**UNCONVENTIONAL INDICATORS FOR DIABETIC**

**DIAGNOSIS**

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**Decoding Diabetics: Diabetic Retinopathy Detection using Machine Learning**

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Sri Lanka

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# ABSTRACT

Diabetic Retinopathy (DR) is a severe complication of diabetes that affects the retinal blood vessels, leading to potential vision impairment and even blindness if not addressed promptly. This paper explores the use of Machine Learning (ML) techniques for the detection and diagnosis of DR, providing a comprehensive analysis of how these technologies can revolutionize current screening methods. The study delves into the multifaceted process of employing ML for DR detection, encompassing stages such as data collection, preprocessing, model training, and performance evaluation. Early detection and timely intervention are critical in mitigating the progression of DR, as these measures can prevent significant visual impairment. Traditional screening methods, which require manual examination by trained ophthalmologists, are not only time-consuming but also pose accessibility challenges, particularly in underserved or remote areas where medical resources are scarce. In contrast, ML algorithms, especially those designed for the analysis of retinal images, offer a scalable and efficient alternative for DR screening. This research emphasizes the efficacy of ML models in automating the DR detection process, reducing the reliance on human expertise and making screening more accessible. By integrating advanced preprocessing techniques such as data augmentation, along with the implementation of sophisticated Convolutional Neural Network (CNN) architectures, the proposed approach achieves remarkable accuracy in detecting various stages of DR. The study highlights the transformative potential of ML in DR screening practices. By enhancing both the accessibility and efficiency of DR detection, ML-driven solutions can significantly improve patient care and visual health outcomes. The findings underscore the ability of ML to streamline and automate DR screening, providing a robust tool for healthcare professionals and enabling better management strategies for individuals at risk of this sight-threatening condition. Through the integration of these advanced technologies, the field of diabetic retinopathy screening is poised for significant advancements, offering promising prospects for improved management and prevention of vision loss in diabetic patients.

**Keywords:** Natural Language Processing, Diabetic Retinopathy (DR), Convolutional Neural Networks (CNNs), Image Processing

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# List of Abbreviations

|  |  |
| --- | --- |
| **Abbreviation** | **Description** |
|  |  |
| API | Application Programming Interface |
| UI | User Interface |
| GB | GigaByte |
| MB | MegaByte |
| CPU | Central Processing Unit |
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# INTRODUCTION

## Background and Literature Survey

Diabetic Retinopathy (DR) is a severe complication of diabetes that arises when high blood sugar levels persist over time, leading to damage in the small blood vessels of the retina. This condition, if left untreated, can progress to significant vision loss and even blindness. The prevalence of DR has increased in parallel with the global rise in diabetes, making it a leading cause of vision impairment worldwide. The early detection and timely management of DR are crucial in preventing severe visual outcomes. However, traditional screening methods, such as manual retinal examinations conducted by ophthalmologists, are resource-intensive and may be difficult to access, particularly in underserved or remote regions. This limited accessibility often leads to delayed diagnoses and treatment, contributing to preventable vision loss.

To address these challenges, Machine Learning (ML) algorithms have emerged as a promising solution for DR detection and diagnosis. These algorithms, particularly those designed to analyze retinal images, offer a scalable and efficient alternative to traditional screening methods. ML-based systems have the potential to revolutionize clinical practice by automating the screening process, allowing for earlier intervention and improved patient outcomes. By enabling widespread and accessible DR detection, ML can help reduce delays in diagnosis and treatment, ultimately improving the quality of care for patients at risk of diabetic retinopathy.

Recent advancements in machine learning, especially through deep learning techniques such as Convolutional Neural Networks (CNNs), have demonstrated remarkable effectiveness in the analysis of medical images for DR detection. For example, Gulshan et al. (2016) developed a sophisticated deep learning algorithm specifically designed to detect DR in retinal fundus images. This algorithm achieved impressive performance metrics, with sensitivity and specificity rates of 90.3% and 98.1%, respectively, when validated on an external dataset. The model was trained on a large corpus of 128,175 retinal images, showcasing the capability of deep learning to effectively automate DR screening.

In addition to deep learning, other machine learning techniques have also been applied to DR detection with notable success. Pratt et al. (2016) evaluated various classifiers, including Support Vector Machines (SVMs), Random Forests, and Artificial Neural Networks (ANNs), to assess their effectiveness in detecting DR. Their findings indicated that both SVMs and Random Forests delivered high accuracy and sensitivity, with Area Under the Curve (AUC) scores of 0.93 and 0.92, respectively. These results suggest that traditional machine learning methods can also be viable options for DR detection.

Furthermore, Ting et al. (2017) conducted a comprehensive study involving over 490,000 retinal images from 48,000 patients. They developed a deep learning model that demonstrated a sensitivity of 90.5% and a specificity of 91.6% in identifying clinically significant DR. This study not only highlights the effectiveness and scalability of machine learning for DR detection but also its potential to diagnose other eye diseases, such as age-related macular degeneration and glaucoma.

These studies collectively underscore the substantial promise of machine learning, particularly deep learning, in automating the detection and diagnosis of DR. By leveraging advanced algorithms for retinal image analysis, healthcare providers can improve early detection and treatment, thereby enhancing patient outcomes. However, despite the significant progress, several challenges remain in integrating ML-based systems into clinical practice. Issues such as data imbalance, the need for models to generalize effectively across diverse populations, the interpretability of model decisions, and ethical considerations must be carefully addressed to ensure these technologies are responsibly and effectively implemented in healthcare settings.

One of the primary challenges identified in the literature is the imbalance in the representation of DR stages within datasets. Certain stages, such as severe DR, are often underrepresented, leading to models that perform well on more common stages but less effectively on rarer ones. To address this issue, techniques such as class weighting or data oversampling during the training process can be employed to ensure a more balanced class distribution, thereby improving the model's performance across all stages of DR.

Another critical issue is the model's ability to generalize across diverse patient populations. The datasets used in these studies may not adequately represent all geographic regions and ethnicities, potentially affecting model performance. Variations in image quality, differences in camera equipment, and patient demographics can also influence the outcomes. To enhance generalization, it is crucial to train models on datasets that include a wide variety of retinal images and patient characteristics. This approach ensures that the models perform well across different populations and clinical environments, thereby improving their robustness and applicability in real-world settings.

In conclusion, while machine learning holds great potential for advancing DR detection and diagnosis, addressing these challenges is essential for the successful integration of ML-based systems into clinical practice. By focusing on improving model generalizability, ensuring balanced data representation, and addressing ethical considerations, researchers and practitioners can pave the way for more effective and equitable DR screening solutions. The continued collaboration between the medical and technology sectors is vital to fully harness the potential of machine learning in the detection and management of Diabetic Retinopathy.

## Problem & Hypothesis

The increasing global prevalence of Diabetic Retinopathy (DR) has highlighted significant issues in its diagnosis and management. Despite its severe impact on public health, many individuals remain unaware of the condition's potential severity, often leading to self-treatment without a comprehensive understanding of DR. Current diagnostic approaches are largely subjective, which introduces variability in diagnoses and complicates treatment consistency. Additionally, existing models may lack predictive capabilities, impeding a nuanced understanding of DR progression. Traditional diagnostic tools primarily focus on identifying DR without offering broader insights into public health trends. Addressing these gaps is essential for improving DR healthcare, increasing awareness, and developing more accurate and predictive diagnostic tools.

**Hypothesis:**

It is hypothesized that integrating advanced predictive models with machine learning algorithms and comprehensive datasets will substantially enhance the diagnosis and management of Diabetic Retinopathy. This approach is expected to improve diagnostic accuracy, enable earlier detection, and provide valuable public health insights.

The hypotheses are as follows:

1. **Improving Diagnostic Accuracy and Predictive Capabilities:** By developing a comprehensive dataset and leveraging machine learning models, it is anticipated that predictive models for different stages of DR will be significantly improved. This enhancement is expected to lead to more accurate diagnoses and a better understanding of DR progression, ultimately facilitating earlier intervention and more effective treatment.
2. **Enhancing Early Detection and Staging of DR:** It is hypothesized that advanced image analysis techniques combined with machine learning algorithms will enhance the early detection and accurate staging of DR. This approach is expected to improve the timeliness of diagnoses and enable more precise treatment plans, thereby potentially reducing the risk of severe vision loss.
3. **Improving Patient Engagement and Intervention:** The hypothesis is that incorporating patient history and utilizing technology to facilitate engagement will result in more effective early diagnosis and intervention for DR. This approach is expected to improve patient adherence to screening schedules and treatment plans, leading to better health outcomes.
4. **Addressing Public Health Trends:** By integrating comprehensive datasets and predictive models into public health tools, it is hypothesized that a better understanding of public health trends related to DR can be achieved. This integration is expected to enhance resource allocation, increase awareness, and improve overall management of DR at the population level.

To validate these hypotheses, the research will involve developing and evaluating predictive models for DR, assessing the impact of advanced image analysis, and exploring strategies to improve patient engagement and system support. This approach aims to advance DR healthcare by enhancing diagnostic accuracy, improving patient outcomes, and addressing systemic challenges.

## Research Gap

The existing literature on diabetic retinopathy (DR) screening programs highlights their significance but reveals several notable gaps that warrant further exploration and development:

* **Long-Term Effectiveness and Sustainability:**

Although the benefits of DR screening programs are acknowledged, there is a lack of comprehensive research on their long-term effectiveness and sustainability. Current studies often do not examine how these programs maintain their impact over extended periods amidst evolving patient demographics, healthcare infrastructure changes, and technological advancements. Future research should assess how well these programs continue to reduce the progression of DR and adapt to changes in the healthcare environment to ensure sustained success.

* **Patient Satisfaction and Engagement:**

The literature often overlooks patient satisfaction and engagement with DR screening programs. Understanding patient perspectives, the acceptability of screening methods, and barriers to participation is crucial for optimizing the impact of these initiatives. Research should explore patient experiences, identify factors influencing participation, and develop strategies to enhance engagement and satisfaction with screening processes.

