FROM ALGORITHMS TO ACCOUNTABILITY: THE ROLE OF MACHINE LEARNING IN SKIN CANCER PREDICTION AND ITS LEGAL IMPLICATIONS

A. Samiha Marium & Sowbarnika. V, Sastra Deemed University

ABSTRACT

Growing concerns about skin cancer, especially melanoma, are being raised in India and around the world due to changes in lifestyle and greater UV exposure. Skin cancers account for a large share of the estimated 12% increase in cancer incidence expected to occur in India over the forthcoming five years. In order to improve patient outcomes, early identification is essential since prompt surgical treatments can result in effective therapy. Using large datasets including digital health records and picture databases, this study investigates the use of machine learning (ML) & artificial intelligence (AI) to improve the precision and efficacy of skin cancer diagnosis. The study starts with a summary of machine learning (ML) concepts and their particular applications in dermatology, showcasing different algorithms that use data to learn and enhance diagnostic performance. The variety of skin malignancies makes it difficult to create a uniform classification model, even with advances in technology, especially when it comes to precisely separating lesions from tissue surrounding them. This is crucial for a successful diagnosis because uneven lesion borders can substantially affect the accuracy of predictions. In addition, the study discusses the regulatory ramifications of AI-powered skin cancer detection technologies as well as the challenges associated with assigning blame when ML systems are involved in medical blunders. By looking at these elements, the study hopes to shed light on how to successfully incorporate machine learning (ML) into the prediction of skin diseases, highlighting the need of responsibility and safety when using AI-powered medical devices to diagnose skin cancer.

Keywords: Machine learning (ML), Convolutional Neural Networks (CNN), Consumer Protection Act (CPA), Medical Devices Rules, 2017.

I. INTRODUCTION.

Skin cancer, including melanoma, is a growing concern both in India and globally. The rise in incidence rates can be attributed to various factors, including increased UV exposure and lifestyle changes. Cancer cases in India are expected to rise approximately 12% over the next five years, with skin cancer being a significant contributor to this increase . As of 2022, there were about 14.61 lakh new cancer cases reported in India, with skin cancers representing a notable portion of these cases[1]. In terms of mortality, global statistics indicate that skin cancer led to approximately 58,667 deaths in 2022. Melanoma represents a smaller percentage of total skin cancers but is more severe. In Europe, melanoma accounts for about 48.3% of all cancers in males and 53.5% in females. Key risk factors contributing to the rise in melanoma include excessive sun exposure and tanning bed use. The rising incidence of skin cancer and melanoma is a significant public health issue that requires attention both in India and globally. With lifestyle changes and increased UV exposure being major contributors to this trend, awareness and preventive measures are essential to combat this growing concern.

Therefore, Early detection of skin cancer, particularly melanoma is crucial for improving patient outcomes and reducing mortality rates. When diagnosed at an early stage, surgical procedures can often lead to successful outcomes. Machine learning (ML) and artificial intelligence (AI) are increasingly being utilized to enhance the accuracy and efficiency of skin cancer diagnosis. extensive datasets, including electronic medical records and image databases.

The employment of machine learning in dermatology requires an understanding of how it works. This research begins with the workings of Machine learning in general and highlighting how it is applied in dermatology field by encompassing various algorithms that learn from data and improve their performance over time. In healthcare, ML has been applied to predict outcomes based on patient data, including symptoms, test results, and medical history.

However, Skin cancers exhibit a wide range of types, each with distinct characteristics. This diversity complicates the development of a universal model capable of accurately classifying

[1] Labani S, Asthana S, Rathore K, Sardana K. Incidence of melanoma and nonmelanoma skin cancers in Indian and the global regions. J Cancer Res Ther. 2021 Jul-Sep;17(4):906-911. doi: 10.4103/jcrt.JCRT_785_19. PMID: 34528540.

all skin lesions(any area of the skin that exhibits different characteristics compared to the surrounding skin). Accurately segmenting skin lesions from surrounding tissue is critical for effective classification. therfore, irregular and fuzzy borders of lesions can complicate this process, impacting the overall accuracy of predictions. The use of Convolutional Neural Networks (CNNs) for skin cancer prediction has made significant strides, but it also faces challenges, particularly regarding the inclusion of a diverse patient population and the full range of melanoma subtypes.[2]

While AI-induced tools are being developed for skin cancer detection by analysing dermatoscopic images to classify skin lesions accurately; do they come under the purview of medical devices? Additionally. Determining liability in cases where machine learning (ML) systems, particularly AI-induced medical devices, commit medical errors in skin cancer prediction involves medical malpractice and product liability.

