

Integrating Social Determinants of Health in Machine Learning-Driven Decision Support for Diabetes Case Management: A Sequential Mixed Methods Study Protocol

Seung-Yup (Joshua) Lee, Leslie Hayes, Bunyamin Ozaydin, Steven Howard, Alison Garretson, Heather Bradley, Andrew Land, Erin DeLaney, Amy Pritchett, Amanda Furr, Ashleigh Allgood, Matthew Wyatt, Allyson Hall, Jane Banaszak-Holl

Submitted to: JMIR Research Protocols
on: January 03, 2024

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 21

 Figures 22

 Figure 1..... 23

 Figure 2..... 24

 Figure 3..... 25

 Figure 4..... 26

 Figure 5..... 27

Integrating Social Determinants of Health in Machine Learning-Driven Decision Support for Diabetes Case Management: A Sequential Mixed Methods Study Protocol

Seung-Yup (Joshua) Lee¹ PhD; Leslie Hayes² MD, LSSBB; Bunyamin Ozaydin¹ PhD; Steven Howard¹ PhD; Alison Garretson³ MBA, RN, NEA-BC; Heather Bradley³ MHQS, RN, NE-BC; Andrew Land⁴ MD, FACP; Erin DeLaney⁵ MD; Amy Pritchett² BSN, RN, OCN; Amanda Furr² BSN, RN; Ashleigh Allgood¹ MPH, MBA; Matthew Wyatt⁶ MSHI; Allyson Hall¹ PhD; Jane Banaszak-Holl¹ PhD

¹School of Health Professions University of Alabama at Birmingham Birmingham US

²Quality Outcomes University of Alabama at Birmingham Medicine Birmingham US

³Care Transitions University of Alabama at Birmingham Medicine Birmingham US

⁴Primary Care Line University of Alabama at Birmingham Medicine Birmingham US

⁵Heersink School of Medicine University of Alabama at Birmingham Birmingham US

⁶Informatics Institute University of Alabama at Birmingham Birmingham US

Corresponding Author:

Seung-Yup (Joshua) Lee PhD

School of Health Professions

University of Alabama at Birmingham

1716 9th Ave S

Birmingham

US

Abstract

Background: Diabetes case management provides surveillance of symptoms and care coordination that benefits from considering the patient's age, comorbidities, and social determinants of health (SDoH). Research finds that SDoH are important to the complexity of diabetes care. However, current referral practices, based mainly on clinical records, lead to unmet diabetes case management needs. While decision support systems have been developed to address the disparities, their effective application is hindered by healthcare professionals' limited understanding of these models' performance and their clinical and operational relevance.

Objective: This study proposes the development of a data-driven decision support system that incorporates SDoH to prioritize care and employs a mixed-methods evaluation approach to mitigate disparities in diabetes case management services within a healthcare system.

Methods: The proactive risk assessment decision support (PRADS) model for a clinical population with diabetes will use both SDoH and clinical data to prioritize the patient's urgency of case management need, identifying those most likely to need high-cost healthcare resources, such as the emergency department (ED). It will be developed using data on demographics, SDoH (e.g., food access, transportation, medication availability), comorbidities, hospitalization-related factors, laboratory test results, medications, and outcome variable (i.e., ED visits). We will employ a mixed-methods evaluation approach, combining quantitative validation of the model's performance with qualitative insights from case managers, clinicians, and quality and patient safety experts, employing a modified Delphi method and a semi-structured focus group.

Results: As of December 2023, we gathered data on 174,871 inpatient encounters from January 2018 to September 2023, involving 89,355 unique inpatients meeting our inclusion criteria. All clinical and SDoH data items for these patients and their encounters were fully collected as of December 2023.

Conclusions: The current case management referral process for diabetic patients lacks a comprehensive assessment of patient information, leading to disparities in care. By integrating a critical suite of SDoH with clinical data, a tailored data-driven decision support system like PRADS can more effectively identify patients at elevated risk to use services. By aligning the model with the hospital's specific quality and patient safety considerations through a mixed-methods approach, we aim to enhance the quality of patient care and optimize case management resource allocation.

(JMIR Preprints 03/01/2024:56049)

DOI: <https://doi.org/10.2196/preprints.56049>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in [JMIR Publications](#)

Original Manuscript

Integrating Social Determinants of Health in Machine Learning-Driven Decision Support for Diabetes Case Management: A Sequential Mixed Methods Study Protocol

Abstract

Background: The use of both clinical factors and social determinants of health (SDoH) in referral decision-making for case management may improve optimal use of resources and reduce outcome disparities among patients with diabetes. This study proposes the development of a data-driven decision support system incorporating interactions between clinical factors and SDoH into an algorithm for prioritizing who receives case management services. The paper presents a design for prediction validation and pre-implementation assessment that employs a mixed-methods approach to guide the implementation of the system.

Methods: Our study setting is a large, tertiary care academic medical center in the Deep South of the United States, where SDoH contribute to disparities in diabetes-specific hospitalizations and emergency department (ED) visits. This project will develop an interpretable artificial intelligence model for a population with diabetes using SDoH and clinical data to identify which post-hospitalization cases have a higher likelihood of subsequent ED utilization. The electronic health record data collected for the study include demographics, SDoH, comorbidities, hospitalization-related factors, laboratory test results, and medication use to predict post-hospitalization ED visits. Subsequently, a mixed-methods approach will be used to validate prediction outcomes and develop an implementation strategy from insights into patient outcomes from case managers, clinicians, and quality and patient safety experts.

Results: As of December 2023, we had abstracted data on 174,871 inpatient encounters between January 2018 and September 2023, involving 89,355 unique inpatients meeting inclusion criteria. Both clinical and SDoH data items were included for these patient encounters. 85% of the inpatient visits (N=148,640) will be used for training (learning from the data) and the remaining 26,231 inpatient visits will be used for mixed-methods validation (testing).

Discussion: By integrating a critical suite of SDoH with clinical data related to diabetes, the proposed data-driven risk stratification model can enable individualized risk estimation and inform health professionals (e.g., case managers) about the risk of patients' upcoming ED utilization. The prediction outcome could potentially automate case management referrals, helping to better prioritize services. By taking a mixed-methods approach, we aim to align the model with the hospital's specific quality and patient safety considerations for the quality of patient care and the optimization of case management resource allocation.

Keywords: Diabetes, social determinants of health, disparities, mixed-methods, case management, decision support, predictive analytics

1. Introduction

Diabetes is a major source of morbidity and mortality in the United States (US). According to the Center for Disease Control and Prevention, over 38 million people or 11.6% of the US population have diabetes [1-3]. Poorly managed diabetes leads to poor glycemic control and associated significant complications that require hospitalization. Furthermore, having diabetes can complicate recovery from other medical and surgical morbidities leading to a greater likelihood for longer hospitalization, repeat hospitalizations, and emergency department (ED) use [4-6]. Since 2010, hospitalizations associated with diabetes and related conditions have increased likely due to an increase in prevalence and deterioration in diabetes control [7, 8].

There is convincing evidence that social determinants of health (SDoH), or the conditions where people are born, grow, live, work, and age are associated with the prevalence of diabetes as well as outcomes among those with a diagnosis [9-11]. SDoH frameworks suggest that there are multiple causal pathways that link SDoH to outcomes. Some frameworks appropriately acknowledge

upstream regional determinants such as the political environment or government policy having impact on downstream determinants such as living conditions and health behavior which in turn impact health outcomes [12]. Another framework uses educational attainment as a starting point leading to various other determinants such as health literacy, work, income, social supports, and social standing, which in turn are related to health behaviors, access to nutrition, and healthcare, which are then linked to health outcomes [13].

Strategies for moderating the negative impacts of diabetes involve participation in lifestyle changes related to diet and exercise, the use of drugs, as well as screenings for acute and chronic complications [14]. The effectiveness of these strategies is impacted by SDoH as well as underlying other comorbidities. Therefore, health systems focused on reducing diabetes related ED and inpatient utilization are working to incorporate the social context within programs aimed at helping patients with diabetes improve their health outcomes [11].

However, there are three important caveats to consider in applying an SDoH framework in attempting to explain inequalities in diabetes health outcomes. First, although descriptions and pictures of these frameworks imply that the relationship between SDoH factors and health are linear, in truth the interactions between these variables are complicated and difficult to isolate. Second, SDoH factors are both at the individual (e.g., a person's wage) and societal level variables (e.g., community infrastructure). Third, case managers and nurses must figure out how to assess patients' SDoH characteristics and health needs to properly identify patients who will most benefit from case management and then design a program specifically tailored to that patient's needs. [15, 16]. There are constraints in a health system's ability to provide comprehensive case management care [17, 18] as exemplified at the University of Alabama at Birmingham Health System (UABHS), where the limited availability of registered nurse (RN) case managers for identifying and managing post-hospitalization high-risk diabetes cases hinders effective case management. These three factors combined make it difficult to identify and address the individual and community level factors that might have a nuanced relationship on desired patient outcomes.

