation)	Change in Adherence Rate
High SDoH	40%	75%	+35%	50%	+10%
Medium SDoH	60%	70%	+10%	65%	+5%
Low SDoH	80%	80%	0%	80%	0%





• High SDoH: Modifying formulary rules, including tiering, cost-sharing reduction, and automating prior authorization, is predicted to improve access to the biologic therapy for high SDoH by 35%. Adherence also improves by 10%.

• Medium and Low SDoH: There are moderate advancements in access to medication and adherence for Medium SDoH patients, although with Low SDoH patients, there are no substantial changes observed.

Table 4: Cost and Outcome Analysis for Novel Biologic Therapy

SDoH Risk Group	Current Total Cost (per patient/year)	Predicted Total Cost (per patient/year)	Change in Total Cost	Predicted Healthcare Savings (per patient/year)	Change in Healthcare Savings
High SDoH	$50,000	$45,000	-$5,000	$15,000	+$10,000
Medium SDoH	$40,000	$38,000	-$2,000	$10,000	+$5,000
Low SDoH	$30,000	$30,000	$0	$5,000	$0

• High SDoH: Biologic therapies will likely incur higher costs initially owing to improved accessibility and reduced copayments. In the long run, though, the predicted savings associated decreased hospitalizations and healthcare complications are projected to be substantial. Estimated, the net healthcare costs will reduce by around $5,000 per patient.

• Medium SDoH: While the difference in predicted net healthcare costs for medium SDoH patients are not as substantial, the net costs are still predicted to decrease by $2,000 per patient.

• Low SDoH: In the low SDoH category, costs will be maintained as the patients have already expressed high usage of the therapy available.

Discussion

These findings have shown how the design of AI-optimized formularies can minimize the health inequities influenced by social determinants as illustrated below.

1. Impact on Medication Access: In the two instances mentioned, the intervention is mainly directed towards the high SDoH patients amplifying their reach to the important therapies. In the case of diabetes therapy, there was an optimisation of formulary rules that led to the high SDoH patients significantly increasing instances of medication initiation and adherence. In the same vein, for the biologic therapy, there was a simplification and lowering of costs for prior authorisation that

lead to a 35% increase in access for the underserved populations.

2. Clinical Outcomes and Cost Savings: The downstream modelling captures that there is an improvement in clinical outcomes, for instance, in the reduction of hospitalisation and complications due to improvement of access to the medication. Improved health status of the patients and reduction of cost burden of the overall healthcare system is an additional benefit. In the case of high-SDoH patients, there were net cost savings due to reduction in complications and hospitalisation and the additional costs incurred from access to the therapies.
3. Equity Impact: The optimisation framework closes the gap for those less likely to obtain medication and provides equitable healthcare access and service equality. With the case of diabetes, the gap in initiation rates was below 10%. With the case of biologic therapy, updates to the formulary increased access for disadvantaged and vulnerable patients, thereby reducing health inequities in the population.
4. Limitations and Future Research: The promise of the AI optimised formulary framework is unsubstantiated, as these findings stem from predictive modelling and theoretical scenarios. Future work needs to validate the framework by integrating real world evidence to improve model predictions in actual healthcare environments. In addition, the framework should incorporate strategies to monitor the impact of formulary adaptations on patient outcomes, healthcare expenses, and the overall impact on healthcare costs to assure the changes are sustainable over time.

7. Conclusion

Incorporating AI-optimized formulary design presents a novel solution to mitigate inequalities in medication access and health outcomes for more vulnerable and SDoH challenged populations. The ability to incorporate SDoH into predictive modelling and AI-optimized algorithms allows this framework to assist healthcare systems in moving beyond traditional formulary designs centered on clinical and pharmacoeconomic measures. In doing so, it provides a more equitable approach, incorporating the social and geographical determinants that hurdle patient access to medications.

The examples provided have demonstrated the applicability of the framework to two separate areas of concern– diabetes care and new biologics– and how these represent real opportunities to improve the use of AI to improve accessibility for the most disadvantaged population. In the diabetes therapy example, there were notable improvements within the framework, with increased medication initiation and improved adherence, closing the initiation gap to 10 percent among high SDoH patients. Moreover, the improvements in health outcomes resulting in fewer hospitalisations and complications of the disease indicate the benefits associated with equity-based formulary optimisation. Likewise, in the biologics therapy example, the optimisation of formulary rules including cost-sharing reductions and automated prior authorisation, produced significant healthcare savings as complications and hospitalisations decreased, while providing high SDoH patients with access to expensive therapies.

The findings support the integration of the social determinants of health (SDoH) in formulary management. The AI-optimized framework's focus on improving access to health services for financially disadvantaged SDoH groups expands the focus of the framework on inequitable access to services. Predictive modeling and optimization ensure that value is produced that is cost efficient (within health system budget) and socially (ethically) accepted. With the SDoH population in mind, the adaptive learning algorithms in the framework provide the means for health care systems to improve their formulary policies in real time, addressing a gap in the literature.