Given these considerations, this research aims to provide insights into the effective functioning of machine learning in predicting skin diseases, while also emphasizing the importance of safety and accountability in its application for skin cancer prediction.

II. RESEARCH OBJECTIVES

I. To explore the use of Convolutional Neural Networks (CNNs) in melanoma detection, and assess how effectively CNNs classify and identify melanoma and other forms of skin cancer by examining dermatological images. Focus on their accuracy in differentiating between malignant and benign lesions.

II. To highlight the challenges and limitations of machine learning in skin cancer prediction, examine issues like data quality, diversity, and the need for real-world validation. These factors significantly affect the performance and reliability of machine learning models in clinical environments.

III. To investigate liability gaps in medical errors related to AI-based systems, analyze the legal framework governing responsibility for errors caused by machine learning models in medical diagnosis, especially in dermatology. Focus

[2] Panda S. Nonmelanoma skin cancer in India: current scenario. Indian J Dermatol. 2010 Oct;55(4):373-8. doi: 10.4103/0019-5154.74551. PMID: 21430894; PMCID: PMC3051301.

on the obligations of healthcare professionals, AI developers, and device manufacturers in these scenarios.

IV. To assess the impact of the Consumer Protection Act, 2019, on AI-infused medical devices, evaluate how it, alongside the Medical Devices Rules, 2017, addresses liability issues related to AI-based medical devices. Focus on the responsibilities of manufacturers, service providers, and sellers within this regulatory framework.

III. RESEARCH METHODOLOGY:

For this study, a comprehensive literature review was conducted to explore the intersection of AI and ML in skin cancer prediction and the associated legal implications, particularly in the context of liability and accountability. Given the interdisciplinary nature of this topic, relevant journals across multiple fields, including healthcare, law, and technology, were selected for review.

We conducted keyword searches using terms such as "AI in skin cancer prediction," "medical malpractice in AI diagnostics," "AI liability in healthcare," and "product liability for AI systems" to identify relevant literature. The research was performed across various academic databases and platforms, including **Google Scholar, Springer Journals, HeinOnline, JSTOR, and specific journal websites**, ensuring a diverse and comprehensive collection of studies.

These sources were chosen based on their relevance to the evolving role of AI in healthcare, particularly in diagnostics, as well as the legal challenges and frameworks that need to be addressed. This approach allowed us to identify existing discussions while highlighting the significant research gap in liability for AI-driven skin cancer prediction errors.

IV. RESEARCH GAP:

Traditionally, medical malpractice claims focus on the actions and decisions of healthcare professionals. However, as AI systems increasingly influence diagnostic processes, particularly in skin cancer prediction, the determination of liability becomes more nuanced.

While numerous studies explores about AI and ML applications in Healthcare fields, there is no clear legal framework addressing this emerging challenge, representing a significant research gap. Additionally there is limited research addressing how existing product liability laws should evolve to accommodate AI applications, particularly in specialized areas like skin cancer predictions.

V. RESEARCH PROBLEM

This study aims to clarify who is responsible for medical errors caused by AI-enabled systems in the detection of skin cancer, especially when these systems include machine learning models such as Convolutional Neural Networks (CNNs). Healthcare providers use artificial intelligence (AI) to improve diagnostic accuracy; however, current legal frameworks do not explicitly clarify who is responsible for system failures—the healthcare provider utilising AI, the AI's creators, or the manufacturers of the equipment. **When an AI system misclassifies a skin lesion or generates an inaccurate recommendation, resulting in harm to the patient, who bears responsibilityWho should be held responsible for medical errors caused by AIbased systems in skin cancer prediction: the healthcare provider who relied on the technology, the AI developer, or both?**

VI. Literature Review

1."Machine Learning and Its Application in Skin Cancer" published in the *International Journal of Environmental Research and Public Health*

This research paper discusses the growing role of artificial intelligence (AI), particularly machine learning (ML), in diagnosing skin cancer. The authors, Kinnor Das et al., emphasize that despite dermatology's potential for AI integration, it lags behind radiology in acceptance and application.

The study highlights the alarming global cancer statistics, with nearly 10 million deaths attributed to various cancers in 2020, and underscores skin cancer's rising incidence, particularly malignant melanoma. Early detection is crucial for effective treatment, as progressive stages of melanoma significantly reduce survival rates. Traditional diagnostic methods, such as histopathology, have limitations, including invasiveness and the need for specialized expertise, which are not always available.