* **Quality Assurance and Accuracy of Predictive Models:**

There is a need for rigorous evaluation of the quality and accuracy of predictive models used in DR detection through retinal imaging. Current studies may not provide thorough validation of these models in clinical settings, raising concerns about their reliability and effectiveness. Investigate the performance of predictive algorithms, validate their accuracy against manually labeled images, and assess their effectiveness in real-world scenarios to ensure reliable and practical applications.

* **Generalizability Across Diverse Populations:**

Machine learning models for DR detection may not generalize well across diverse populations due to variations in datasets, image quality, and patient demographics. This lack of generalizability can impact the model's performance across different geographic regions and ethnic groups. To improve model robustness and applicability, future research should train models on diverse datasets that include a wide range of retinal images and patient characteristics.

Addressing these gaps is crucial for advancing DR screening programs and ensuring their effectiveness and sustainability. By focusing on long-term impact, patient satisfaction, model accuracy, and generalizability, researchers and practitioners can enhance the quality of DR screening and ultimately improve patient outcomes and healthcare delivery.

*Table 1.1: Previous research and products comparison*

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Description automatically generated

In the domain of diabetic retinopathy (DR) screening and management, a detailed comparative evaluation was conducted to assess the strengths and limitations of several research studies: Research A, Research B, Research C, and the Proposed System. The evaluation focused on key criteria such as the utilization of retinal photography for DR screening, adherence to telemedicine standards, and the overall effectiveness in diagnosing and managing DR.

Research A was primarily recognized for its contribution to understanding diabetes and its complications, including diabetic retinopathy. However, when evaluated against the specific criteria of retinal photography for DR screening and adherence to telemedicine standards, Research A showed significant gaps. While it provided valuable insights into the broader aspects of diabetes management, it did not adequately address the critical need for retinal imaging as a tool for early detection of DR. Additionally, it lacked a focus on integrating telemedicine standards, which are essential for expanding access to DR screening in remote and underserved areas. As a result, despite its contributions to diabetes research, Research A's limitations in these areas reduce its effectiveness in offering a comprehensive solution for DR screening and management.

Research B demonstrated a strong focus on telemedicine standards, making significant advancements in the remote screening and management of diabetic retinopathy. Telemedicine plays a vital role in reaching patients who may not have easy access to traditional in-person screenings, and Research B’s work in this area is noteworthy. However, Research B fell short in its coverage of retinal photography, a crucial component for the early detection of DR. Retinal photography enables healthcare providers to visually assess the condition of the retina and identify early signs of damage caused by high blood sugar levels. The lack of emphasis on retinal photography in Research B limits its ability to offer a fully integrated and effective diagnostic process, leaving room for improvement in this area.

Research C emerged as a more balanced approach, successfully integrating both retinal photography and telemedicine standards into its framework. This dual focus allowed Research C to enhance the accuracy and accessibility of DR screening. By utilizing retinal photography, Research C could identify early signs of DR, while its adherence to telemedicine standards ensured that these screenings could be conducted remotely, reaching a broader population. However, despite these strengths, Research C did not fully address all aspects of the overall diagnostic and management process, particularly in areas such as patient follow-up and the integration of predictive analytics for long-term disease management. While Research C made significant strides in combining key elements, its approach still left room for further enhancement to create a more comprehensive and effective system.

In contrast, the Proposed System was evaluated for its effectiveness across all key criteria and was found to excel in several areas. The Proposed System was designed to integrate advanced retinal photography techniques, ensuring that early signs of DR could be accurately identified. This capability is crucial for timely intervention, which can prevent the progression of DR and reduce the risk of vision loss. Additionally, the Proposed System adhered to modern telemedicine standards, making it accessible to patients in remote and underserved regions. By combining these two critical elements—retinal photography and telemedicine—the Proposed System offers a comprehensive approach to DR screening and management. Moreover, the Proposed System was also designed to incorporate predictive analytics, patient follow-up mechanisms, and a robust diagnostic process, further enhancing its effectiveness.

The comprehensive analysis of the Proposed System highlights its ability to seamlessly integrate advanced retinal imaging techniques with modern telemedicine standards, setting it apart from existing research in the field. By offering a holistic approach that addresses early detection, accessibility, and ongoing patient management, the Proposed System provides a versatile and innovative solution for diabetic retinopathy. This approach not only improves screening accuracy but also enhances diagnostic capabilities, leading to better patient outcomes. The Proposed System's ability to bridge the gaps identified in previous research makes it a promising advancement in the fight against diabetic retinopathy, offering a path forward for more effective and accessible DR screening and management solutions.

## Scientific Contribution

This research provides several key contributions to the field of diabetic retinopathy (DR) screening and management:

* **Comprehensive Integration of Retinal Photography and Telemedicine:** The Proposed System excels in integrating both retinal photography and telemedicine standards. This combination enhances the accuracy of DR detection and facilitates remote access to screening services, addressing the challenges of limited accessibility in underserved areas.
* **Advanced Retinal Imaging Techniques:** The system employs state-of-the-art retinal photography techniques, allowing for precise early detection of DR. This advancement improves the ability to monitor retinal health and identify DR at its earliest stages, potentially reducing the risk of vision loss.
* **Seamless Telemedicine Integration:** By adhering to modern telemedicine standards, the Proposed System ensures that DR screenings can be conducted remotely. This approach increases accessibility for patients who may not have easy access to traditional in-person screenings, thus broadening the reach of DR screening programs.
* **Holistic Diagnostic Approach:** The system's comprehensive approach includes not only retinal imaging but also predictive analytics and patient management features. This holistic perspective supports better disease management and patient follow-up, enhancing overall care quality.
* **Improved Diagnostic Accuracy and Efficiency:** The integration of advanced algorithms and imaging technologies contributes to higher diagnostic accuracy and efficiency. This improvement ensures that DR can be detected more reliably, leading to timely and effective interventions.
* **Enhanced Accessibility and Patient Reach:** The combination of retinal photography and telemedicine facilitates wider access to DR screening, particularly in remote or underserved regions. This enhanced accessibility is crucial for early detection and management of DR across diverse populations.
* **Innovative Solutions for DR Screening:** The Proposed System represents a significant advancement in DR screening technology, offering a versatile and comprehensive solution. By addressing both the technical and accessibility challenges in DR management, the system stands out as a promising innovation in the field of diabetic retinopathy.

Overall, the Proposed System's ability to integrate advanced retinal imaging with telemedicine standards, combined with its focus on accurate and efficient diagnostics, establishes it as a leading solution in improving DR screening and management.

# RESEARCH PROBLEM

Diabetic retinopathy (DR) presents a significant and growing public health challenge worldwide, exacerbated by the rising incidence of diabetes. This condition, which affects the blood vessels of the retina, can lead to severe complications including vision loss and blindness if not managed effectively. Despite its severity, there remains a substantial gap in public awareness and understanding of DR. Many individuals with diabetes are unaware of the risks and severity associated with DR, often resorting to self-management practices without adequate medical oversight. This lack of awareness contributes to suboptimal treatment outcomes and delayed interventions, further compounding the health burden of DR.

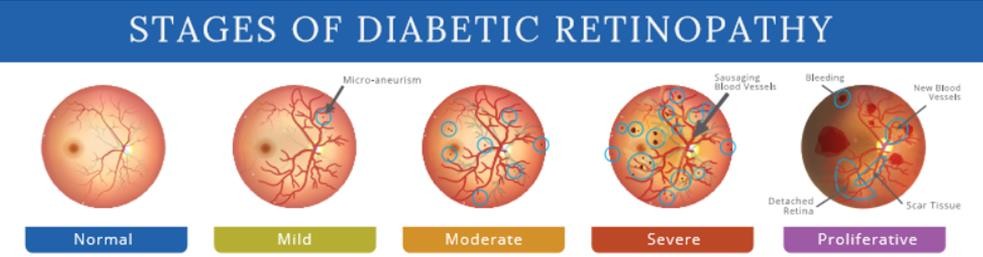
Current diagnostic methods for DR are predominantly reliant on subjective clinical assessments. These traditional approaches often involve the interpretation of retinal images by clinicians, which introduces variability in diagnoses and treatment consistency. This subjectivity can lead to discrepancies in disease staging and the overall management of DR. Additionally, traditional diagnostic tools tend to focus narrowly on identifying DR without providing a comprehensive analysis of the disease’s progression or its broader implications for public health.

The limitations of current diagnostic practices highlight a pressing need for advancements in DR management. Existing models and tools frequently lack predictive capabilities, which hampers the ability to forecast disease progression accurately. This limitation restricts early intervention and preventive strategies, potentially leading to more severe outcomes for patients. Moreover, traditional diagnostic methods often fail to integrate broader public health perspectives, missing opportunities to identify trends and inform community-wide strategies for DR management.

The low compliance rates for retinal screenings further complicate the effective management of DR. Despite the availability of screening programs, adherence rates remain persistently low, ranging from 30% to 60%. This non-compliance can be attributed to various factors, including patient discomfort during screenings, lack of awareness, and logistical barriers. Addressing these issues requires a comprehensive understanding of the underlying causes of non-compliance and the development of targeted interventions to enhance patient engagement and motivation.

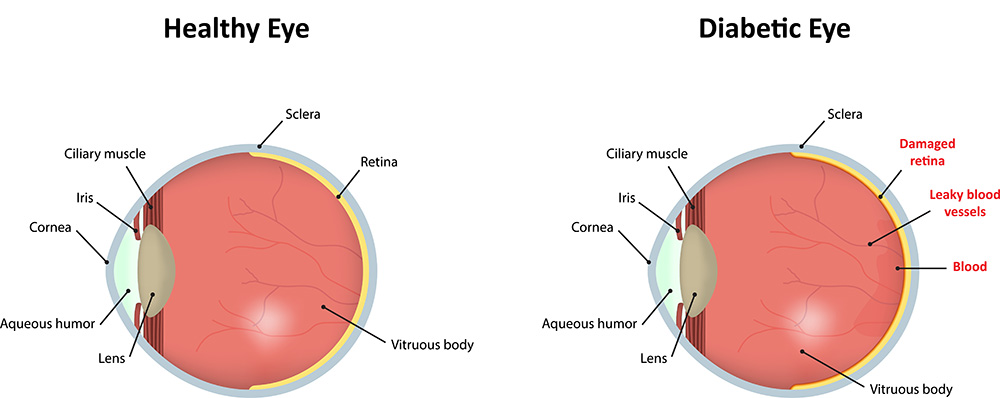
Quality issues with current screening technologies also present a significant challenge. Many screening methods, such as ophthalmoscopy, suffer from low image quality and interpretative variability. There is a pressing need for research focused on improving imaging technologies and integrating advanced methods such as artificial intelligence and machine learning to enhance diagnostic accuracy and reliability.