Decision support tools and predictive analytics holds promise for assisting health systems in identifying populations most at risk and developing targeted interventions. These tools can take a holistic approach [19-21], incorporating both health status and SDoH and address the nuanced relationships between these variables (e.g., non-linearity and interactions) and their combined effect on health outcomes. However, although predictive analytic and decision support systems can easily identify high-risk diabetes cases [22, 23], many of these tools only relied on health system data overlooking the nuances of daily practice and operations and user perception, hindering the implementation of a developed tool. Stakeholders, including healthcare professionals, struggle to support implementation due to a lack of clear insights into the performance and clinical and operational relevance of these systems.

Our study responds to these significant research gaps and practical challenges by proposing the development of a Proactive Risk Assessment Decision Support (PRADS) model through a mixed-methods (qualitative and quantitative) approach. The quantitative component will use classification performance metrics and their visualization to identify and then validate a risk stratification model for predicting an ED visit post-discharge among diabetes patients. A focus group and survey will be done with nurse manager, case managers, clinicians, and care transition leaders at UABHS to qualitatively assess the model's fit with clinical and operational workflows and its potential impact on quality of care (motivated by [24, 25]). Combined quantitative outcomes and qualitative feedback will be used to refine diabetes case management protocols, making them more effective and aligned with real-world healthcare delivery.

This new tool will be used to support UABHS' case managers in identifying and prioritizing patients with diabetes with a higher risk of subsequent ED utilization post-hospitalization. The data-driven predictive model will amalgamate repositories of patient data that include both clinical and

SDoH factors [26, 27]. This predictive approach has potential to automate case management referrals in a data-driven manner, helping to better prioritize services and utilization.

2. Methods

UABHS is a large public hospital with an academic mission and a level 1 trauma center. The health system has implemented a case management program using RN case managers with training in diabetes care to improve outcomes for those with diabetes recently hospitalized. With over 50,000 patients with diabetes receiving care in the health system, the case management referrals prioritize cases based on two highly exclusive, pre-set clinical rules at point of discharge: 1) HgbA1c > 10.5% or 2) blood glucose > 300 mg/dL and pH < 7.3. Our methodology aims to create an expanded set of data-driven referral criteria and validate the criteria through a mixed methods evaluation. Figure 1 depicts our study framework. The research will be conducted by a large multidisciplinary team, including experts from the five groups below:

- Case management providers, including directors of care transitions and diabetes case management RNs,
- Primary care physicians from internal and family medicine,
- Quality and patient safety experts, including the associate chief quality officer and quality outcome nurses,
- Health data scientists and system analysts,
- Large-scale electronic health record (EHR) experts, in this case the Director and staff for the UAB Enterprise Data Warehouse.

The large-scale EHR experts have already helped develop a process for standardizing data acquisition to use long-term in implementation of case management system changes. Our study framework requires several stages of data collection and analysis as shown in Figure 1 and described below.

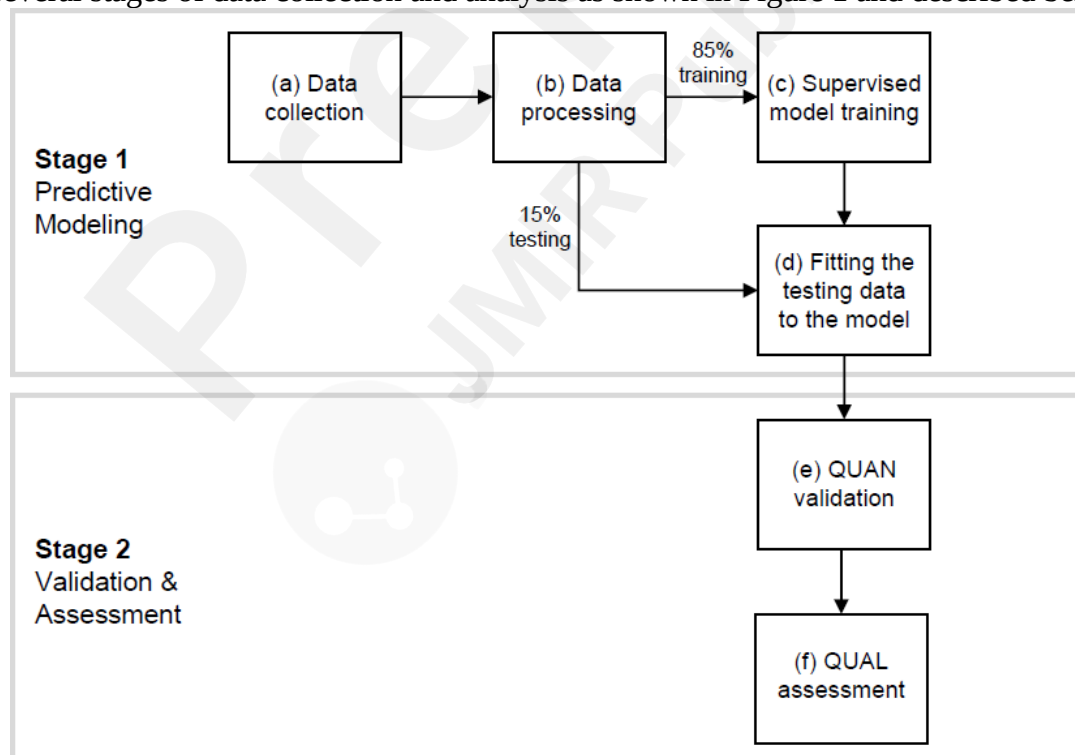


Figure 1. Study framework

2.1. Stage 1: Predictive Modeling

We will model the risk of a post-hospitalization ED visit among inpatients with diabetic concerns

admitted to UABHS between January 2018 and September 2023 using patient predictors and ED visit history, including health outcome post-hospitalization. Patient predictors include both SDoH and clinical factors collected from the UABHS EHR repository. This approach aims to prioritize patients based on their likelihood of visiting the ED within a specific timeframe. Predictions will be retrospectively generated for the daily inpatient mix at UABHS, aligning with the current practices in case management.

2.1.1 Steps (a & b): Developing measures for analysis

Our initial study population includes those who were hospitalized with the following conditions (in Table 1) recorded as of October 2023:

Items
HgbA1c \geq 6.5% OR
Diabetes mellitus due to underlying condition (E08) OR
Drug or chemical induced diabetes mellitus (E09) OR
Type 1 diabetes mellitus (E10) OR
Type 2 diabetes mellitus (E11) OR
Other specified diabetes mellitus (E13) OR
Elevated blood glucose level (R73) OR
Hypoglycemia (E16.2) OR
Foot ulcer (L97.509) OR
Wound infection (T14) OR
Gastroparesis (K31.84)

Table 1. Laboratory test item and ICD-10 codes included in the sample inclusion criteria

The proposed criteria in Table 1 are more inclusive than the current restrictive case management referral criteria that are based exclusively on HgbA1c, blood glucose, and pH levels; yet the sample size is not too expansive to perform large-scale machine learning modeling.

Figure 2 lists all the key diabetes-related clinical and socioeconomic factors collected from the UAB Enterprise Data Warehouse for the sample in this study. We choose to include variables that measure both individual levels of risk and societal/area-level measures of risk since SDoH frameworks suggest that both type of variables have some impact on the risk of poor health. Indeed, at our own institution we have recognized that individuals from certain communities are more likely to return to the ED compared to individuals at other communities. What is not clear from the literature is the relative impact of each type of variable on the specific risk of the individual. For example, there is some evidence that area level measures such as the ADI may predict individual risk [28-30], and there is also evidence that such area level variables cannot predict individual risk [31]. Further, even if the area-level variables demonstrate less importance in predicting ED utilization, program planners must understand the context in which an individual lives. Area-level factors (including, the Area Deprivation Index (ADI) and Social Vulnerability Index (SVI)) were collected from the Neighborhood Atlas® and Agency for Toxic Substances and Disease Registry databases. The ADI and SVI were selected to reflect essential community-level barriers and resources that impact diabetes outcomes [32].

The importance of certain kinds of individual level factors (e.g. race, insurance status, prior medical history, and comorbidities) have long been established as predictors of risk [33]. However, other kinds of socio-economic data will help identify specific patient needs. The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE™) [34] is a self-reported survey completed by patients during healthcare encounters, and include reports of access to housing and transportation, food security, and whether the patient is employed. The significance of these factors in the diabetes context has been discussed in the literature [35-37]. At UABHS, the PRAPARE survey has been implemented in the ED and inpatient settings as part of the health

system's initiative, and our study will utilize PRAPARE data where available via the EHR repository for the study population. We will also incorporate individual-level variables included in administrative data and the medical record such as insurance status, utilization and visit history, age, gender, race and ethnicity. To ensure the robustness of our findings, we will analyze and report on the missingness of the PRAPARE data items. This approach will help us assess potential biases in data collection and address their impact on the study results.