The authors explore various machine learning techniques, particularly convolutional neural networks (CNNs), which excel in recognizing patterns in medical images. They present evidence from multiple studies demonstrating that ML algorithms can outperform dermatologists in diagnosing skin lesions. For instance, research shows that CNNs achieved higher specificity and sensitivity in identifying malignant lesions compared to human specialists.

The article also discusses the importance of utilizing large datasets for training these algorithms, noting various available resources, including the International Skin Imaging Collaboration (ISIC) datasets and others. The acceptance of AI among patients and clinicians is considered, with survey results indicating a general willingness to embrace AI in healthcare, particularly for early skin cancer diagnosis.

In conclusion, the authors argue that AI has the potential to revolutionize dermatology by enhancing diagnostic accuracy and efficiency. They stress the need for ongoing research, data sharing, and regulatory harmonization to facilitate AI's integration into clinical practice. The paper advocates for viewing AI as a complementary tool for dermatologists rather than a replacement, emphasizing the importance of collaboration between AI systems and medical professionals to improve patient outcomes in skin cancer detection and management.

2."Machine Learning and Deep Learning Integration for Skin Diseases Prediction" published in the *International Journal of Engineering Trends and Technology*

This Research paper explores the application of artificial intelligence (AI), specifically machine learning (ML) and deep learning (DL), in diagnosing skin diseases. The authors, Samir Bandyopadhyay et al., highlight the complexity of skin disease detection due to variations in skin tone and the diverse nature of skin conditions, emphasizing the need for rapid and accurate diagnosis.

The study introduces a hybrid model that integrates DL and ML techniques to enhance the detection of various skin diseases. For feature extraction, four pre-trained deep learning models—AlexNet, GoogLeNet, ResNet50, and VGG16—were employed. The classification was performed using three ML algorithms: Support Vector Machine (SVM), Decision Tree, and AdaBoost Ensemble Classifier.

The researchers conducted a comparative analysis to identify the most effective prediction model, ultimately finding that the combination of ResNet50 for feature extraction and SVM for classification yielded the highest accuracy of 99.11%. This hybrid model significantly outperformed other combinations and individual models, showcasing its potential for accurate skin disease diagnosis.

The study utilized a dataset of approximately 40,000 images from the ISIC repository, encompassing nine different skin disease classes. The results indicate that the automated system can effectively identify and classify skin diseases, potentially reducing the burden on healthcare professionals and improving patient outcomes.

Overall, the findings underscore the importance of integrating ML and DL in dermatology. The authors advocate for the adoption of such automated systems in clinical settings to facilitate early detection and treatment of skin diseases, which can ultimately decrease morbidity and mortality rates associated with skin conditions. The research contributes to the growing body of evidence supporting AI's role in enhancing diagnostic accuracy in healthcare.

3. Enhancing skin cancer diagnosis through an optimized Convolutional Neural Network (CNN) architecture.

Recognizing skin cancer as a leading challenge in oncology, the research emphasizes the importance of early detection for successful treatment outcomes. Traditional diagnostic methods rely heavily on dermatologists' expertise, highlighting the need for reliable, automated diagnostic tools.

Utilizing the HAM10000 dataset, which comprises over 10,000 diverse dermatoscopic images, the study introduces a sophisticated CNN model specifically designed for skin lesion classification. The model architecture includes multiple convolutional, pooling, and dense layers, allowing it to capture complex visual features associated with various skin lesions. To tackle the issue of class imbalance in the dataset, the researchers implemented innovative data augmentation strategies, ensuring a balanced representation of each lesion category during training.

The model's learning process was optimized using the Adam optimizer, fine-tuned over 50 epochs with a batch size of 128. A Model Checkpoint callback was used to preserve the best model iteration for future applications. The results demonstrated impressive performance, achieving an accuracy of 97.78%, a precision of 97.9%, a recall of 97.9%, and an F2 score of

97.8%. These metrics underline the model's potential as a robust tool for early skin cancer detection, thereby supporting clinical decision-making and improving patient outcomes in dermatology.

The introduction of deep learning into dermatology through this study aims to democratize access to high-quality diagnostic tools, particularly in regions with limited dermatological expertise. By leveraging large datasets of dermatoscopic images, the study illustrates how machine learning can aid in the accurate classification of skin lesions, ultimately enhancing the effectiveness of skin cancer diagnosis and treatment.

In summary, this research presents a significant advancement in automated skin cancer diagnosis, combining deep learning techniques with comprehensive data analysis to improve diagnostic accuracy and support early intervention in dermatological care.

4."Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation" by George Maliha et al.