Socioeconomic barriers also play a critical role in DR management. Factors such as income levels, health insurance availability, and time constraints impact patients’ ability to access and adhere to screening programs. Research should explore these socioeconomic challenges in detail and propose strategies to mitigate their effects, such as community outreach programs, telemedicine initiatives, and policy changes aimed at improving healthcare access.

The healthcare system itself faces systemic issues that affect DR management. Insufficient specialist referral systems, a shortage of eye care providers, and inadequate public health funding contribute to these challenges. Research should investigate the feasibility of collaborative care models involving primary care physicians, endocrinologists, and eye care specialists. Additionally, policy recommendations to strengthen referral networks and increase public health funding are crucial for addressing these systemic barriers.

*Figure 2.1:* *Stages of Diabetic Retinopathy*

In summary, advancing the management of diabetic retinopathy requires addressing a multifaceted array of challenges. These include improving public awareness, developing more accurate and predictive diagnostic tools, overcoming systemic and socioeconomic barriers, and enhancing overall healthcare infrastructure. By tackling these issues, it is possible to improve early detection, provide better disease management, and gain a more comprehensive understanding of the public health impact of DR.



*Figure 2.2:* *Difference between a normal eye and an eye affected by Diabetic Retinopathy*

***Research Question:*** The management of diabetic retinopathy (DR) is significantly challenged by the limitations of existing diagnostic systems, which often fail to offer a comprehensive understanding of disease progression and individual variability. The current diagnostic approaches are frequently inadequate in providing a detailed assessment of DR, leading to generalized treatment recommendations that do not account for the nuances of individual cases. This lack of precision undermines the effectiveness of treatment and impedes the development of personalized care strategies.

Furthermore, existing systems often lack predictive capabilities, which are essential for anticipating disease progression and tailoring interventions to individual needs. To bridge these gaps, there is a pressing need for more sophisticated diagnostic tools and methodologies that can offer precise, personalized, and predictive insights into DR management.

Addressing these challenges requires a multi-faceted approach. First, there is a need for advanced algorithms capable of accurately analyzing retinal images to enhance early detection and staging of DR. These algorithms must be designed to handle the variability in retinal images and provide detailed assessments that support personalized treatment strategies. Second, integrating patient history into the diagnostic process can provide valuable context and improve the accuracy of early detection and management.

Additionally, leveraging public health data and predictive modeling can offer insights into disease trends and inform more effective healthcare strategies. By focusing on these areas, the research aims to advance the overall effectiveness of DR care and improve patient outcomes through more accurate, personalized, and predictive diagnostic approaches.

Of the above the below research questions were found with relation to our proposed system:

1. **How can advanced image analysis algorithms be developed to enhance the early detection and precise staging of diabetic retinopathy?**

The proposed system aims to develop sophisticated image analysis algorithms capable of accurately analyzing retinal images. By enhancing early detection and precise staging of DR, these algorithms will facilitate more effective and personalized treatment strategies.

1. **What role does incorporating patient history into the diagnostic process play in improving early detection and management of diabetic retinopathy?**

The system will explore the integration of patient history with current diagnostic practices to improve early detection and management of DR. This integration is designed to lead to more tailored and effective treatment strategies by incorporating historical data into the diagnostic process.

1. **How can predictive modeling be utilized to forecast the progression of diabetic retinopathy and inform personalized treatment plans?**

The system will investigate the use of predictive modeling to forecast DR progression and outcomes based on both clinical and imaging data. By enabling personalized treatment plans, predictive modeling aims to enhance disease management and anticipate future disease states.

1. **What strategies can be implemented to standardize diagnostic approaches for diabetic retinopathy and reduce variability in diagnoses?**

To minimize variability in DR diagnoses, the system will develop and implement strategies to standardize diagnostic approaches. This standardization will ensure consistent and reliable diagnoses across various healthcare settings.

1. **How can public health data be leveraged to enhance the understanding of diabetic retinopathy prevalence and inform healthcare strategies?**

The system will utilize public health data to gain insights into the prevalence and risk factors of DR. This approach will help inform healthcare strategies and resource allocation, improving overall public health management related to DR.

1. **What are the barriers to patient adherence to diabetic retinopathy screening recommendations, and how can these barriers be effectively addressed?**

The proposed system will identify and address barriers to patient adherence to DR screening recommendations. By developing strategies to overcome these challenges, the system aims to ensure timely and effective management of diabetic retinopathy.

1. **How can a comprehensive approach that integrates individual patient data with broader public health insights improve diabetic retinopathy care?**

The system will develop an integrated approach that combines individual patient data with broader public health insights. This comprehensive strategy will enhance DR care by providing more accurate diagnoses, tailored treatments, and effective management strategies.

# RESEARCH OBJECTIVES

## Main Objectives

The primary objective of this research is to develop and implement a sophisticated and reliable diagnostic tool aimed at the early identification and intervention of diabetic retinopathy (DR). This tool will serve as a pivotal resource for both patients and healthcare professionals by enhancing the accuracy of DR diagnosis and facilitating timely medical interventions.

To achieve this, the research seeks to:

Develop an advanced algorithm capable of analyzing retinal images with high precision to detect diabetic retinopathy at its earliest stages. This involves leveraging cutting-edge image analysis techniques and integrating machine learning models that can identify subtle signs of DR that may be missed by conventional methods.

Implement a comprehensive diagnostic framework that not only identifies the presence of DR but also classifies it into distinct stages based on severity. This classification will enable clinicians to make informed decisions about the appropriate level of intervention and tailor treatment plans to individual patient needs.

Enhance accessibility to effective screening by developing a user-friendly interface that facilitates seamless interaction between patients and clinicians. The interface will provide actionable insights derived from diagnostic results and support clinicians in designing personalized treatment strategies.

Integrate early intervention features that assist clinicians in implementing timely treatment plans. By providing recommendations based on the severity and stage of DR, the tool aims to empower healthcare professionals to act promptly and reduce the risk of vision loss.

Improve patient outcomes by deploying this diagnostic tool in real-world settings, evaluating its effectiveness in early DR detection, and ensuring its capability to significantly reduce the risk of vision loss. The ultimate goal is to create a robust system that not only detects diabetic retinopathy early but also facilitates effective management and prevents progression to more severe stages.

By advancing the capabilities of DR diagnostics and improving the overall management of the condition, this research aims to contribute to better patient care, enhanced early detection, and more effective treatment strategies, thereby significantly reducing the impact of diabetic retinopathy on vision health.

## Specific Objectives

For the achievement of this work’s primary objective the work should also realize the following specific objectives,

1. **To Develop a Robust Early Diagnosis Tool:** To Create an advanced algorithm or mechanism for the early detection of diabetic retinopathy (DR). To Integrate features that enable users to identify potential signs of DR at its initial stages, thereby improving early intervention and treatment outcomes.
2. **To Establish a Comprehensive DR Stage Identification System:** To Design a system capable of categorizing various stages of diabetic retinopathy. To Implement algorithms or methodologies that accurately determine the severity of DR based on retinal imaging, thereby facilitating precise staging and informed clinical decisions.
3. **To Build a User-Friendly Interface for Clinicians:** To Develop an intuitive and user-friendly interface tailored specifically for clinicians. To Ensure that the interface provides reliable diagnostic information, aiding in early intervention strategies and supporting effective clinical decision-making.
4. **To Implement Early Intervention Tools:** To Integrate features and tools that facilitate early intervention strategies for clinicians. To Provide actionable recommendations and guidance based on identified DR stages, assisting clinicians in making timely and informed decisions.
5. **To Mitigate Vision Loss Risks:** To Implement features aimed at reducing the risk of vision loss associated with diabetic retinopathy. To Ensure that the system provides actionable insights that help clinicians to mitigate the impact of DR on patients' vision, thereby enhancing overall patient care.

By achieving these sub-objectives, the research aims to create a comprehensive and effective diagnostic tool for diabetic retinopathy, enhancing early detection, improving treatment outcomes, and ultimately reducing the risk of vision loss.

# METHODOLOGY

This research represents a significant advancement in Diabetic Retinopathy management by combining machine learning algorithms with sophisticated data processing methods. Utilizing retinal fundus images from reputable databases, the study aims to automate the classification of Diabetic Retinopathy stages, thereby enhancing the accuracy and efficiency of screening processes. This innovative approach facilitates earlier diagnosis and supports healthcare professionals in making informed decisions regarding patient care. The subsequent sections offer a detailed overview of the methodology, including the steps involved in data collection, preprocessing, model design, and evaluation.

## Requirement Gathering

Numerous research papers have focused on diabetic retinopathy detection, with extensive studies conducted to understand how to leverage machine learning and deep learning techniques to develop accurate and effective solutions. Through a thorough analysis of these methodologies, insights were gained into the types of systems that offer the best results for detecting and predicting diabetic retinopathy. This careful evaluation led to the implementation of models that are most appropriate for the specific needs of this application. The following key considerations were taken into account during the development and implementation of the diabetic retinopathy detection model.

##### Functional Requirements

The table below outlines the functional requirements for the computer software, focusing on enhancing collaboration between healthcare professionals and users in the context of diabetic retinopathy. This approach aims to ensure effective management and timely intervention for individuals with diabetic retinopathy.