While area-level factors provide a broader view of SDoH for patients, individual-level SDoH factors also provide information a patient's unique socioeconomic situation and together should be useful in predicting the most vulnerable and at-risk patients.

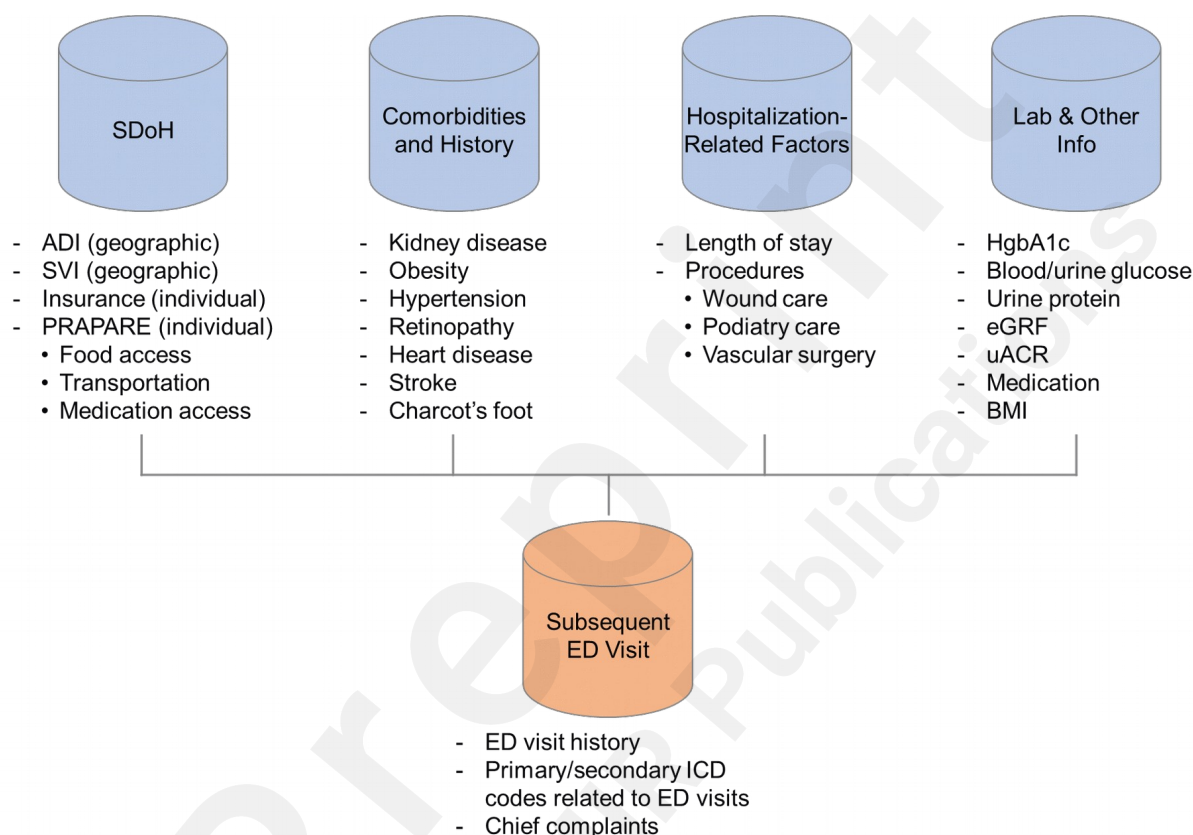


Figure 2. Data items utilized to build the PRADS model

Our retrospective predictive modeling approach will use 85% of the data (148,640 inpatient visits) for training (learning from the data) and the rest of the data (26,231 inpatient visits) for validation (testing). Data elements will be cleaned and transformed based on expert clinicians' input (knowledge-driven) to create categorical and numerical variables for modeling. . Categorical variables will be created from comorbidities, medications, and PRAPARE data, while ADI and SVI scales will be treated as numerical. Missing information on categorical variables will be coded as Not Measured. Our outcome variable, whether the individual returned to the ED post-discharge for diabetic concerns, is a binary variable that will be taken from either the primary or secondary diagnosis at admission (see Table 1).

2.1.3. Step (c) Supervised Model Training

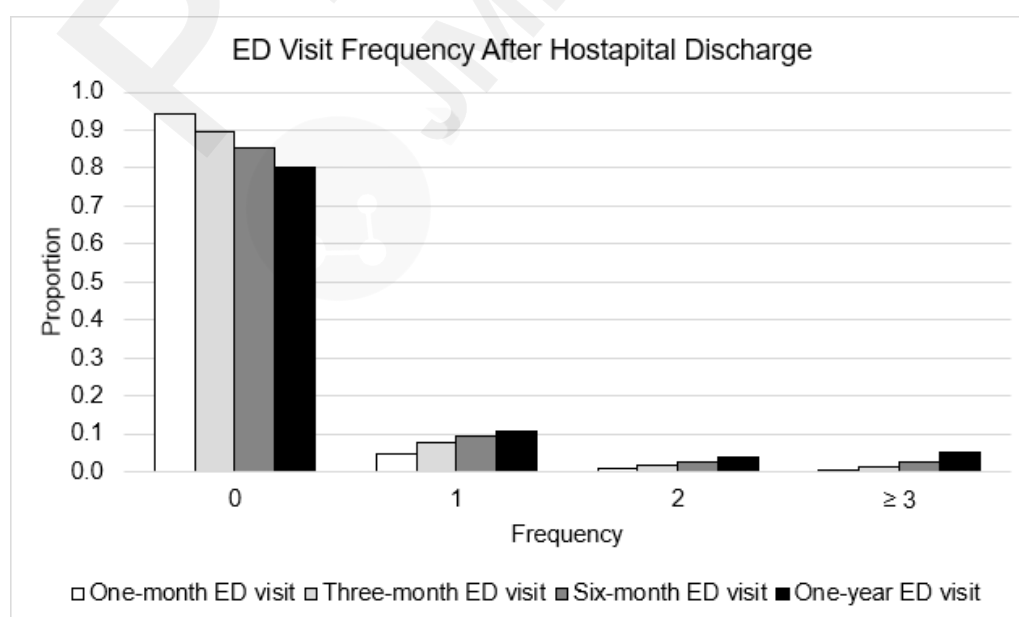
Given the availability of a wide range of EHR data elements at UABHS covering both predictors and the outcome variable, we choose to conduct supervised learning of patterns between the predictors and outcomes [38]. Our predictive model develops a scale of care urgency (e.g., the Emergency Severity Index [39]) that identifies the likelihood that a patient may return to the ED within a specified timeframe post-discharge, which can inform prioritization of patient cases in case

management. We factor in a set of covariates X_i at the time that the patient (say, patient i) is hospitalized (T_i). These covariates include SDoH and the other three types of variables represented in Figure 2.

In our modeling framework, defining t is an important task to ensure the practical applicability of prediction outcomes. The grouped bar graph in Figure 3 shows a preliminary analysis of the post-discharge diabetes-related ED visit frequency. The x-axis represents the frequency of ED visits from one-month to one-year post discharge. The y-axis shows the proportion of inpatients who returned to the ED with diabetic concerns specified in Table 1 as either the primary or secondary diagnosis. The result indicates that 5.7% visits to the ED occurred within a month of discharge and 10.6% within three months of discharge. Given the overall average of 42 daily hospitalizations with diabetes-related concerns, on average, 2.4 inpatients were likely to return to the ED within one month, and 4.5 were likely to return within three months. Discussions with the case management and clinical teams suggest that although a one-month timeframe provided a more manageable number of cases for patient follow-ups, a three-month period offered greater flexibility and aligned better with the projected capacity for post-hospitalization case management. Therefore, we will examine whether a patient i will return to the ED post-hospitalization between T_i and $T_i +$ three months.

Using binomial classification structures, we will develop an Interpretable Artificial Intelligence (IAI) framework from the decision tree algorithm. The core algorithm will use a top-down search through the space of possible branches to create a tree-like decision structure [40]. Decision tree algorithms use a measure of information gained from choosing features that split the data best [40, 41]. Decision trees can handle non-linear relationships between predictors and outcome variables and interactions between predictors. Moreover, they generate inherently interpretable models, allowing for easy visualization and interpretation of the decision-making paths, which facilitate the understanding of how decisions are reached. These features make decision trees particularly suitable for meeting our study objectives, incorporating SDoH and conducting mixed-methods validation. In our study, to be specific, we will apply the Classification and Regression Trees (CART) algorithm that utilizes the Gini impurity measure as a criterion for splitting [42]. Using the CART algorithm, the IAI model will be trained in a supervised manner (i.e., learning from patterns between X_i and the outcome variable). After the model is trained, we will fit the testing data to the trained model to derive the prediction outcome.