This discusses the complex interplay between artificial intelligence (AI), machine learning (ML), and medical liability. It emphasizes the growing integration of AI/ML technologies in clinical practice, particularly in diagnostic and predictive capacities, and the accompanying concerns regarding algorithm inaccuracy, which can lead to patient harm and potential liability issues.

Over 40 AI/ML-based medical devices received FDA approval between 2017 and 2019. These technologies are increasingly used for improving diagnostic accuracy, especially in areas like radiology. However, the performance of these algorithms has faced scrutiny, particularly regarding their efficacy across diverse patient populations.

The authors argue that current liability frameworks are inadequate, primarily focusing on physician malpractice while neglecting the broader ecosystem involving health systems and

AI developers. This oversight poses risks for both patient safety and the encouragement of innovation.The document categorizes liability into medical malpractice, other negligence theories, and products liability. Physicians may face malpractice claims if they fail to critically evaluate AI recommendations, while algorithm developers could be liable for design defects. The interplay of these liabilities complicates the legal landscape for AI/ML integration in healthcare.

The authors advocate for policy reforms to establish a more balanced liability system that promotes safe AI implementation while encouraging innovation. Proposed solutions include changing the standard of care, implementing insurance and indemnification mechanisms, and possibly creating specialized adjudication systems to handle AI-related claims.

The role of regulatory bodies, such as the FDA, is crucial in shaping the liability landscape. Stricter regulations could mitigate developer liability but may also impact physician and health system liabilities.

The study highlights the urgent need for a comprehensive approach to liability that accommodates the rapid advancements in AI/ML technologies in medicine. By addressing the gaps in existing frameworks, policymakers can create a legal environment that fosters innovation while ensuring patient safety. The document calls for collaborative efforts among stakeholders to adapt and reform liability structures, ultimately balancing the benefits of AI/ML integration with the imperative of patient protection.

5."Advancements in Skin Cancer Classification: A Review of Machine Learning Techniques in Clinical Image Analysis"

This Paper provides an extensive overview of the application of machine learning and deep learning techniques for the diagnosis of skin cancer, particularly through clinical image analysis.

The paper highlights the challenges faced in the early detection of skin cancer, particularly through visual inspection by dermatologists, which can be inconsistent and requires significant expertise. It emphasizes the advantages of using machine learning models, which have shown promising results in accurately diagnosing skin cancers, including melanoma. Key advancements in this field include improved accuracy, sensitivity, and specificity compared to human dermatologists.The authors categorize machine learning methods into traditional approaches and modern deep learning techniques. Traditional methods, such as K-nearest neighbours (KNN), decision trees, and support vector machines (SVM), have been successful but often require extensive feature engineering and can struggle with variability in image characteristics. In contrast, deep learning models, particularly convolutional neural networks (CNNs), can automatically extract features from high-dimensional data, leading to superior diagnostic performance.

The review presents a detailed analysis of various machine learning techniques, including their methodologies, effectiveness, and the datasets utilized for training and testing. The authors also discuss the significant challenges that remain, such as image segmentation, noise filtering, and inconsistencies in image capture environments, which hinder the reliability of these automated systems.

Furthermore, the paper identifies future directions for research, emphasizing the need for more robust models that can handle the inherent variability in skin lesion appearances. The authors advocate for a comprehensive approach that combines both traditional and deep learning techniques to enhance the precision and accessibility of skin cancer diagnostics.

In conclusion, the study underscores the transformative potential of machine learning in improving early detection and diagnosis of skin cancer, advocating for continued innovation and research in this critical area of healthcare. The integration of advanced computational methods could lead to better patient outcomes and more effective interventions in skin cancer management.

VII. ANALYSIS

1) MACHINE LEARNING ALGORITHMS.

There are a variety of ML algorithms commonly used in dermatology. Most ML algorithms are examples of statistical learning; for example, some of the most common statistical learning methods are linear regression, logistic regression, k-nearest neighbor (k-NN), support vector machine (SVM), random forest (RF), and natural language processing (NLP).

k-NN is used for data classification and regression based on the number of k neighbours.[3] SVMs are used to classify data by finding a hyperplane to differentiate between groups. RFs generate a network of random decision trees to find the most common outcome among all the randomly generated decision trees . NLP analyzes large bodies of text in order to identify patterns.