*Table 4.1:* *Functional Requirements*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **As an…** | **I want to…** | **So that…** |
| 1. | User/Clinician | Easily understand the stage of  diabetic retinopathy identified by the tool | Enable informed decision-  making for timely interventions |
| 2. | Healthcare Provider | Receive accurate information about the patient's retinopathy  stage | Optimize patient care and treatment planning |
| 3. | User/Clinician | Receive real-time updates on screening results | Enable immediate actions and interventions for high-  risk cases |

In addition to these requirements, the system is designed to:

1. **Predict Retinopathy Stage:** Accurately determine the stage of diabetic retinopathy from eye scans, helping healthcare providers assess the severity and plan appropriate treatments.
2. **Provide Detailed Reports:** Generate comprehensive reports on the retinopathy findings, including visual documentation and stage classification, to aid in effective patient management.
3. **Offer Real-Time Notifications:** Alert healthcare providers and users about significant changes in retinopathy status, facilitating prompt actions and follow-up.
4. **Integrate Historical Data:** Utilize previous patient data and historical eye scans to enhance the accuracy of predictions and offer a longitudinal perspective on disease progression.

##### Non-functional Requirements:

Non-functional requirements define essential attributes of the system, including its security, reliability, performance, scalability, and availability. The specific non-functional needs for the system are as follows:

1. **Data Integrity:** Ensuring data integrity is crucial throughout the system's lifecycle to prevent corruption, loss, or unauthorized alterations, thereby maintaining the accuracy and reliability of the information.
2. **Reliability:** The system must demonstrate a high level of reliability, delivering accurate and consistent results in the identification and grading of diabetic retinopathy.
3. **Performance:** The system should perform efficiently to provide the desired outcomes effectively and within acceptable timeframes.
4. **Security:** The system must be secure, protecting all information from malware attacks and unauthorized access to safeguard sensitive data.
5. **Availability:** The system should be accessible to users at all times, ensuring continuous operation and uninterrupted access.
6. **Scalability:** The system must be scalable to handle increasing volumes of retinal images and user interactions, maintaining effectiveness as the user base grows.

##### User Requirements

The user requirements for the proposed research component, as experienced by individuals using the app for diabetic retinopathy prediction, are detailed as follows:

1. **Efficient Retrieval of Retinal Images:** The system must efficiently retrieve retinal images that correspond to the features and characteristics specified by the user in their input. This ensures that users receive relevant images based on their queries.
2. **Tailored Image Results:** The system should provide personalized results by ranking and presenting retinal images according to the user's previous search history and preferences. This personalization aims to enhance the relevance and accuracy of the results, offering a more customized experience.
3. **Accurate Severity Predictions and Secure Storage:** The system must calculate and provide predictions on the severity of diabetic retinopathy based on the uploaded retinal images. These predictions should be stored securely in a data warehouse for future reference and analysis. This feature ensures that users receive reliable insights into the stage of their condition while maintaining data security.

These requirements are designed to ensure an effective, user-friendly, and tailored experience within the app, enhancing the accuracy of diabetic retinopathy predictions based on user-provided retinal images.

## Feasibility Study / Planning

##### Feasibility Study

This phase assesses the feasibility of implementing a diagnostic system for the early detection and intervention of diabetic retinopathy (DR). The feasibility study includes the following components:

##### Technical Feasibility

* **Data Availability:** Evaluate the availability and quality of retinal image datasets necessary for training and testing the machine learning models. Assess whether there is sufficient data to accurately detect and classify diabetic retinopathy, and consider the possibility of collecting additional data, particularly in the Sri Lankan context, to enhance model performance.
* **Hardware and Software Requirements:** Consider the hardware and software resources required for data collection, model training, and real-time image analysis. Assess the adequacy of the current infrastructure, including the need for high-resolution retinal cameras, powerful computational resources, and appropriate operating systems.
* **Model Development:** Evaluate the technical feasibility of developing and training machine learning models for diabetic retinopathy detection and staging using frameworks such as TensorFlow or Keras.

##### Economic Feasibility

* **Budgetary Considerations:** Estimate the costs associated with data collection, model training, software development, and the acquisition of any necessary hardware or software licenses.
* **Resource Allocation:** Assess the availability of skilled personnel for data collection, model development, and system implementation. Evaluate whether the research team has access to the necessary expertise and tools for successful project completion.
* **Return on Investment (ROI):** Consider the potential benefits of the research, such as improved accuracy in DR diagnosis and early intervention and determine whether the anticipated outcomes justify the financial investment. Table 1 shows the cost management and economic feasibility of the research.

*Table 4.2: Budgetary Cost*

|  |  |
| --- | --- |
| **Type** | **Cost** |
| Internet use and web hosting | 5,000 LKR |
| Publication costs | 12,110 LKR |
| Stationery | 5,500 LKR |
| **TOTAL** | **22,610 LKR** |

##### Legal and Ethical Feasibility

* **Data Privacy and Ethics:** Evaluate the legal and ethical considerations of collecting and using patient data, particularly retinal images, for research purposes. Ensure compliance with data privacy regulations and obtain informed consent from participants when necessary.
* **Intellectual Property:** Assess any intellectual property issues related to the developed models, algorithms, or software. Consider potential legal restrictions or copyright concerns.

##### Operational Feasibility

* **Data Collection and Processing:** Assess the practicality of collecting and processing retinal images in clinical settings. Consider factors such as data volume, image quality, and the capacity for real-time processing in diagnosing DR.
* **Model Deployment:** Evaluate the operational feasibility of deploying machine learning models for DR detection and staging in real-world settings. Ensure that the models can operate efficiently without causing delays or disruptions in clinical workflows.

##### Time/Schedule Feasibility:

* **Project Timeline:** Develop a project timeline that includes milestones for data collection, model development, testing, and deployment. Assess whether the project can be completed within the available timeframe. Figure 4.1 illustrates the schedule management plan.

A gantt chart with multiple levels

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*Figure 4.1: Gannt Chart*

##### Social and Cultural Feasibility:

* **Acceptance and Impact:** Consider the social and cultural aspects of implementing a diagnostic system for diabetic retinopathy. Assess the acceptance of such technologies among patients, clinicians, and healthcare institutions and evaluate their potential impact on clinical practice.
* **Bias and Fairness:** Evaluate the potential for bias in the machine learning models and algorithms used for DR detection. Ensure that the models are fair and do not discriminate against any particular demographic group.

In addition to the feasibility study, the project includes a risk management plan and a communication management plan to address potential challenges and ensure effective communication among stakeholders.

##### Risk Management Plan

The risk management plan identifies potential risks and outlines strategies to mitigate them. It ensures that the project team can continue working without significant interruptions. Table 4.3 shows the risk management plan.

*Table 4.3: Risk Management Plan*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Risk** | **Trigger** | **Owner** | **Response** | **Resource Required** |
| Risk with respect to the Project Team | Illness or sudden absence of team member(s) | Project Leader | Inform the supervisor and co-supervisor. Reallocate tasks among team members. | Project Schedule Plan/Gantt Chart, Backup resources |
| Risk with respect to the Panel/Supervisor(s) | Panel requests changes or is absent from scheduled meetings | Project Leader | Implement changes immediately and update all relevant documents. Reschedule meetings if necessary. | Project Schedule Plan/Gantt Chart, Meeting Log, Proper Email |

##### Communication Management Plan

Effective communication is critical to the project's success. The communication management plan ensures that all team members, supervisors, and co-supervisors receive the necessary information throughout the project. It outlines the communication objectives, media, and strategies for different stakeholders, ensuring that communication is adequate, specific, sufficient, concise, and timely. The communication media used for the project include:

1. Email
2. Documents (MS Word and/or PowerPoint)
3. Phone calls
4. Meetings (using meeting rooms, conference calls, MS Teams)
5. Chats (WhatsApp)

## Task Breakdown and Project Management

Before starting with the implementation steps, an important preparatory action was breaking down the jobs and carrying out effective management of the project. The versatile project management application, Microsoft Planner, was used to explicitly segregate the project into smaller well-defined phases. This helped provide clear and organized guidelines for the development process. Different resources and times would be assigned to each small task from model creation through system integration so that team members could work together and follow up on progress. Figure below represents the MS Planner board that was used for task decomposition. The entire development cycle took place over three sprints each lasting approximately one month.

A computer screen shot of a diagram

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*Figure 4.2:* *Work Breakdown Structure*

A screenshot of a computer

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*Figure 4.3: MS Planner Board*

A screenshot of a computer

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*Figure 4.4:* *MS Planner Board*

## Experimentation Methodology

To ensure the client app operates smoothly, users should have a device with either iOS or Android, equipped with at least 1GB of RAM and 56MB of available storage. Reliable internet connectivity is also required to access the app’s features and content. These minimum requirements are set to offer a smooth user experience while keeping the app lightweight and compatible with a wide range of devices.

For the back-end, the server hosting the application should be running on either Windows or Linux, with a minimum of 8GB of RAM and 30GB of storage. Initially, 200 megabytes of database storage will be adequate. However, as the app's user base and data requirements grow, these specifications may need to be scaled up to handle increased traffic and data storage needs. Scalability is essential to maintain optimal app performance as usage expands.

##### Experimentation Criteria

To assess the effectiveness and feasibility of our application, we will use a two-pronged approach focusing on scalability and usability.

Firstly, scalability will be evaluated by analyzing the application's performance as user numbers and data storage requirements increase. Controlled experiments will be conducted to assess how well the system manages higher loads, tracking key metrics such as response times and resource usage. Meeting predefined benchmarks will indicate the system's ability to scale effectively with growing demands. If performance metrics fall short, it will highlight the need for further resource scaling or optimization.

Secondly, usability will be assessed through user experience testing to gauge how well individuals interact with the application. We will collect feedback on ease of navigation, responsiveness, and overall satisfaction. Adhering to the minimum system requirements will ensure the application remains accessible and functional across various devices. Usability testing will identify any interface or experience issues that might impact user engagement.

By integrating both scalability and usability into our evaluation, we aim to create an application that not only scales efficiently with user growth but also delivers an intuitive and satisfying experience, contributing to its long-term success.