Figure 3. Diabetes-Related Post-Hospitalization ED Visit Frequency



2.1.4. Step (d) Fitting the Testing Data to the Model

A simplified example of trained decision trees is shown in Figure 4. The order of the variables partitioned (branches) and the threshold values that split the branches (in red) are determined in the training process, and the tree structure does not change during the testing step. Depending on the predicted likelihood of an ED admission assigned to a patient during testing, the visit will fall into one of the groups identified by the trained decision tree. For example, the simplified decision tree in Figure 4 shows seven groups. Each of the groups (in Figure 4, that would be each of the seven groups) is assigned an estimated probability of experiencing an ED visit as well as yes/no indicators (for whether the probability leads to ED visit or not).

As represented in Figure 4, our IAI framework enables humans to comprehend the AI's decisions and facilitates discussion about the prediction outcomes and the variables involved between researchers and practitioners [43]. The prediction outcomes will be the basis for focus group follow-up during Stage 2 of the study.

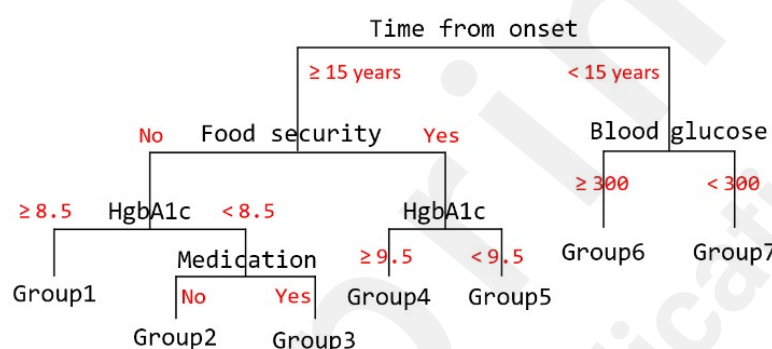


Figure 4. A tree form example

2.2. Stage 2: Validation of the Model's Results

The results of our CART analysis will be validated by quantitative performance measures as well as qualitative data from case management, clinician, and quality and patient safety experts. A procedural diagram for our evaluation process is presented in Figure 5. The model development and validation are formative because the evaluation outcomes will be integrated in further development of the PRADS model.

2.2.1. Step (e) Quantitative Validation of Prediction

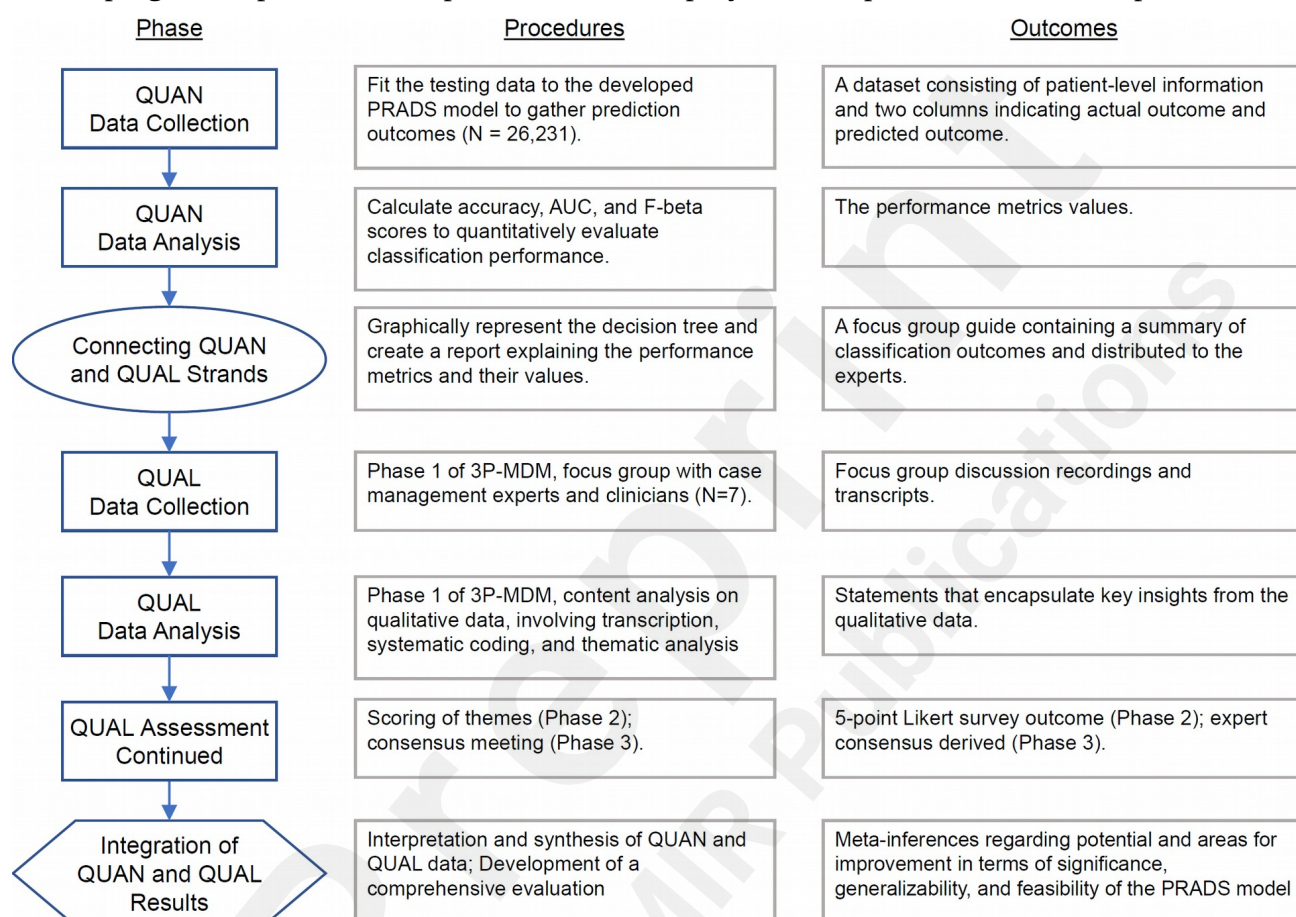
For quantitative validation of the PRADS model, predicted outcomes will be generated for the 15% testing data (N=26,231). We will take three steps to validating our predicted model. First, prediction accuracy, the most fundamental metric, will be evaluated. Prediction accuracy measures the proportion of true results (both true positives and true negatives) among the total number of cases examined [44]. Prediction accuracy can be misleading, particularly in imbalanced datasets where one class (e.g., no ED visits within three months in our study) significantly outnumbers the other [45]. Second, we will estimate the Area Under the Curve (AUC) measure, which estimates the area under the Receiver Operating Characteristics curve in a graphical plot illustrating the predictive ability of a binary classifier. AUC is widely used as a measure of validity because it provides an aggregate measure of performance across all binary classification probability thresholds [46]. Lastly, we will estimate the F-beta score, which measures a model's accuracy both for precision and sensitivity. It can be more informative than prediction accuracy on imbalanced datasets because it considers the model's ability to identify positive results from the minority class, not just the majority class [47, 48]. With $\beta > 1$, the measure puts more emphasis on sensitivity than precision. In our scenario, sensitivity (i.e., detection rate) and precision (i.e., prediction reliability) deliver their unique

implications; therefore, we will evaluate both F-1 and F-2 scores. It will be useful to examine these three metrics to provide a well-rounded understanding of the model's performance.

Figure 5. Sequential mixed methods evaluation of the PRADS for Stage 2

2.2.2. Step (f) Qualitative Assessment of Prediction

The qualitative assessment of the model's performance will be a crucial counterpart to our quantitative analysis, ensuring the clinical validity and practical utility of our predictions for developing an implementation plan. We will employ a three-phase modified Delphi method (3P-



MDM) [49], guided by the Consolidated Framework for Implementation Research (CFIR). The CFIR systemically evaluates factors that can impact the success of implementation in complex settings like healthcare and is applicable to the early stages prior to implementation [50, 51]. Key figures from UAB Medicine Quality and Patient Safety, including the Associate Chief Quality Officer, the Director of Quality Outcomes, and the Quality Outcomes Coordinator, will develop key questions for the initial focus group, which will set the overall direction of our 3P-MDM approach. Details of the 3P-MDM are as follows.