a) Neural Networks and Deep Learning

Deep learning is a subset of ML that uses statistical and mathematical models to mimic how neurons process information. Artificial neural networks (ANNs), or neural networks (NNs), are based on a collection of connected units (e.g., nodes, neurons, or process layers). ANNs are inspired by the network of neurons in the human brain. The neurons, or nodes, that make up the ANN are organized into linear arrays called layers . Each node receives inputs from other connections that have associated weights . Creating an ANN includes choosing the number of nodes in each layer, the number of layers in the network, and the path of the connections among the nodes , and the typical ANN has input layers, output layers, and hidden layers. ANNs are trained to perform specific tasks, such as classification, through a learning process. Learning within ANNs can be supervised or unsupervised; however, supervised learning is more common. In supervised learning, a training set contains examples of input targets and output targets . As the ANN is trained, the weights of the inputs are adjusted to minimize the error between the network output and the correct output.[4] Once the network produces the desired outputs for a series of inputs, the weights are fixed and the NN can be applied to other datasets. Convolutional NNs (CNNs) are a special subclass of ANNs that contain one or more layers called convolutional units (pooling units). CNNs take in two-dimensional or three dimensional inputs which are passed through multiple hidden layers. An image can be broken down into motifs, or a collection of pixels that form a basic unit of analysis. The first few layers of the CNN compare each part of an input image against some small sub-image. Each node is assigned a certain feature (e.g., color, shape, size, etc.), and the node's output to the next layer depends on how much a part of the image resembles the feature, a process performed by convolution .After these convolutional layers, pooling layers,

[3] Chan S, Reddy V, Myers B, Thibodeaux Q, Brownstone N, Liao W. Machine Learning in Dermatology: Current Applications, Opportunities, and Limitations. Dermatol Ther (Heidelb). 2020 Jun;10(3):365-386. doi: 10.1007/s13555-020-00372-0. Epub 2020 Apr 6. PMID: 32253623; PMCID: PMC7211783.

[4] Jeong HK, Park C, Henao R, Kheterpal M. Deep Learning in Dermatology: A Systematic Review of Current Approaches, Outcomes, and Limitations. JID Innov. 2022 Aug 23;3(1):100150. doi: 10.1016/j.xjidi.2022.100150. PMID: 36655135; PMCID: PMC9841357.

which are a standard NN, classify the overall image. CNNs first showed promise for medical image classification at the historic 2012 ImageNet Large Scale Visual Recognition (ILSVRC) conference. A CNN, called AlexNet, was trained to classify 1.2 million images into 1000 different categories with a top-5 error rate of 15.3%, which is the percentage of images for which the correct class was not among the top five predicted classes . This was the first CNN to display such a low error rate. Previous image datasets were relatively small, comprising only of tens of thousands of images. By 2016, all methods to classify medical images at the 2016 International Symposium on Biomedical Imaging used CNNs .Another subtype of CNNs is called a region based CNN (R-CNN). RCNN is a type of CNN that can detect a desired object within an image. In the case of dermatology, it can detect the location of cutaneous lesions by combining region proposal algorithms with CNNs.

VIII. MACHINE LEARNING IN SKIN DISEASE PREDICTION

ML algorithms analyze clinical images to assist in diagnosing various skin conditions, including skin cancers and other dermatological diseases. These algorithms can process large datasets to identify patterns that may not be immediately evident to human clinicians. Following are the three majorly usedimage technologies among others.

Dermoscopy involves using a dermatoscope to examine skin lesions with magnification (up to 10× or more). This technique helps visualize subsurface structures and colors that are not readily observable with the naked eye. This involves using a dermatoscope to examine skin lesions with magnification and illumination. This technique enhances visualization of surface structures and colors, aiding in the differentiation between benign and malignant lesions. ML algorithms analyze dermoscopic images to classify skin lesions, often achieving high accuracy rates comparable to dermatologists.

Digital photographic imaging plays a crucial role in dermatology by enabling dermatologists to monitor patients over time and assess therapeutic responses both quantitatively and qualitatively. This technique relies on the principles of light interaction with skin, specifically reflectance and backscatter, which are essential for effective imaging.

Confocal microscopy is an advanced imaging technique that provides high-resolution, cellularlevel visualization of skin and cutaneous structures. This method is particularly valuable in dermatology for diagnosing skin conditions and monitoring treatment responses.