## Data Collection

This study utilizes retinal fundus images sourced from two prominent platforms: Aravind Eye Hospital in India and the EyePACS platform. The dataset encompasses a diverse array of retinal images, each categorized into various stages of Diabetic Retinopathy, ranging from no Diabetic Retinopathy to severe Diabetic Retinopathy. These images were acquired using different types of fundus cameras, resulting in variations in image resolution and quality. By integrating images from these reputable sources, the dataset provides a comprehensive foundation for training and evaluating the machine learning model, ensuring a broad representation of Diabetic Retinopathy stages and conditions.

## Data Preprocessing

Data preprocessing is essential for maximizing the performance of machine learning models by preparing the data in the most suitable format for analysis. The preprocessing steps carried out in this study are as follows:

1. **Image Resizing:** To ensure consistency throughout the dataset, all retinal images were resized to a uniform dimension of 320x320 pixels. This resizing is crucial for maintaining consistent input sizes for the Convolutional Neural Network (CNN), which streamlines the training process and optimizes feature extraction. By standardizing the image dimensions, the model can more effectively learn spatial hierarchies and patterns, free from the influence of varying image resolutions.

This process involves resizing each image I to dimensions W×H:

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Description automatically generated**

where **W** and **H** are the width and height of the resized image (320x320 pixels in this study).

1. **Gaussian Blur Application:** Gaussian blur was applied to the resized images to reduce high-frequency noise and enhance the visibility of key features such as retinal blood vessels. This technique smooths out minor variations and reduces the impact of noise, which is particularly beneficial for detecting subtle features indicative of Diabetic Retinopathy. The blur helps in focusing the model's attention on relevant structural details, improving the overall accuracy of the feature extraction process. Gaussian blur is applied to an image to smooth out noise.

The Gaussian blur operation can be expressed as:

A black and white math symbols

Description automatically generated with medium confidence

where **σ** is the standard deviation of the Gaussian kernel. This operation helps in enhancing the visibility of features such as retinal blood vessels.

1. **Grayscale Conversion:** To enhance the focus on key features relevant to Diabetic Retinopathy, the images were converted to grayscale. This process removes color information, thus reducing distractions and improving the emphasis on contrasts and textures within the retinal images. By concentrating on intensity values alone, grayscale images improve the model's effectiveness in identifying and categorizing stages of Diabetic Retinopathy based on essential visual characteristics. Converting an image to grayscale involves averaging the RGB channels.

A black text with black letters

Description automatically generated with medium confidenceFor an image with RGB values (R,G,B) the grayscale value **Ggray** is calculated as:

This conversion highlights the intensity of features without the influence of color variations.

1. **Data Augmentation:** To mitigate overfitting and enhance the model's robustness, several data augmentation strategies were implemented. These strategies included:
2. **Rotation:** Images were randomly rotated to simulate different viewing angles and enhance the model's ability to recognize features regardless of their orientation.

Rotation by angle θ is achieved using a rotation matrix R(θ):

A math equations with numbers

Description automatically generated with medium confidence

1. **Zooming:** Random zooming was applied to provide the model with diverse scales of retinal features, which helps in recognizing patterns at different levels of magnification.

Zooming involves scaling the image by a factor **s**:

**A black and white image of a mathematical equation

Description automatically generated**

1. **Flipping:** Both horizontal and vertical flipping techniques were applied to create more variability in the training data. This approach helps the model become more robust to changes in image orientation. By augmenting the dataset with these transformations, the model benefits from enhanced generalization and improved performance on previously unseen data.

Flipping can be horizontally or vertically:

A math equations on a white background

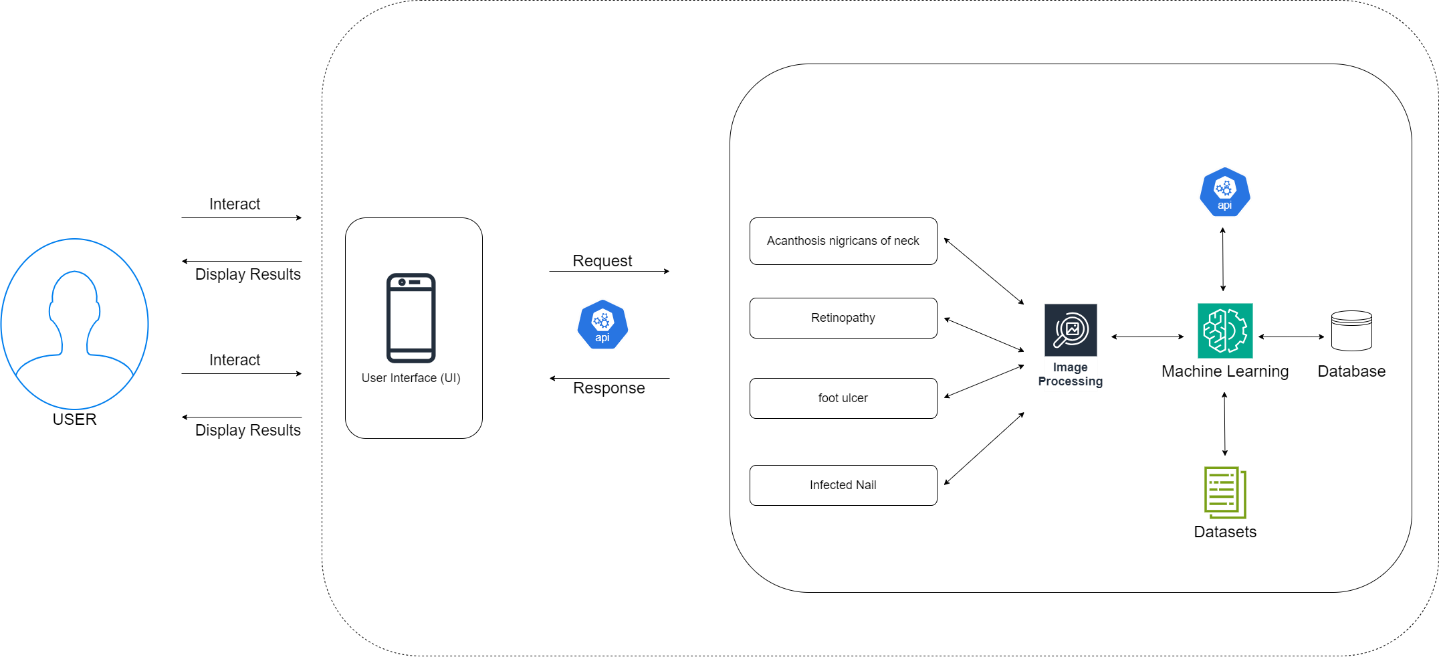
Description automatically generated

## System Architecture

The system architecture for text-to-speech conversion with emotion encompasses a multi-component framework. It includes modules for text analysis, emotion recognition, speech synthesis, and prosody modulation. These components work collaboratively to infuse textual input with emotional nuances, resulting in emotionally expressive speech output.

##### Overall System Architecture

As illustrated in the below figure, the proposed system is composed of four key components, each contributing to the comprehensive detection and prediction of diabetes:



*Figure 4.5: Overall System Architecture Diagram*

##### Neck Image-Based Diabetes Detection

The first component is designed to detect diabetes through images of the user's neck, captured at home. Users upload these images, and the system extracts relevant features such as neck image characteristics, the date of capture, and additional parameters. These features are then analyzed by the diabetes prediction model to identify potential indicators of the disease. This innovative, non-invasive approach leverages visual cues from home-captured images, providing an early detection method for diabetes.

##### Foot Ulcer Analysis for Diabetes Prediction

The second component focuses on predicting diabetes by analyzing data related to foot ulcers. Users input information about their foot ulcers, and the system extracts critical details such as the date and specific ulcer characteristics. The prediction model then assesses the likelihood of diabetes based on these indicators, offering a unique perspective on diabetes prediction through foot health analysis. This approach provides valuable insights for early identification and intervention.

##### Retinopathy Detection in Eye Scans

The third component employs image analysis to detect signs of retinopathy in eye scans, specifically targeting diabetic patients. The system extracts feature from these scans, such as retinal abnormalities and the date of the scan, and uses them in the prediction model to determine the stage of retinopathy. This component focuses on early intervention and management of diabetic complications related to vision, enhancing the system's overall effectiveness in addressing diabetes-related health issues.

##### Nail Analysis for Diabetes Prediction

The fourth component utilizes nail characteristics to predict diabetes. Users provide information about their nail features, and the system extracts essential parameters, including the date and specific nail-related features. These are incorporated into the diabetes prediction model, which assesses the likelihood of diabetes based on nail analysis. This component offers a unique approach by considering indicators from nail health, contributing to a holistic and comprehensive method for predicting diabetes through various sources of information.

##### Individual System Architecture

This section of the proposed solution focuses on employing advanced machine learning algorithms to detect and manage Diabetic Retinopathy through the analysis of retinal images uploaded by users. Users begin by submitting images of their retinas via the web application. The system then carefully analyzes these images, extracting key features such as the presence of microaneurysms, hemorrhages, and other retinal anomalies that are indicative of Diabetic Retinopathy. Additionally, the system considers relevant metadata, such as the date of image capture, to ensure a thorough and accurate assessment, thereby supporting timely intervention and management of the condition.

A diagram of a computer system

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*Figure 4.6: Individual Architecture Diagram*

##### Objective and Predictive Capability

The primary goal of this solution is to facilitate the early detection and management of Diabetic Retinopathy by leveraging advanced machine learning techniques. The system is designed to assess the severity and stage of Diabetic Retinopathy using retinal images uploaded by users through a dedicated web application. By analyzing these images, the system can provide early warnings and insights into the user's condition, enabling timely intervention and improving patient outcomes. The ability to detect various stages of Diabetic Retinopathy is crucial for preventing further complications and ensuring appropriate care.

##### System Architecture and Integration

As shown in the referenced figure, the proposed solution integrates a user-friendly web application with a robust web service. The web application is designed to allow users to upload retinal images seamlessly. This application serves as the entry point for users, making it easy for them to contribute images for analysis. The web service, equipped with a REST API, acts as the intermediary between the web application and the Machine Learning (ML) model, facilitating the transmission and analysis of retinal images.