Phase 1 of 3P-MDM: Initial Focus Group for Qualitative Feedback

- 1) Semi-structured Assessment Focus Group: The focus group will involve a semi-structured discussion session, engaging a panel of experts from the UAB Medicine Department of Care Transition, including the Vice President of Care Transitions, the Senior Director of Care Transition, and an RN case managers, all of whom have extensive experience in case management. Additionally, Family & Community Medicine and Internal Medicine clinicians from UABHS will offer clinical insights from their respective fields. The combined perspectives of these professionals (N=7) will be critical for a comprehensive review of the model's predictive outcomes, ensuring that the decision-support tool is statistically robust, clinically relevant, and operationally feasible within UABHS. The focus group session will

be asked to elaborate on how to implement the model's predictions based on the five major domains of CFIR:

- Intervention Characteristics: How do you perceive the strength and quality of the predictive models? Are there specific features that particularly stand out or need improvement to better serve socioeconomically vulnerable groups?
 - Outer Setting: What patient needs and resources are being addressed by these models? How does it align with the external policies and incentives in our healthcare system?
 - Inner Setting: How do the models fit into the existing workflow and systems? What is the level of readiness for implementing these models?
 - Characteristics of Individuals: From your perspective, how do the models affect your decision-making in patient care? What are the potential barriers and facilitators to using these models?
 - Process of Implementation: What strategies would you suggest for the successful implementation of these models in our practice? How can we ensure ongoing adaptations and sustainability?
- 2) Identification of Key Findings: The discussion will generate rich qualitative data that will be analyzed through content analysis, involving transcription, systematic coding, thematic analysis, and comprehensive reporting. This analysis will highlight key themes and patterns that can offer deep insights into the facilitators and barriers to implementation of the prediction model [52].

Phase 2 of 3P-MDM: Structured Evaluation and Ranking

- 1) Scoring of Statements: The derived themes from Phase 1 will be presented back to the seven experts, who will then score them on a 5-point Likert scale (1 being 'strongly disagree' and 5 'strongly agree'. This scale is specifically designed to quantify the importance and applicability of each finding.
- 2) Ranking of Statements: Statements will be ranked based on their assigned scores.

Phase 3 of 3P-MDM: Expert Consensus and Prioritization

- 1) Consensus Meeting: An online expert panel, consisting of three experts from case management and two primary care physicians, will conduct an anonymous poll to reach a consensus on the most critical findings for model adjustment and implementation. The poll will focus on which ranked findings should be prioritized in further model adjustment and for implementation.
- 2) Top Insights for Model Adjustment: The identified top statements, as agreed upon by the expert panel, will inform the refinement of the predictive model and guide the implementation process.

This process underscores our commitment to developing a decision-support tool that is not just empirically sound but also pragmatically grounded and clinically endorsed. The qualitative development of an implementation plan, encompassing both the priority rankings and the rich discussions and comments from the focus groups, will provide a comprehensive understanding of the model's context and importance.

3. Results

As of December 2023, we have collected data on 174,871 inpatient encounters that occurred from January 2018 to September 2023. These encounters involve 89,355 unique inpatients who have met the criteria in Table 1. For this patient population and their respective inpatient encounters, we have fully collected the data items in Figure 2, and data collection was completed as of December 2023.

4. Discussion

The anticipated findings of this study would include the predictive capability of the decision tree model, interactions among clinical factors and SDoH, and qualitative assessment results. Our protocol is unique in three main aspects. First, the PRADS model will leverage SDoH information to improve diabetes risk stratification. Second, our model results will be interpretable to ensure the users understand how the model reached a recommendation. Third, our model validation and assessment for developing an implementation plan will take a mixed-methods approach, which will be guided by performance metrics (quantitative) and the CFIR (qualitative). Therefore, our protocol will ensure that our findings are grounded in the complex reality of healthcare delivery, where both numerical data and human insights are equally important. We expect to have the model that is not only statistically sound but also resonates with the needs and constraints of healthcare providers, ultimately enhancing patient outcomes.

The study has potential limitations. First, its findings, based on one institution, may not be broadly generalizable. Future research could consider comparing different diabetes case management settings, despite challenges due to differences in EHR systems across healthcare organizations. Second, while our study will include user's perspectives for model validation, it would still not demonstrate the effectiveness of our approach on patient outcome. This can be done by performing cost-effectiveness analysis on a potential intervention strategy [53], driven by the prediction system or by conducting a pilot implementation of the system to perform prospective data collection and analysis on patient outcome. While analysis on effectiveness is not within the scope of this protocol, future research should address these questions for the successful implementation of the system.

For the development and implementation of the PRADS model within the health system, a comprehensive approach encompassing training, education, system integration, and continuous feedback is critical [54, 55]. In our future research, we plan to initiate this with a combination of practical workshops, where case managers engage with a simulated PRADS environment, and theoretical lectures to clarify the model's computational aspects, especially the use of SDoH data in assessing patient risk. These sessions will allow case managers to voice concerns and discuss practical applications. Simultaneously, we will focus on integrating PRADS into the existing decision support framework, evaluating its compatibility with current case management strategies, IT infrastructure, and anticipated cost-benefit ratios, for agile development to create a comprehensive system blueprint [56].

As long-term consideration, central to our initiative is the establishment of a robust feedback loop that allows case managers to report discrepancies and contribute insights, keeping the model dynamic and responsive. This will be complemented by thorough documentation, encompassing the model's design, data processing, and methods of feedback integration, with a strong focus on data sensitivity and patient confidentiality. Ethical considerations will guide our approach, ensuring PRADS augments clinical judgment, and we will develop strategies for enhanced patient engagement in their care planning. Additionally, the PRADS model's deployment may have implications on health policy, particularly in the context of reimbursement models and value-based care. Continuous research and validation will compare PRADS with traditional risk stratification methods, using longitudinal studies to assess its long-term impact on patient outcomes and healthcare utilization.

In summary, the development of the PRADS model will be more than a technological advancement in diabetes care; it can serve as a catalyst for a holistic and nuanced understanding of patient management and a systematic incorporation of human insights into the model development and implementation process. Our model development protocol and the long-term strategy offer a blueprint for enhancing chronic disease management. The modeling and analysis results from this research protocol will be submitted to a medical informatics journal and be discussed in national and international academic conferences. The initial results will serve as preliminary data for follow-up

studies, including multi-institutional model development, cost-effectiveness analysis, and prospective data collection and analysis on patient outcome. The research team will pursue extramural funds to fulfill the team's goal of optimizing chronic disease management and healthcare resource utilization.

List of Abbreviations

ED, emergency department; PRADS, proactive risk assessment decision support; PRAPARETM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences; RN, registered nurse; SDoH, social determinants of health; UABHS, University of Alabama at Birmingham Health System; IAI, interpretable artificial intelligence; 3P-MDM, three-phase modified Delphi method.

Conflicts of Interest

None declared.

Acknowledgements

- Ethics approval and consent to participate: The University of Alabama at Birmingham Office of the Institutional Review Board for Human Use (UAB Office of IRB) has waived ethics approval. Also, the UAB Office of IRB has waived informed consent to participate. The UAB Office of IRB determined this project is not subject to FDA regulations and is not Human Subjects Research. All methods will be carried out in accordance with relevant guidelines and regulations.
- Availability of data and materials: The datasets generated and/or analyzed during the current study are not publicly available because the de-identified electronic health record data are obtained from the UAB Enterprise Data Warehouse and intended to be used for internal purpose only. Data are however available from the authors upon reasonable request and with permission of the UAB health system. Dr. Seung-Yup (Joshua) Lee and the UAB Enterprise Data Warehouse (researchdata@uabmc.edu) should be contacted if someone wants to request the data from this study.
- Competing interests: The authors declare that they have no competing interests.
- Funding: Interdisciplinary Collaborative Research Grant at the University of Alabama at Birmingham
- Authors' contributions: SL designed the overall study framework and analytical methods and was the primary writer of the manuscript. LH contributed to establishing the research framework, identifying the issue of staffing shortage in diabetes case management, and forming the interdisciplinary research team. BO contributed to the manuscript and designing the analytical methods. SH contributed to the manuscript and investigated the current case manager's workflow. AG provided knowledge and experience of how electronic health records system can support diabetes case management practice and contributed to the manuscript. HB provided clinical guidelines in ambulatory/inpatient case management and defined key variables influencing decision-making in case management. AL contributed to identifying meaningful social determinants of health for this study and contributed to the manuscript. ED contributed to identifying key clinical variables and provided the outpatient clinic's perspective on diabetes case management. AP contributed to forming the quality and patient safety team for the focus group and reviewed the manuscript. AF contributed to defining and providing clarity on care quality evaluation metrics and contributed to the manuscript. AA provided knowledge of system implementation for designing analysis approaches and significantly contributed to the IRB submission and revision process. MW contributed to identifying the variables in the UAB Enterprise Data Warehouse database and standardizing the data acquisition process for this project. AH contributed to designing the structured qualitative validation approach and

contributed to the manuscript, particularly discussion on SdoH. JBH served as the senior author of this manuscript, supporting SL in preparing the manuscript. All authors read and approved the final manuscript.