Confocal microscopes typically use an 830-nm near-infrared laser, which penetrates the skin to create images based on intrinsic differences in refractive indexes of various cellular components, such as melanin, collagen, and keratin. When the laser light interacts with the skin, some light is absorbed while some is reflected. A pinhole aperture allows only light reflected from the focal plane to reach the detector, effectively eliminating signals from adjacent planes. This results in high-resolution images even from thick, in vivo samples.[5]

CNNs (convultional neuro network)are a type of deep learning architecture specifically designed for image analysis. They consist of multiple layers that automatically extract features from images, making them particularly effective for recognizing complex patterns in skin lesions. CNNs have been successfully applied to classify various skin conditions, including melanoma and non-melanoma skin cancers. Studies have reported test accuracies exceeding 97% for distinguishing between different lesion types using datasets like HAM10000..[6]

MACHINE LEARNING IN MELANOMA DETECTION

Machine learning (ML) is playing an important role in the early detection of melanoma, a dangerous type of skin cancer. Traditionally, dermatologists have depended on visual inspections to identify melanoma, but this method can be subjective and slow.ML algorithms, especially deep learning models, are proving to be much more accurate and faster* at diagnosing melanoma by analyzing vast numbers of skin images.

Recent research has shown that ML is very effective at distinguishing between malignant melanoma and non-cancerous lesions. For instance, a study that used a dataset of 793 images of skin conditions showed high accuracy in identifying melanoma based on specific features of the images. In this study, the researchers **used convolutional neural networks (CNNs**), a type of deep learning model, to extract important features from the images, which helped the model in accurately classifying the lesions. CNNs require a large dataset of labeled images of skin lesions, including benign and malignant cases. Preprocessing steps, such as

[5] Ilie MA, Caruntu C, Lixandru D, Tampa M, Georgescu SR, Constantin MM, Constantin C, Neagu M, Zurac SA, Boda D, Boda D, et al: In vivo confocal laser scanning microscopy imaging of skin inflammation: Clinical applications and research directions (Review). Exp Ther Med 17: 1004-1011, 2019.
[6] Brinker T, Hekler A, Utikal J, Grabe N, Schadendorf D, Klode J, Berking C, Steeb T, Enk A, von Kalle C Skin Cancer Classification Using Convolutional Neural Networks: Systematic Review J Med Internet Res 2018;20(10):e11936 DOI: 10.2196/11936

normalization and augmentation, are often applied to enhance the dataset and improve model performance.[7]

A major breakthrough in this field came from researchers at MIT, who developed a deep convolutional neural network (DCNN)that can analyze wide-field images taken with regular cameras. Their system achieved more than 90% sensitivity in identifying suspicious pigmented lesions (SPLs). This technology can be used to automate the screening process, which means that patients can be screened for melanoma even during routine primary care visits. This could help in catching melanoma early, potentially saving lives and reducing treatment costs.

Another innovative approach uses a hybrid model that combines U-Net and MobileNet architectures. This model not only improves the quality of images by enhancing contrast but also fine-tunes the hyperparameters to achieve better results. When this model was tested using the ISIC datasets, it showed impressive performance with precision rates of over 98%, indicating its potential for use in real-world clinical settings.

Deep learning techniques have also been applied to improve image quality. One such method involves using Enhanced Super-Resolution Generative Adversarial Networks (ESRGAN) to boost the resolution of images. After enhancing the image quality, CNNs are used to segment and classify the images. Some of these models have reported accuracy rates of around *86%, showing the effectiveness of combining these advanced techniques.

However, despite these advancements, there are still some challenges that need to be addressed. The quality of the training data is a critical factor that can greatly influence how well the model performs. Therefore, it is essential to have diverse and high-quality datasets for training these ML models. Moreover, further validation in real-world clinical environments is necessary to confirm whether these models can perform as well in practice as they do in research settings.

[7] Azeem M, Kiani K, Mansouri T, Topping N. SkinLesNet: Classification of Skin Lesions and Detection of Melanoma Cancer Using a Novel Multi-Layer Deep Convolutional Neural Network. Cancers (Basel). 2023 Dec 24;16(1):108. doi: 10.3390/cancers16010108. PMID: 38201535; PMCID: PMC10778045.

IX. CHALLENGES IN ML PREDICTION

Skin cancers exhibit a wide range of types, each with distinct characteristics. This diversity complicates the development of universal models capable of accurately classifying all skin lesions. The irregular and fuzzy borders of lesions can significantly impact segmentation accuracy, which is critical for effective classification.

Cases have demonstrated that CNNs can effectively analyze dermoscopic images for skin cancer detection. For instance, a novel deep CNN model achieved an accuracy of 97.49% in differentiating between malignant and benign lesions by utilizing data augmentation from the ISIC dataset.

- Class imbalance remains a significant challenge in training ML models for skin cancer detection. Some studies have proposed innovative data augmentation strategies to ensure balanced representation during training, which enhances classification accuracy.

Incorporating patient metadata alongside lesion images has been shown to improve classification accuracy by at least 5%, highlighting the importance of comprehensive data in enhancing diagnostic performance.