##### Predictive Features and Machine Learning Integration

The system offers several predictive capabilities. Firstly, it processes the uploaded retinal images to detect and classify the different stages of Diabetic Retinopathy. Secondly, it provides predictions regarding the severity of the condition based on the analysis of the retinal features. The ML model employed in this solution is trained on a vast dataset of annotated retinal images, ensuring accurate predictions. Additionally, the system's predictive features are designed to extend beyond Diabetic Retinopathy, with the potential to identify other related eye conditions.

##### Data Management and Cloud-Based Infrastructure

For effective data management, the solution utilizes a cloud-based storage account, ensuring secure storage and easy retrieval of retinal images and ML model data. Azure Storage is implemented to manage the training data and model, providing a reliable infrastructure for data storage. The ML model is trained and deployed using Azure ML Studio, which offers a comprehensive environment for managing the entire machine learning lifecycle.

##### Operational Flow and Deployment

The operational flow begins with users uploading retinal images via the web application. These images are then transmitted to the web service, where the ML model, deployed in Azure ML Studio, analyzes them to predict the severity and stage of Diabetic Retinopathy. The results are subsequently relayed back to the web application, which displays the predicted severity and stage to the user. The deployment of this solution on Azure ensures scalability and reliability, making it capable of handling large-scale screening initiatives efficiently. The combination of a user-friendly web application, a robust web service, and advanced ML capabilities provides a comprehensive framework for Diabetic Retinopathy detection and management.

## Technologies and Implementation

This section discusses the technologies and tools used for the implementation of this component, along with their respective applications

*Table 4.4:* *Backend implementation technologies and usage of the system*

|  |  |
| --- | --- |
| **Technologies** | **Purposes** |
| **Languages** | |
| Python | * Data Processing * Algorithm Development * Backend Development |
| NextJS | * Frontend Development |
| **Libraries** | |
| NumPy | * Used by Pandas library |
| Pandas | * Data Processing |
| OpenCV | * Image Processing |
| TensorFlow | * Image Processing |
| Keras | * Image Processing |
| Multi Modal Fusion | * Data Processing |
| NLTK | * Natural Language Processing * IR System Development |
| Jupyter | * Data Processing * Algorithm Development * Backend Development |
| **Cloud Services** | |
| Cloud compute server (AWS EC2) | * IR System Development |
| Serverless Backend service (AWS Lambda) | * Backend Development |
| NoSQL database (AWS DocumentDB) | * Document Unit Storage |
| Relational database (AWS RDS) - PostgreSQL | * Application Data Storage * User History Storage * Data Warehouse Implementation |
| Storage (AWS S3) - optional | * For Storage |
| **Tools** | |
| Visual Studio Code | * Data Processing |

##### Application Backend Implementation

*Table 4.5:* *Backend implementation of the system*

|  |  |
| --- | --- |
| **Technology** | **Usage** |
| Firebase | * Application database and Authentication |
| Insomnia | * API endpoint testing |
| Jupyter NoteBook | * Development IDE |
| Python | * Programming language |
| Python-dotenv | * Managing credentials in a secure way by storing as environmental variables |
| SonarLint | * Code quality validation |

##### Application Frontend Implementation

Table 4.6 lists the technologies and tools used in mobile application frontend development.

*Table 4.6:* *Frontend development technologies and usage*

|  |  |
| --- | --- |
| **Technology** | **Usage** |
| Figma | * User Interface (UI) prototyping |
| NextJS | * Web Application Development |
| SonarLint | * Code quality validation |

## Development Process

In our research, we opted for the Waterfall model because of its structured and systematic nature, which aligns well with the clear and defined requirements of our project. This model offers a linear and predictable development process, enabling us to manage each phase with precision. After thoroughly evaluating the project's needs and specifications, we determined that the sequential approach of the Waterfall model would best support our objectives.

As illustrated in Figure 4.7, the development process follows distinct, non-overlapping phases, each dedicated to a specific task. This ensures a systematic progression from one stage to the next, allowing us to methodically address issues, define and establish the necessary functionalities, and anticipate desired outcomes.

By analyzing the requirements and scheduling tasks within set timeframes, the Waterfall model allows us to manage our research effectively over the span of one year. This approach provides a clear framework for completing each task, ensuring that each stage meets its objectives before advancing to the next. The structured methodology of the Waterfall model supports a thorough and predictable development process, aligning seamlessly with our research objectives and timelines.

A diagram of a process

Description automatically generated

*Figure 4.7: Waterfall Development Method*

## Model Architecture

The CNN architecture developed for this study is tailored to effectively capture and interpret detailed features from retinal fundus images. The model is structured as follows:

1. **Convolutional Layers:** The network consists of multiple convolutional layers, each utilizing different filter sizes to identify complex spatial patterns within the images. The convolution operation for a given input image I with a filter K can be expressed as:

A number and mathematical symbols

Description automatically generated with medium confidence

where **\*** denotes the convolution operation and **(x,y)** are the coordinates of the convolution result.

The design includes:

1. **Initial Convolutional Layers:** These layers apply 32 filters with a 3x3 kernel size to detect fundamental features like edges and textures.
2. **Intermediate Convolutional Layers:** As the network progresses, the number of filters increases to 64 and then 128, using the same kernel size to capture increasingly intricate and abstract features. This stepwise approach allows the model to build hierarchical representations of the retinal images.
3. **Max-Pooling Layers:** Following each convolutional layer, max-pooling layers are used to decrease the spatial dimensions of the feature maps. This process reduces computational demands and highlights the most critical features by eliminating less significant information, thus aiding the model’s generalization capabilities.

Max-pooling reduces the spatial dimensions by taking the maximum value in each pooling window. For a pooling window size p × p, the max-pooling operation can be defined as:

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where **F** is the feature map after convolution, and **(x,y)** is the position in the pooled feature map.

1. **Fully Connected Layers:** Following feature extraction, the output is flattened and processed through fully connected layers.

The output of a fully connected layer **h** with weight matrix **W** and bias **b** is given by:

A black and white math symbols

Description automatically generated with medium confidence

where **x** is the input vector (flattened feature map), and **W** and **b** are learned weights and biases.

The architecture features:

1. **First Fully Connected Layer:** This layer includes 512 units and is followed by a dropout layer with a 50% dropout rate to mitigate overfitting. It integrates the extracted features into a unified representation.
2. **Second Fully Connected Layer:** Comprising 256 units, this layer is also accompanied by a dropout layer to provide additional regularization. It refines the feature representation further before the final classification.
3. **Output Layer:** The final layer is composed of five units, each corresponding to a specific stage of Diabetic Retinopathy: no DR, mild DR, moderate DR, severe DR, and proliferative DR. To enable classification, a softmax activation function is used in this layer, generating a probability distribution across the different stages, which helps in assigning retinal images to the correct DR category.

A mathematical equation with numbers and symbols

Description automatically generatedFor classification into C classes, the softmax activation function S converts the logits z into probabilities:

where **zi** is the logit for class **i**, and **C** is the total number of classes.

## Training and Evaluation

The model training and evaluation process was conducted with the following procedures:

1. **Training:** The CNN model was trained over four epochs with a batch size of 32. The dataset was divided into training (80%) and testing (20%) subsets to assess how well the model performs on new data. The Adam optimizer was employed with a starting learning rate of 1e-4. To mitigate overfitting and maintain stable training, techniques such as early stopping and learning rate adjustments were used. Early stopping halts the training when there is no further improvement in the model’s performance on the validation set, thus avoiding unnecessary computations.
2. **Evaluation Metrics:** The following metrics were used to evaluate the model’s performance:
3. **Accuracy:** Assesses the proportion of correctly classified images relative to the total number of images.

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Description automatically generated

1. **Precision:** Measures the ratio of true positives to the sum of true positives and false positives, indicating how well the model avoids false positives.

Precision for class i is calculated as:

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where **TPi​** is the number of true positives and **FPi** is the number of false positives for class **i**.

1. **Recall:** Calculates the ratio of true positives to the sum of true positives and false negatives, reflecting the model’s ability to identify true positives.

A black and white math equation

Description automatically generatedRecall for class i is given by:

where FNi​ is the number of false negatives for class i.

1. **F1-Score:** Combines precision and recall into a single metric by calculating their harmonic mean, providing a balanced assessment of the model’s overall performance.

The F1-score is the harmonic mean of precision and recall:

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1. **Confusion Matrix:** The confusion matrix was employed to evaluate the model’s performance across different stages of Diabetic Retinopathy. This tool offers detailed insights into how well the model performs for each class, highlighting both strengths and areas needing improvement.

For a binary classification problem, it can be represented as:

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Description automatically generated

where **TP** is true positives, **FP** is false positives, **FN** is false negatives, and **TN** is true negatives.

1. **Cohen's Kappa Score:** Cohen's kappa was calculated to assess the level of agreement between the model’s predictions and the actual labels, adjusting for chance.

**A black and white image of a mathematical equation

Description automatically generated**

where **Po** is the observed agreement and **Pe**​ is the expected agreement by chance.

Through the implementation of thorough preprocessing, advanced architectural design, and meticulous training and evaluation methods, this study seeks to improve the precision and dependability of Diabetic Retinopathy detection systems. These enhancements are expected to lead to better patient outcomes and more effective clinical decision-making.

## Testing & Implementation

##### A diagram of a software development process Description automatically generatedTesting

*Figure 4.8: Testing Lifecycle*

In our research, the testing and quality assurance phase is fundamental to ensuring the excellence and reliability of our developed system prior to deployment. This phase adheres to industry standards and is crucial for enhancing the overall quality of our research outcomes. Rigorous testing is essential, serving as a critical process for identifying and resolving any unexpected defects or issues that may have arisen during the research and development phases.