- Acknowledgements: Not applicable

References

- Centers for Disease Control and Prevention. National Diabetes Statistics Report website. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>. Accessed 2023 Oct 24.
- Iglay K, Hannachi H, Joseph Howie P, Xu J, Li X, Engel SS, Moore LM, Rajpathak S. Prevalence and co-prevalence of comorbidities among patients with type 2 diabetes mellitus. *Current medical research and opinion*. 2016;32(7):1243-52.
- McCoy RG, Lipska KJ, Van Houten HK, Shah ND. Association of cumulative multimorbidity, glycemic control, and medication use with hypoglycemia-related emergency department visits and hospitalizations among adults with diabetes. *JAMA Network Open*. 2020 Jan 3;3(1):e1919099-.
- Thyagaturu HS, Bolton AR, Li S, Kumar A, Shah KR, Katz D. Effect of diabetes mellitus on 30 and 90-day readmissions of patients with heart failure. *The American Journal of Cardiology*. 2021 Sep 15;155:78-85.
- Ostling S, Wyckoff J, Ciarkowski SL, Pai CW, Choe HM, Bahl V, Gianchandani R. The relationship between diabetes mellitus and 30-day readmission rates. *Clinical diabetes and endocrinology*. 2017 Dec;3:1-8.
- Belligund P, Attaway A, Lopez R, Damania D, Hatipoğlu U, Zein JG. Diabetes Associated With Higher Health Care Utilization and Poor Outcomes After COPD-Related Hospitalizations. *American Journal of Managed Care*. 2022 Sep 1;28(9).
- Rubens M, Ramamoorthy V, Saxena A, McGranaghan P, McCormack-Granja E. Recent trends in diabetes-associated hospitalizations in the United States. *Journal of clinical medicine*. 2022 Nov 9;11(22):6636.
- Kazemian P, Shebl FM, McCann N, Walensky RP, Wexler DJ. Evaluation of the cascade of diabetes care in the United States, 2005-2016. *JAMA internal medicine*. 2019 Oct 1;179(10):1376-85.
- Miles DB. Brief commentary: social determinants of health and treatment targets for type 2 diabetes. *Annals of internal medicine*. 2018 Aug 21;169(4):252.
- World Health Organization, Social Determinants of Health. https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1. Accessed 2024, June 17.
- Hill-Briggs F, Adler NE, Berkowitz SA, Chin MH, Gary-Webb TL, Navas-Acien A, et al. Social determinants of health and diabetes: a scientific review. *Diabetes Care* 2020;44:258-79
- Bay Area Regional Health Inequities Initiative. Framework. Oakland, CA: Bay Area Regional Health Inequities Initiative, 2015. <http://barhii.org/framework/>. Accessed 2024, June 17
- Braveman P, Egerter S, Williams DR. The social determinants of health: coming of age. *Annual review of public health*. 2011 Apr 21;32:381-98.
- Gregg EW, Buckley J, Ali MK, Davies J, Flood D, Mehta R, Griffiths B, Lim LL, Manne-Goehler J, Pearson-Stuttard J, Tandon N. Improving health outcomes of people with diabetes: target setting for the WHO Global Diabetes Compact. *The Lancet*. 2023 Apr 15;401(10384):1302-12.
- Samia LW, Ellenbecker CH, Friedman DH, Dick K. Home care nurses' experience of job stress and considerations for the work environment. *Home Health Care Services Quarterly*. 2012 Jul 1;31(3):243-65.
- Bray P, Thompson D, Wynn JD, Cummings DM, Whetstone L. Confronting disparities in

- diabetes care: the clinical effectiveness of redesigning care management for minority patients in rural primary care practices. *The Journal of Rural Health*. 2005;21(4):317-21.
17. Wilkinson MJ, Nathan AG, Huang ES. Personalized decision support in type 2 diabetes mellitus: current evidence and future directions. *Current diabetes reports*. 2013 Apr;13:205-12.
 18. LaVeist TA, Thorpe RJ, Galarraga JE, Bower KM, Gary-Webb TL. Environmental and socio-economic factors as contributors to racial disparities in diabetes prevalence. *Journal of general internal medicine*. 2009 Oct;24:1144-8.
 19. Lee DC, Koziarek CA, Shim CJ, Osorio M, Vinson AJ, Ravenell JE, Wall SP. Peer reviewed: age disparities among patients with type 2 diabetes and associated rates of hospital use and diabetic complications. *Preventing chronic disease*. 2019;16.
 20. Park EJ, Huber DL. Case management workforce in the United States. *Journal of Nursing Scholarship*. 2009;41(2):175-83.
 21. Alotaibi A, Gholizadeh L, Al-Ganmi AH, Perry L. Factors influencing nurses' knowledge acquisition of diabetes care and its management: A qualitative study. *Journal of clinical nursing*. 2018;27(23-24):4340-52.
 22. Iyengar V, Wolf A, Brown A, Close K. Challenges in diabetes care: can digital health help address them?. *Clinical Diabetes*. 2016;34(3):133-41.
 23. Aktaş E, Ülengin F, Şahin ŞÖ. A decision support system to improve the efficiency of resource allocation in healthcare management. *Socio-Economic Planning Sciences*. 2007;41(2):130-46.
 24. Cresswell K, Callaghan M, Mozaffar H, Sheikh A. NHS Scotland's decision support platform: a formative qualitative evaluation. *BMJ Health & Care Informatics*. 2019;26(1).
 25. Yumoto M. Development of decision support system for product selection based on AHP, using the decision rule of rough set for qualitative evaluation. *Electronics and Communications in Japan*. 2019 Dec;102(12):15-29.
 26. Betancourt JR, Duong JV, Bondaryk MR. Strategies to reduce diabetes disparities: an update. *Current diabetes reports*. 2012;12(6):762-8.
 27. Schmittiel JA, Gopalan A, Lin MW, Banerjee S, Chau CV, Adams AS. Population health management for diabetes: health care system-level approaches for improving quality and addressing disparities. *Current diabetes reports*. 2017;17(5):1-5.
 28. Field C, Grobman WA, Yee LM, Johnson J, Wu J, McNeil B, Mercer B, Simhan H, Reddy U, Silver RM, Parry S. Community-level social determinants of health and pregestational and gestational diabetes. *American journal of obstetrics & gynecology MFM*. 2024 Feb 1;6(2):101249.
 29. Kind AJ, Jencks S, Brock J, Yu M, Bartels C, Ehlenbach W, Greenberg C, Smith M. Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study. *Annals of internal medicine*. 2014 Dec 2;161(11):765-74.
 30. Kurani SS, Heien HC, Sangaralingham LR, Inselman JW, Shah ND, Golden SH, McCoy RG. Association of area-level socioeconomic deprivation with hypoglycemic and hyperglycemic crises in US adults with diabetes. *JAMA Network Open*. 2022 Jan 4;5(1):e2143597-.
 31. Bensken WP, McGrath BM, Gold R, Cottrell EK. Area-level social determinants of health and individual-level social risks: Assessing predictive ability and biases in social risk screening. *Journal of clinical and translational science*. 2023 Jan;7(1):e257.
 32. Jain V, Al Rifai M, Khan SU, Kalra A, Rodriguez F, Samad Z, Pokharel Y, Misra A, Sperling LS, Rana JS, Ullah W. Association between social vulnerability index and cardiovascular disease: a behavioral risk factor surveillance system study. *Journal of the American Heart Association*. 2022 Aug 2;11(15):e024414.
 33. Hayward MD, Crimmins EM, Miles TP, Yang Y. The significance of socioeconomic status in explaining the racial gap in chronic health conditions. *American sociological review*. 2000 Dec;65(6):910-30.
 34. Weir RC, Proser M, Jester M, Li V, Hood-Ronick CM, Gurewich D. Collecting social