- Various studies report high performance metrics for CNNs in skin cancer classification, with accuracies ranging from 89.3% to 94.5% for distinguishing between benign and malignant lesions. These metrics indicate that ML models can match or exceed traditional diagnostic methods.

- The inherent variability in lesion sizes, shapes, and colors complicates the accurate diagnosis of malignant versus benign conditions. This complexity necessitates advanced feature extraction techniques within CNN architectures to enhance model robustness.

- Training ML models requires significant computational resources and time, particularly when working with large datasets like HAM10000 or ISIC. The need for powerful hardware can be a barrier to widespread adoption.

In the study "Deep learning for AI based Diagnosis of skin related neglected tropical diseases A Pilot Study", it was highlighted that:

The two convolutional neural networks (ResNet-50 and VGG-16) showed improved performance with an increased number of training samples, indicating that *the more images used for training, the more accurate the diagnosis became specifically, a model trained with PCR-confirmed cases of Buruli ulcer yielded a 1–3% increase in prediction accuracy across all diseases, except for mycetoma, compared to a model trained with unconfirmed cases.

This finding suggests that using images from more accurately diagnosed cases in the training models can contribute to better accuracy in the generated AI models.

X. WHO CAN BE HELD LIABLE FOR MEDICAL ERRORS CAUSED BY MACHINE LEARNING?

Here the concept of strict liability comes in to play, Strict liability, often called absolute liability, is typically used in regard to unreasonable harmful items and actions. This idea states that without requiring the defendant to show fault, responsibility arises wherever damage happens. This suggests that the hospital could be held liable for using AI-based technology, even if the manufacturer took great care in creating, promoting, and selling the AI-enabled medical device and even if the device's operations were approved, planned, or under control.[8]

This Doctrine of liability might discourage medical professionals from employing robots and other AI-enabled medical equipment, as well as discourage companies from creating selflearning systems. The acceptance of this concept appears convincing when it comes to dangerous items that have the potential to seriously harm or kill users, but that is not the case with medical devices, which are largely employed to improve patient care and lower the number of fatalities and injuries.

In order to prove medical Errors, the plaintiff must first show that the defendant owed them a duty of care, which must then be proven to have been broken, and last, that the plaintiff suffered damages as a result of the breach . The duty of care is the first component of a medical error claim. This speaks to a healthcare provider's dedication to providing a patient with care that meets accepted standards in the medical community. This obligation to provide treatment is established by the doctor-patient relationship. In a medical error case, the plaintiff

[8] ldakak, A., Alremeithi, A., Dahiyat, E. *et al.* Civil liability for the actions of autonomous AI in healthcare: an invitation to further contemplation. *Humanit Soc Sci Commun* **11**, 305 (2024). https://doi.org/10.1057/s41599024-02806-y

must demonstrate that a doctor positively acts in the plaintiff's case by examining, diagnosing, treating, or giving permission to do so in order to establish the existence of a duty of care .

Furthermore, even in cases when the patient and the doctor have not personally met, a duty of care can still be established. In the case **of Hand v. Tavera (1993),** Mr. Hand, a Humana HMO member, went to the emergency room at a hospital that was approved by the HMO, claiming to have had a headache for three days. Dr. Tavera, who was in charge of approving patients' admission to hospitals, was called by the emergency physician after reviewing and examining Mr. Hand's medical history. However, he declined to admit Mr. Hand to the hospital and instructed the emergency physician to treat him as an out-patient, sending him home. Mr. Hand had a heart attack not long after getting home. .. Mr. Hand filed a case against Dr. Tavera, but the latter denied any liability, arguing that since he had not seen Mr. Hand in person, there could not have been a physician-patient connection. "When a patient who has enrolled in a prepaid medical plan goes to a hospital emergency room and the plan's designated doctor is consulted, the physician-patient relationship exists and the doctor owes the patient a duty of care," the court ruled, finding that there was a physician-patient relationship in this case.

Therefore, **strict liability** in the context of AI-based medical technology imposes liability on healthcare providers and hospitals, regardless of fault, whenever harm occurs from the use of such devices and the **duty of care** is often rooted in the physician-patient relationship.

XI. FINDINGS

CONSUMER PROTECTION ACT 2019 IN DEALING WITH MEDICAL DEVICES UNDER MEDICAL DEVICES RULES,2017.[9]

I. The CPA, 2019 applies to all goods and services unless specifically exempted by the Central Government. No goods or services have been excluded so far. As a result, the CPA, 2019 also applies to medical devices.