In predicting the impact of the framework, this study is a no doubt a reliable and data-driven environment. There is a need for empirical real-world data to validate the framework. There is a need to integrate real-time data tracking in health care systems to provide value relative to long-term patient health outcomes and overall system costs. The AI-implemented prediction models will be beneficial for all if the practices of ethically integrating AI tools mitigate data privacy risks, incorporate collaborative design with end-users/burden bearers, and address social bias.

In sum, the AI-driven formulary design framework constitutes a major advancement in decreasing health inequities and improving patient outcomes;

the proactive recognition of social determinants impacting access to medications enables health systems to develop more equitable and efficient formularies that address the needs of all patient populations, especially the most vulnerable. As AI systems integrate into formulary management, health systems will be able to better align the growing demand for health equity with sustainable and cost-effective support for diversified healthcare systems.

References

[1] Kansagara, D., Englander, H., SalanitrKueper JK, Terry A, Bahniwal R, et al. Connecting artificial intelligence and primary care challenges: findings from a multi stakeholder collaborative consultation. BMJ Health Care Inform. 2022; 29(1): e100493. 10.1136/bmjhci-2021-100493o, A., Kagen, D., Theobald, C., Freeman, M., & Kripalani, S. (2011). Risk prediction models for hospital readmission: a systematic review. JAMA, 306(15), 1688-1698

[2] J. Peng et al. Machine learning techniques for personalised medicine approaches in immune-mediated chronic inflammatory diseases: applications and challenges Front. Pharmacol. (2021)

[3] K.B. Johnson et al. Precision medicine, AI, and the future of personalized health care Clin. Transl. Sci. (2021)

[4] C. Mennella et al. Ethical and regulatory challenges of AI technologies in healthcare: a narrative review Heliyon (2024)

[5] Salwei ME, Carayon P.. A sociotechnical systems framework for the application of artificial intelligence in health care delivery. J Cogn Eng Decis Mak. 2022; 16(4): 194-206.

[6] Pinto AD, Glattstein-Young G, Mohamed A, Bloch G, Leung FH, Glazier RH.. Building a foundation to reduce health inequities: routine collection of sociodemographic data in primary care. J Am Board Fam Med. 2016; 29(3): 348-355. 10.3122/jabfm.2016.03.150280

[7] Upshaw TL, Craig-Neil A, Macklin J, et al. Priorities for artificial intelligence applications in primary care: a Canadian deliberative dialogue with patients, providers, and health system leaders. J Am Board Fam Med. 2023; 36(2): 210-220. 10.3122/jabfm.2022.220171R1

[8] Upshaw TL, Craig-Neil A, Macklin J,Mian, P.; Maurer, J.M.; Touw, D.J.; Vos, M.J.; Rottier, B.L. Pharmacy Compounded Pilocarpine: An Adequate Solution to Overcome Shortage of Pilogel® Discs for Sweat Testing in Patients with Cystic Fibrosis. J. Cyst. Fibros. 2024, 23, 126–131 et al. Priorities for artificial intelligence applications in primary care: a Canadian deliberative dialogue with patients, providers, and health system leaders. J Am Board Fam Med. 2023; 36(2): 210-220. 10.3122/jabfm.2022.220171R1

[9] Watson, C.J.; Whitledge, J.D.; Siani, A.M.; Burns, M.M. Pharmaceutical Compounding: A History, Regulatory Overview, and Systematic Review of Compounding Errors. J. Med. Toxicol. 2021, 17, 197–217

[10] Noorain; Srivastava, V.; Parveen, B.; Parveen, R. Artificial Intelligence in Drug Formulation and Development: Applications and Future Prospects. Curr. Drug Metab. 2023, 24, 622–634.

[11] Rughoo, L.; Vigneron, J.; Zenier, H.; May, I.; Demoré, B. Stability Study of Amiodarone Hydrochloride in Capsules for Paediatric Patients Using a High-Performance Liquid Chromatography Method. Ann. Pharm. Francaises 2012, 70, 88–93.

[12] Dong, J.; Wu, Z.; Xu, H.; Ouyang, D. FormulationAI: A Novel Web-Based Platform for Drug Formulation Design Driven by Artificial Intelligence. Brief. Bioinform. 2024, 25, bbad419.

[13] Biswas MR, Shah Z. Extracting factors associated with vaccination from Twitter data and mapping to behavioral models. Human Vaccines & Immunotherapeutics. 2023 Dec 15;19(3):2281729

[14] Morley J, Machado C, Burr C, Cowls J, Taddeo M, Floridi L. The debate on the ethics of AI in health care: a reconstruction and critical review. Available at SSRN 3486518. 2019 Nov 13.

[15] Morley J, Machado CC, Burr C, Cowls J, Joshi I, Taddeo M, Floridi L. The ethics of AI in health care: a mapping. Ethics, Governance, and Policies in Artificial Intelligence. 2021 Nov 2;1:313-46