- determinants of health data in the clinical setting: findings from national PRAPARE implementation. *Journal of Health Care for the Poor and Underserved*. 2020;31(2):1018-35.
35. Horowitz CR, Colson KA, Hebert PL, Lancaster K. Barriers to buying healthy foods for people with diabetes: evidence of environmental disparities. *American journal of public health*. 2004;94(9):1549-54.
36. Thomas LV, Wedel KR, Christopher JE. Access to transportation and health care visits for Medicaid enrollees with diabetes. *The Journal of Rural Health*. 2018;34(2):162-72.
37. Elhussein A, Anderson A, Bancks MP, Coday M, Knowler WC, Peters A, Vaughan EM, Maruthur NM, Clark JM, Pilla S, Look AHEAD Research Group. Racial/ethnic and socioeconomic disparities in the use of newer diabetes medications in the Look AHEAD study. *The Lancet Regional Health-Americas*. 2022;6:100111.
38. Si Y, Du J, Li Z, Jiang X, Miller T, Wang F, Zheng WJ, Roberts K. Deep representation learning of patient data from Electronic Health Records (HER): A systematic review. *Journal of Biomedical Informatics*. 2021;115:103671.
39. Gilboy N, Tanabe P, Travers D, Rosenau AM. Emergency Severity Index Version 4: Implementation handbook, AHRQ Publication. 2012. <https://www.govinfo.gov/content/pkg/GOVPUB-HE20-PURL-gpo23161/pdf/GOVPUB-HE20-PURL-gpo23161.pdf>. Accessed 2024, June 1.
40. Quinlan JR. Induction of decision trees. *Machine learning*. 1986 Mar;1:81-106.
41. Utgoff PE. Incremental induction of decision trees. *Machine learning*. 1989 Nov;4:161-86.
42. Breiman L. Classification and regression trees. Routledge; 2017 Oct 19.
43. Ghosh A, Kandasamy D. Interpretable artificial intelligence: why and when. *American Journal of Roentgenology*. 2020 May;214(5):1137-8.
44. Bishop CM, Nasrabadi NM. Pattern recognition and machine learning. New York: springer; 2006 Aug 17.
45. Bekkar M, Djemaa HK, Alitouche TA. Evaluation measures for models assessment over imbalanced data sets. *J Inf Eng Appl*. 2013 Apr;3(10).
46. Fawcett T. An introduction to ROC analysis. *Pattern recognition letters*. 2006;27(8):861-74.
47. van Rijsbergen CJ. Information Retrieval, Butterworths, London. 1979.
48. Hastie T, Tibshirani R, Friedman JH, Friedman JH. The elements of statistical learning: data mining, inference, and prediction. New York: springer; 2009 Aug.
49. Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: how to decide its appropriateness. *World Journal of Methodology*. 2021;11(4):116.
50. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. *Implementation Science*. 2015 Dec;11(1):1-3.
51. Keith RE, Crosson JC, O'Malley AS, Crompt D, Taylor EF. Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. *Implementation Science*. 2017 Dec;12(1):1-2.
52. Elo S, Kyngäs H. The qualitative content analysis process. *Journal of advanced nursing*. 2008 Apr;62(1):107-15.
53. Gupta N, Verma R, Dhiman RK, Rajsekhar K, Prinja S. Cost-effectiveness analysis and decision modelling: a tutorial for clinicians. *Journal of Clinical and Experimental Hepatology*. 2020 Mar 1;10(2):177-84.
54. Khaled A, Gulikers J, Biemans H, van der Wel M, Mulder M. Characteristics of hands-on simulations with added value for innovative secondary and higher vocational education. *Journal of Vocational Education & Training*. 2014 Oct 2;66(4):462-90.
55. Reisdorph N, Stearman R, Kechris K, Phang TL, Reisdorph R, Prenni J, Erle DJ, Coldren C, Schey K, Nesvizhskii A, Geraci M. Hands-on workshops as an effective means of learning advanced technologies including genomics, proteomics and bioinformatics. *Genomics*,

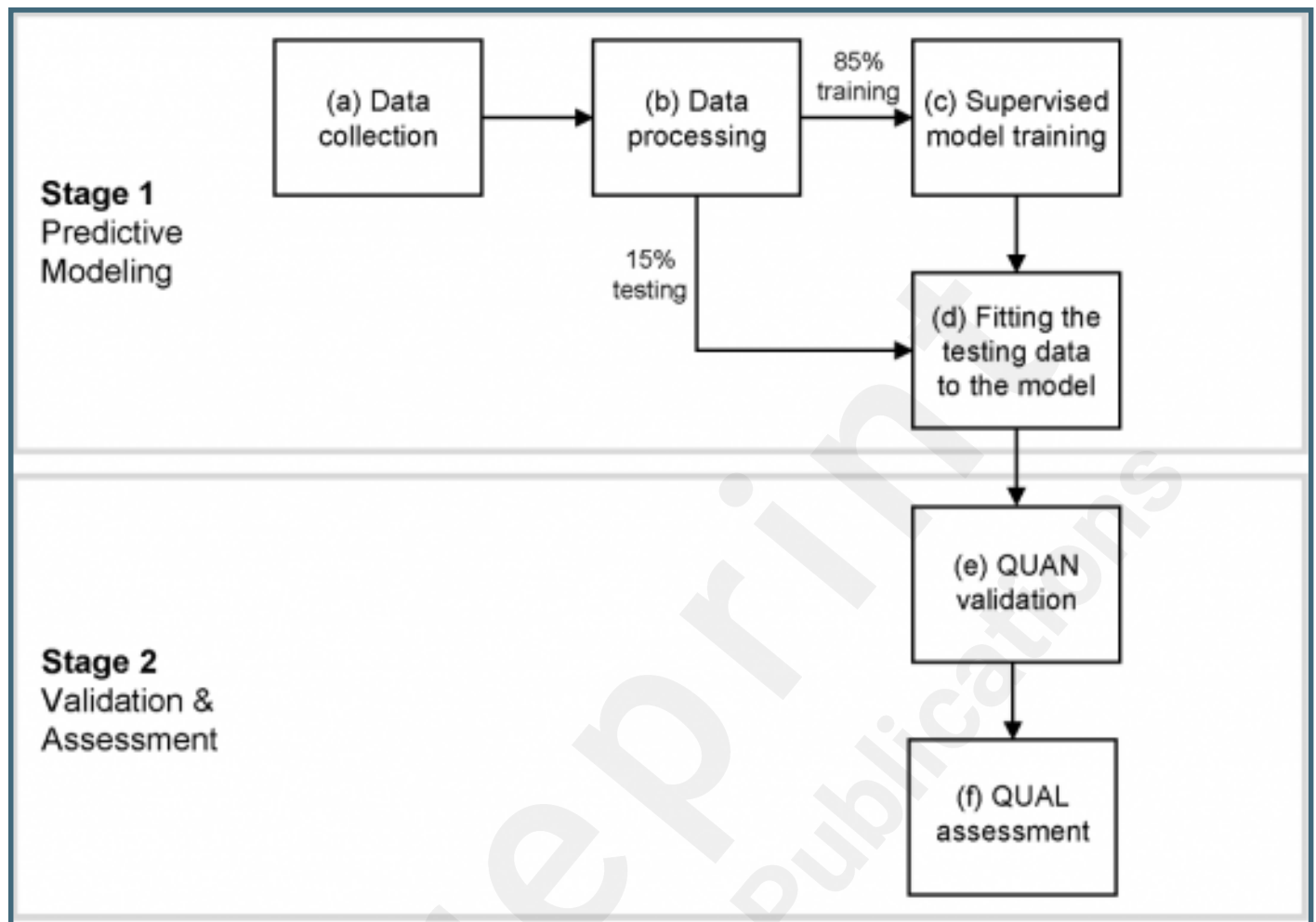
- Proteomics and Bioinformatics. 2013 Dec;11(6):368-77.
56. Cockburn A. Agile software development: the cooperative game. Pearson Education; 2006 Oct 19.