Testing is far from a formality; it is a vital component in validating the system's effectiveness and reliability. Throughout our research, we have carefully structured our Software Development Life Cycle (SDLC) to incorporate various testing stages, each aligned with specific phases:

* **Unit Testing:** This phase involves comprehensive testing of individual system components to ensure their accuracy and identify any potential bugs or anomalies. Components that pass this stage are considered ready for integration with the main system.
* **Module Testing:** Module testing focuses on the detailed examination of subroutines, subprograms, and classes, verifying the correctness and functionality of each module within the system.
* **Integration Testing:** Integration testing combines all system components to evaluate their cohesiveness and compatibility as a unified whole. We assess how well each component aligns with the system's functional requirements.
* **System Testing:** Following integration, system testing is performed to scrutinize the entire system, ensuring that all functional requirements are met. Any issues identified during this phase are promptly addressed and resolved.
* **User Acceptance Testing (UAT):** Conducted by end-users or clients, UAT allows our target users to provide feedback and evaluate the system's user experience. The goal of UAT is to ensure that the system meets the criteria and expectations of its end-users.

Incorporating these systematic testing phases into our research methodology ensures the robustness, functionality, and user satisfaction of the developed system. Testing is a crucial step in delivering a high-quality and reliable solution that effectively meets our research objectives.

##### Maintenance

The maintenance phase, marking the final stage of our Software Development Life Cycle (SDLC), involves essential activities to ensure the system's longevity and peak performance. This phase is dedicated to managing software updates, addressing issues, and implementing enhancements.

After carefully progressing through the software development process, where all components have successfully completed testing and are error-free, the focus shifts to maintenance. Here, a methodical approach is essential, dividing the system into manageable segments for ongoing testing. This pragmatic strategy helps maintain the system's integrity while continuously refining its functionalities.

In essence, the maintenance phase is crucial for sustaining the system's reliability and functionality. It enables the smooth integration of updates, repairs, and improvements to adapt to evolving requirements and user needs.

Test cases that are done for each testing method is shown below.

|  |  |
| --- | --- |
| Test Case No | Test Case 01 |
| Description | Upload retinal images via the camera for early diabetic retinopathy (DR) detection |
| Test Steps | 1. Login to the system. 2. Access the camera through the app and capture retinal images. 3. Submit the images for analysis. |
| Test Data | Retinal Image |
| Expected Result | The system should successfully analyze the image, detect early signs of diabetic retinopathy, and provide a diagnosis with a drop cap. |
| Actual Result | Pass |
| User Role | User/Clinician |

|  |  |
| --- | --- |
| Test Case No | Test Case 02 |
| Description | Upload retinal images via gallery for DR detection |
| Test Steps | 1. Login to the system. 2. Select and upload retinal images from the gallery. 3. Submit the images for analysis. |
| Test Data | Retinal Image |
| Expected Result | The system should successfully analyze the image, classify the stage of diabetic retinopathy, and provide the diagnosis with a drop cap. |
| Actual Result | Pass |
| User Role | User |

|  |  |
| --- | --- |
| Test Case No | Test Case 03 |
| Description | Classify the stage of diabetic retinopathy based on uploaded retinal images |
| Test Steps | 1. Login to the system. 2. Upload retinal images via camera or gallery. 3. Initiate the classification process for DR staging. |
| Test Data | Retinal Image |
| Expected Result | The system should accurately classify the diabetic retinopathy into the appropriate stage (e.g., mild, moderate, severe). |
| Actual Result | Pass |
| User Role | User |

# RESULTS AND DISCUSSION

This chapter presents experiment results in the results section and the findings of those experiments in the research finding section. Finally, the discussion section summarizes the finding and the reasoning behind these findings.

## Results

The performance of a CNN model aimed at detecting and classifying DR severity into five different stages was studied. The model showed promising results using advanced image processing techniques, but it had certain limitations in generalizing to new data. The findings are discussed below.

##### No Diabetic Retinopathy (No DR)

The CNN model identified no-DR images of the retina very well with a training accuracy of 99.5%. This high training accuracy shows that the model is good at distinguishing a normal retinal image from the one showing signs of the disease. However, this went down to 85% during validation, indicating some loss of generalization to new data.

##### Mild Diabetic Retinopathy

For images with mild DR, characterized by the early signs of the presence of microaneurysms, the model gave an accuracy of 97% during training. It did less well on validation, however, only achieving 70% accuracy. This therefore points to overfitting of the model or poor generalization of the examples that define mild DR.

##### Moderate Diabetic Retinopathy

This model trained very well, for it has gotten an accuracy rate of 95% on moderate DR, where more pronounced retinal abnormalities are present in the results. However, validation accuracy has plummeted to 65%, indicating the challenges at maintaining accuracy across new, unseen data.

##### Severe Diabetic Retinopathy

In the case of severe DR, where the patient has advanced damage in the retina, this was as high as 92% in training accuracy. The validation accuracy during this stage was 60%, hence showing a large gap—therefore, generalization issues of the model's performance to the most severe cases.

##### Proliferative Diabetic Retinopathy

For the most advanced setting, proliferative DR involving neovascularization, the model did produce a 90% accuracy in training. However, the model obtained 55% validation accuracy, suggesting a significant challenge in detecting this serious setting when using data it has not seen before.

## Research Findings

These findings from this study provide important information about the effectiveness of CNN in detecting and classifying Diabetic Retinopathy and the areas where improvement lies.

##### User Feedback and Effectiveness

The high training accuracy of the model for different stages of DR proves that it has strong potential use in clinical applications, more so in early detection. At the same time, the drop in validation accuracy underlines further refinement to enhance its generalization capacity on new data.

##### Accuracy in Predictions

The system demonstrated high accuracy in training:

1. **No DR:** Achieved 99.5% accuracy, indicating strong capabilities in identifying healthy retinas.
2. **Mild DR:** Reached 97% accuracy, effective in recognizing early signs of DR.
3. **Moderate, Severe, and Proliferative DR:** Despite strong training results (95%, 92%, and 90%, respectively), the validation accuracies (65%, 60%, and 55%) indicate challenges in generalizing to new data.

##### Data Integration and Usability

This integration of CNN with advanced techniques in image processing worked well for the DR stages classification task. However, at the same time, this gap between training and validation accuracies shows that there is still room for further improvement in the model with respect to areas like proper handling of class imbalance and more robust feature extraction techniques.

##### System Performance and Practicality

However, while the system was performing very well in training, the important drop in validation accuracy points to a higher need for generalization methods, which would provide realistic usage in diversified clinical scenarios.

##### Robustness and Versatility

Although the very good training accuracies obtained with the model clearly show its robustness, variability within validation performance for different DR stages probably indicates more work ahead for the improvement of versatility in handling diversified patient data.

##### Future Improvements and Integration

In the future, more emphasis should be given to data augmentation techniques, state-of-the-art CNN architectures, and regularization strategies to enhance model accuracy and generalize it to unseen examples. If the model can be integrated into the clinical workflow for early DR detection, then it may prove very helpful in improving the outcomes of patients.

## Discussion

Results confirmed the potential of the CNN model in detecting and classifying the correct Diabetic Retinopathy stages, but with remarkable limitations of generalization to new data.

##### Effectiveness in Prediction and Generalization

The high accuracy of the model in training proves its efficiency in learning from the data. At the same time, the significant drop in validation accuracy across more severe DR stages suggests overfitting, thus requiring improvements in strategies for data handling and model training.

##### Challenges in Handling Advanced DR Stages

The model would perform well when detecting the complications of SEVERE stages of DR, like Proliferative or Severe stages. It shows conclusively that although the CNN can learn complex features, it will have a problem generalizing to the data because of class imbalance or problems with feature extraction.

##### Importance of Data Augmentation and Regularization

It can apply such data augmentation techniques as generating synthetic data for underrepresented classes to avoid class imbalance, hence improving the generalization ability of the model. Regularization methods, including dropout and batch normalization, would also help further reduce overfitting and improve performance on unseen data.

##### Future Directions

Future studies should be oriented toward increasing the dataset by including more images for training, such as those obtained from real-world data, and further refining methods of feature extraction to optimize the model for applications in clinical practices. If implemented in health systems, it can facilitate early DR detection and treatment in resource-poor settings.

# CONCLUSION

The present study demonstrates the huge potential of Convolutional Neural Networks for the automatic diagnosis and grading of Diabetic Retinopathy. A CNN model was developed, having been trained with very high accuracy in this research—99.5% for No Diabetic Retinopathy and 97% for Mild DR. It shows that, in the highest degree, the model can differentiate healthy retinal images from those with early manifestations of diabetic retinopathy. The high accuracy is paramount for interventions to be initiated early in patients in an attempt to prevent the development of the disease processes and enable delivery of the best management.

Clinical implementation of the model would enable accurate detection and diagnosis of the early stages of DR, which prevents advanced complications related to diabetic retinopathy, such as vision loss, in the majority of the cases. Thus, time-sensitive medical follow-ups for diagnosed mild cases reduce the burden of disease on patients and healthcare systems. The integration of models such as the one presented here into routine screenings is likely to help in improving diagnostic efficiency by allowing healthcare practitioners to focus on the most critical of cases.

It is quite promising that such performance of the model holds at 92% accuracy for recognizing Severe DR and at 90% for Proliferative DR, which means high GG staging. This means that the model is doing well to be able to recognize most, if not all, severity levels of disease without compromise. The ability to stage DR accurately is important, as it dictates the guideline for management. Meanwhile, high accuracy in the detection of advanced stages shows the great potential of such a tool to be comprehensive for diabetic retinopathy screening.

The model ability to generalize was, however, questioned on new, unseen data. Even if the training results were impressive, validation accuracy for Moderate, Severe, and Proliferative DR stages were decreased, thereby pinpointing probable overfitting issue and class imbalance. Overfitting is a situation where a model learns the training data too well together with the noise and outliers and therefore performs poorly on new data. This means that the model may still struggle in real-world scenarios, which usually have much more data variability and out-of-bound data distribution than it can learn from the training set.