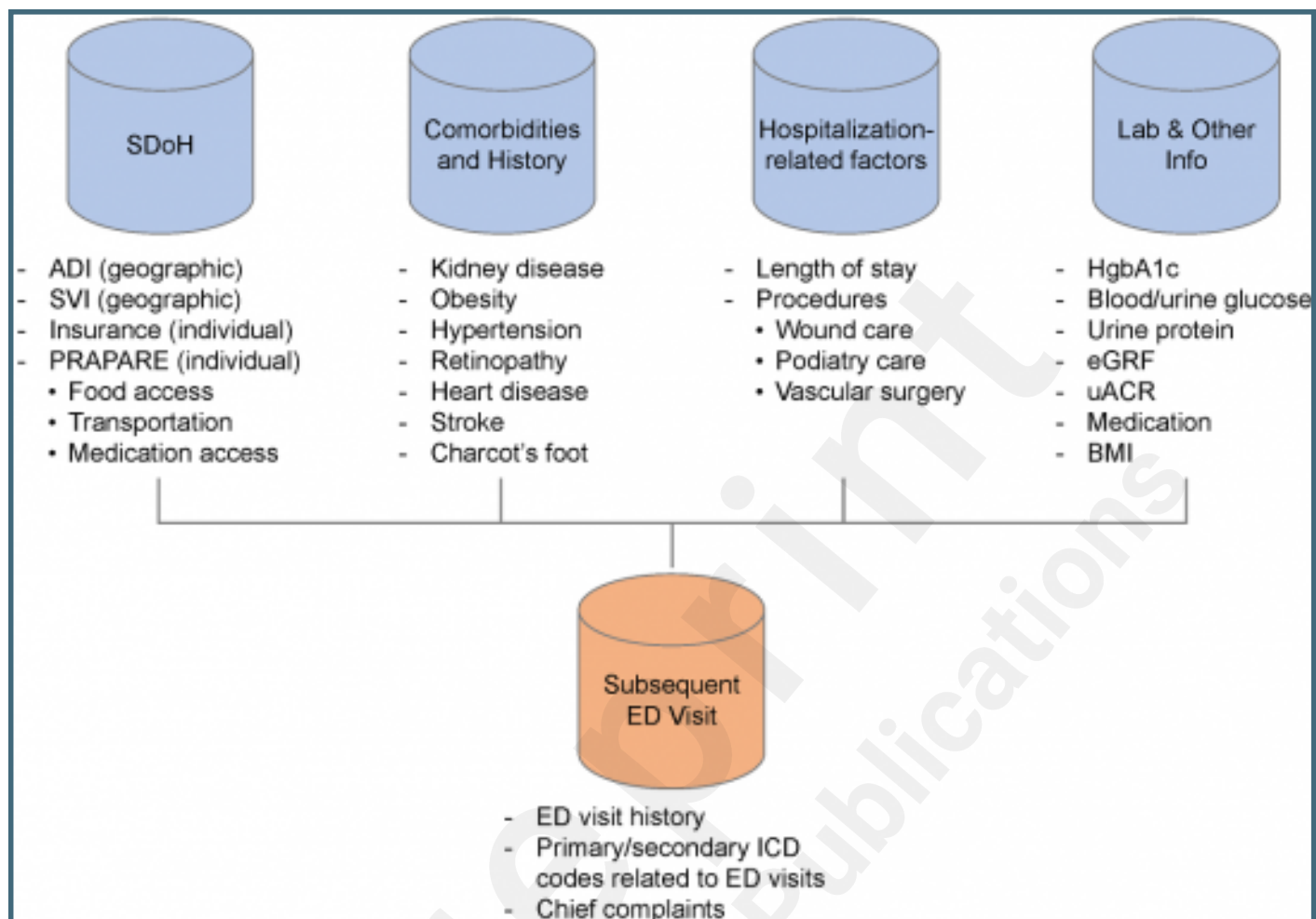
Supplementary Files

Figures

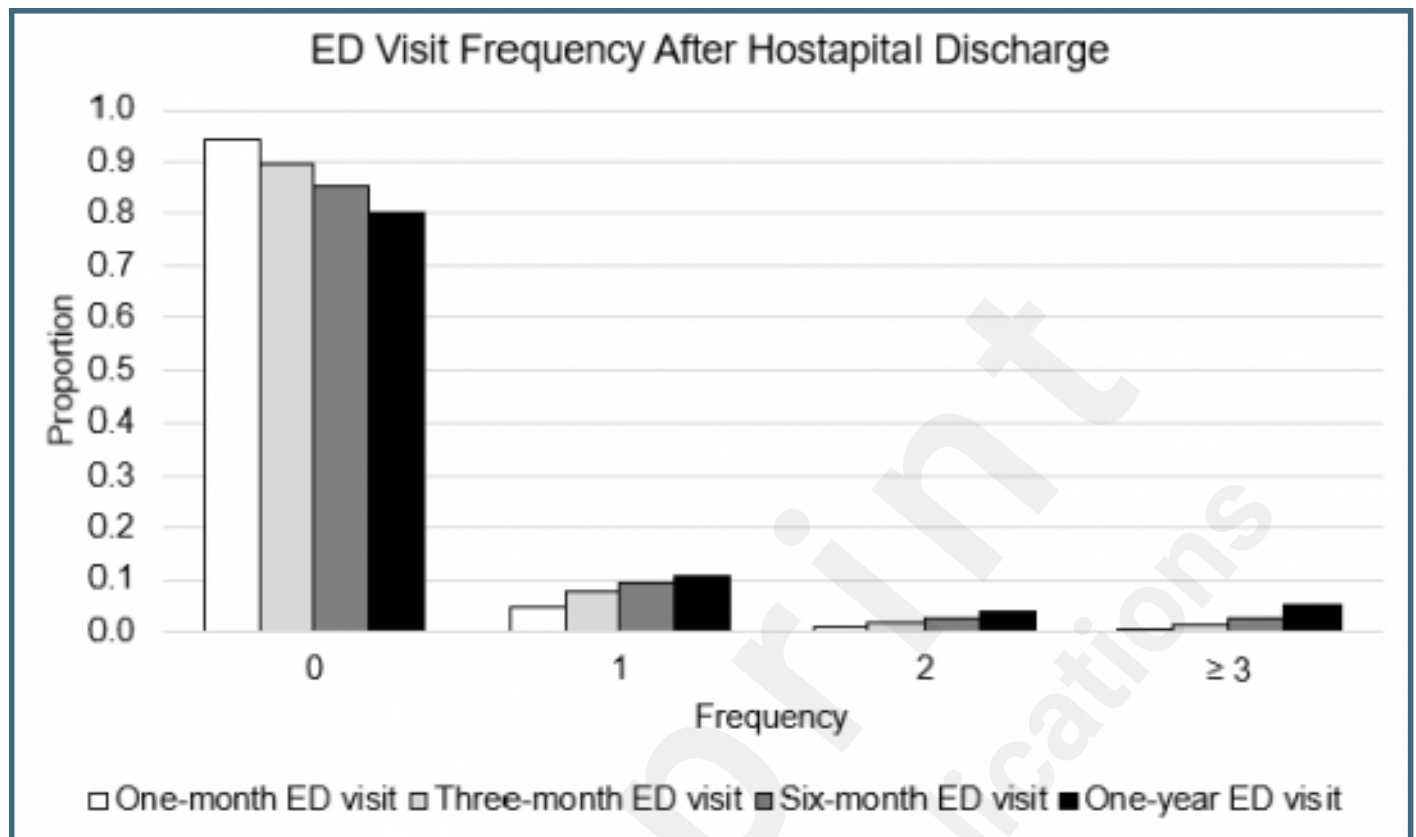
Study framework.



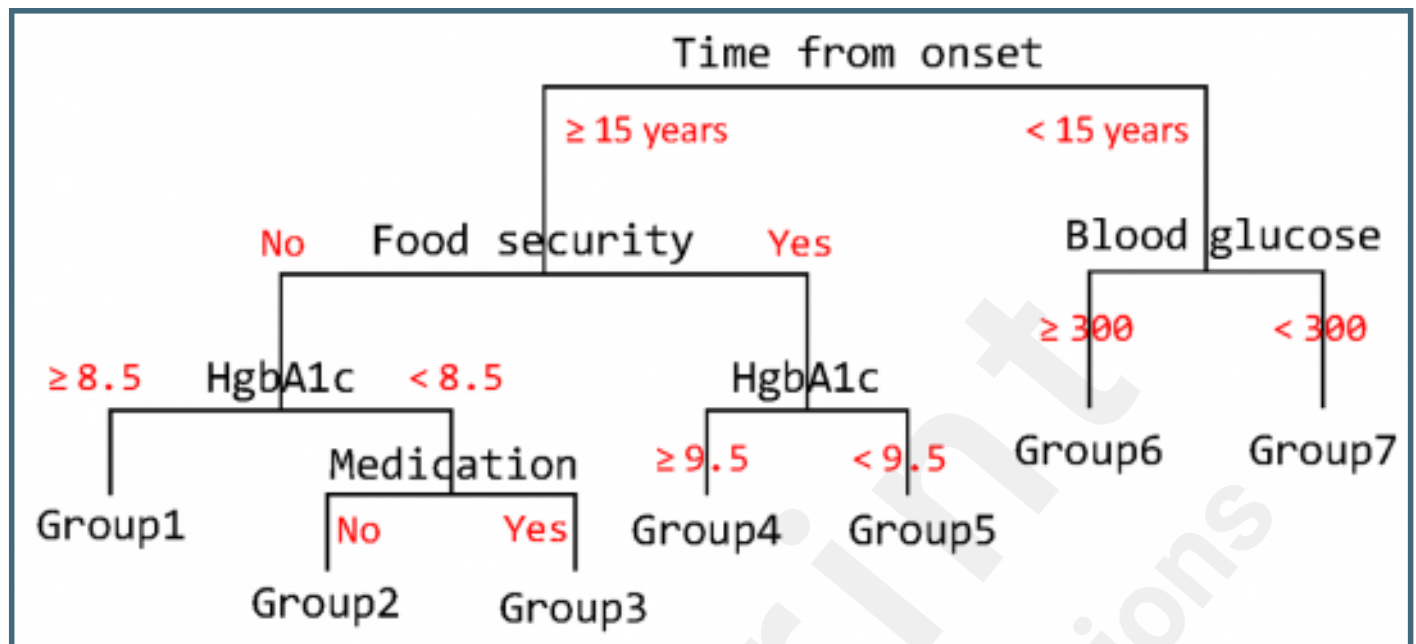
Data items utilized to build the PRADS model.



Diabetes-related post-hospitalization ED visit frequency.



A tree form example.



Sequential mixed methods evaluation of the PRADS for Stage 2.