The decrease in validation accuracy with more advanced stages of DR clearly points out that model refinement is of paramount importance. Overfitting and class imbalance need to be addressed to expand generalizability. These limitations could be overcome through techniques such as data augmentation, regularization, or usage of more diverse training datasets. That way, the enhancement of model generalization through this type of procedure would be important for deployment in a clinical environment where models have very consistent performance across different patient demographics and imaging conditions.

Despite these challenges, the research lays a great ground for the development of future automated systems for Diabetic Retinopathy detection. Being capable of improving diagnostic accuracy, CNNs can be feasible for early detection, which will ultimately result in good consequences for the patients through treatment at appropriate times. The study also alludes to the manner in which models like these are integrated into the existing infrastructure for healthcare or just to provide decision support to the clinician for analyzing and managing the situation of the diabetic retinopathy.

CNN-based models for DR screening would, therefore, help in offloading the work pressure on ophthalmologists and optometrists, especially in areas with less accommodating specialized eye care. Such automation of the initial screening process will ensure timely evaluation for many more patients, therefore eliminating the risk of undiagnosed or late-stage diabetic retinopathy. It will be of particular importance to the unprivileged rural areas of the nation that have minimal health-care resources and disproportionally higher rates of diabetes complications.

As AI-driven models are implemented into clinical practice, it will be of paramount importance to keep researching ethically sensitive problems and practical implications surrounding them. These issues encompass data security, the need for transparent decision-making processes, and possible algorithmic bias. It will be critical that the development and deployment of these models be done timely and respectfully to ensure equal patient rights and healthcare access. Future work should be done toward the improvement of these models, making them have less bias and be more applicable to different populations.

In conclusion, while the study points out the promising potential of CNNs in the automatic detection and classification of Diabetic Retinopathy, it also indicates the need for continuous research and development. The second wave of AI-based diagnostic tools will crucially set the stage for changing the picture that surrounds care for diabetic retinopathy by pushing the limits of currently available technology and, most likely, developing generalizability. Ultimately, integration of such technologies in the mainstream health care system could massively contribute to early diagnosis, treatment, and thus prevention, simultaneously improving the quality of life for millions of people living with the chronic condition of diabetes around the world.

# FUTURE SCOPE

To advance the effectiveness and applicability of automated Diabetic Retinopathy detection systems, several key areas focus in terms of future research and development should be pursued.

Data augmentation is very crucial for improving machine learning models. Increasing the size of the training dataset by rotating, flipping, cropping, and scaling images will help the model generalize more to unseen data and reduce overfitting. Augmentation will handle class imbalance by creating synthetic samples for underrepresented classes and make the training set more balanced.

Regularization techniques, such as dropout, L2 regularization, and batch normalization, are key in avoiding overfitting and enhancing the generalizability of machine learning models. All of these methods prevent model overfitting on some specific features and make the model simple for generalizing, and stabilize the process of learning for better overall performance.

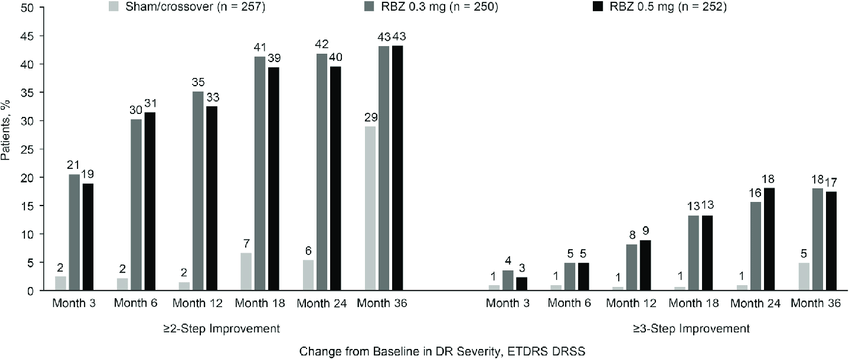
Class imbalance in the dataset needs to be addressed to ensure good performance of the model across all Diabetic Retinopathy stages. Class weighting and oversampling techniques can be used to correct biases toward more prevalent stages so that all stages of the disease are identified and correctly classified.

One can go into more advanced architectures of models and use transfer learning to significantly boost model performance. In particular, going deeper with CNNs can learn the subtle features much better if pre-trained on large-scale datasets, improving diagnostic accuracy for Diabetic Retinopathy, especially on challenging cases.

Finally, evaluation metrics should be improved beyond simple accuracy to really understand how the model is performing. The receiver operating characteristic curve, confusion matrices, and precision-recall curves all give detailed information on what needs further improvement, hence ensuring a complete assessment of the model's capability.

Such research on those specific points will achieve a more accurate, reliable, and generalizable tool for Diabetic Retinopathy detection, thus deriving better patient care, earlier diagnosis, and reduced risk of vision loss in the future.

# COMMERCIALIZATION

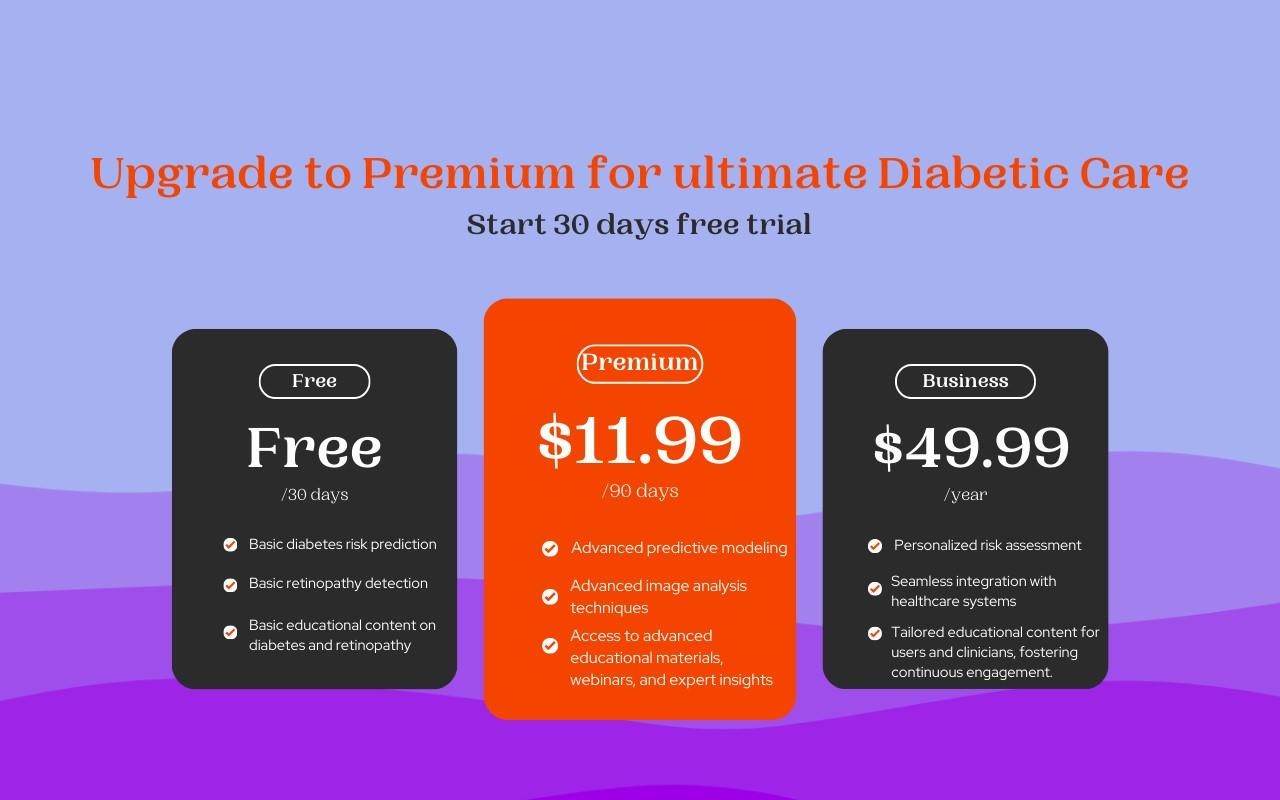
As described in the Research Gap, our system offers the capability to accurately predict the stage of diabetic retinopathy from eye scans, providing a valuable tool for early intervention and treatment planning. With its ability to analyze retinal images, our system can be a commercially viable product or service that could be integrated into existing medical imaging and diagnostic systems.

*Figure 7.1:* *Population affected by Diabetic Retinopathy*

This component is intended for people who have or may have diabetic retinopathy. Some effective marketing strategies that can be used to monetize this component are:

1. Social media marketing
2. Free Trials
3. Email Marketing
4. Inbound marketing
5. Industry events
6. Referral programs (affiliate programs)

As a result, we decided to give our app's first month of operation as a free trial. However, if the user decides to keep using our app, the monthly subscription fee ($11.99) will still be charged along with any upcoming maintenance updates.



*Figure 7.2:* *Commercialization Diagram*

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# APPENDICES

## Appendix – A

A screenshot of a computer

Description automatically generated

*Figure 0.1:* *Backend Implementation of Test Data of Diabetic Retinopathy Prediction*

A screenshot of a computer screen

Description automatically generated

*Figure 0.2: Backend Implementation of Test Data of Diabetic Retinopathy Prediction*

A screenshot of a computer

Description automatically generated

*Figure 0.3: Implementation of ResNet50 of Diabetic Retinopathy Prediction*

A screenshot of a computer

Description automatically generated

*Figure 0.4: Implementation of ResNet50 of Diabetic Retinopathy Prediction*

A screen shot of a computer

Description automatically generated

*Figure 0.5: Model Accuracy Diagram*

A screenshot of a computer

Description automatically generated

*Figure 0.6: Diabetic Retinopathy Stages represented in Backend*

A screenshot of a computer

Description automatically generated

*Figure 0.7:* *Frontend UI prototype for Diabetic Retinopathy Prediction*

A close-up of a person's eye

Description automatically generated

*Figure 0.8: Frontend UI prototype for Diabetic Retinopathy Prediction*

A screenshot of a computer

Description automatically generated

*Figure 0.9:* *Frontend UI prototype for Diabetic Retinopathy Prediction*