II. The CPA, 2019 distributes the responsibility among three parties-the product manufacturer, the product seller and the product service provider. Broadly speaking,

[9] Shenolikar, S., & Punnen, D. (2021). The New Consumer Protection Law and Its Impact on the Medical Device Regulatory Framework. RGNUL Student Research Review, 7(1), 141-146.

liability is assigned to the legal person directly answerable for causing the loss. It should be noted that a bill has been presented to the MDR that would make manufacturers/importers of medical devices liable where a medical device is found to malfunction or not to comply with the terms of the license to manufacture/import granted to the manufacturer/importer, depending on the circumstances of the case ("Compensation Amendment").

III. Most probably, it would be payable to the injured patient himself if injured or to his legal heirs in case of death. The apex body in respect of technical matters pertaining to drugs and medical devices is the Drugs Technical Advisory Board ("DTAB"). It had constituted a sub-committee to look into the matter of compensation in the event of faulty medical devices. It was expected to present its report to the DTAB. According to reports, the Sub-Committee Report has recommended the setting up of a 'causality assessment committee' to determine the quantum of compensation.

IV. From the above, it can be easily noted that the wide grounds under which liability can be attached to the manufacturer is considered the same in CPA, 2019 and MDR. Though the CPA, 2019 and the MDR hold the manufacturer liable in product liability cases in some cases, an extra component of the CPA, 2019 is that the product seller or product service provider can also be made liable in a product liability case. Currently, the MDR does not provide provisions whereby the producer service provider will be liable. Product sellers under the MDR may be held liable only in limited cases-virtually only by way of violating license conditions.

XII. DISCUSSIONS:

Reports indicate that consumer courts are increasingly handling cases related to defective medical devices, with several judgments favouring plaintiffs. In the Notable case of Dr. Reddy's Laboratories vs. State of Maharashtra, A faulty medical device was involved that resulted in patient harm. The court emphasized the responsibility of manufacturers to ensure that their products meet safety standards. The court found that Dr. Reddy's Laboratories failed to ensure that their medical device was safe for use, leading to patient harm. Courts have increasingly adopted a pro-consumer stance, leading to favorable judgments for plaintiffs. Now when Artificial intelligence induced medical devices comes under the purview of medical devices, there might be significant increase in the lawsuits however there remains a significant lack of awareness among patients regarding their rights and the potential risks associated with AI-enabled medical devices. Many consumers are unaware that they can seek compensation for injuries caused by defective products especially which is caused by AI and ML.

XIII. RECOMMENDATIONS:

1. **Lack of clarity needs to be addressed:**: The Consumer Protection Act (CPA), 2019 makes no mention of the specific obligations that data scientists, AI developers, and other parties in AI systems must adhere to. It is currently unclear who would be responsible for errors made by AI-based medical equipment because there is no defined division of labour between data scientists, AI developers, and manufacturers. Clarification of Liability for AI Developers and Data Scientists should be explicitly staed in the provisions.

2. **An amendment should be proposed to the CPA, 2019,** specifically inserting a new Section 84A after Section 84 (which deals with product manufacturers' liability). This new section should explicitly state the liability of AI developers and data scientists in cases where AI-driven systems cause harm to patients. This amendment will establish an enforceable system to hold these parties accountable for errors made and bring much-needed clarity.

3. **Urgent needs to raise Awarness**; Educational campaigns and public initiatives should be launched to ensure that patients are aware of their legal rights under the CPA, 2019, particularly in relation to medical malpractice and product liability claims involving AI. As AI technology becomes more integrated into medical practice, there is an urgent need to raise awareness among patients regarding their rights to seek legal recourse if they are harmed by AI-enabled medical devices.

4. **Incorporation of Insurance Provisions**; The CPA, 2019 does not address insurance coverage for medical errors caused by artificial intelligence. while it offers compensation mechanism for people injured by medical device defects.There should be an incorporation of Insurance coverage which would shield developers and healthcare providers from having to pay for all associated costs.

XIV. CONCLUSION

The accuracy of diagnosing skin cancer has greatly increased with the integration of artificial intelligence (AI) and machine learning (ML), especially with the use of sophisticated models like Convolutional Neural Networks (CNNs). Artificial intelligence (AI)-enabled systems, like those used to diagnose melanoma, offer improved clinical results, lower death rates, and earlier detection. But these developments also bring with them difficult legal issues, especially when it comes to who is responsible for medical mistakes brought on by AIenabled medical equipment.

The Medical Devices Rules of 2017 and the Consumer Protection Act (CPA) of India are two examples of current legal frameworks that do not specifically address who is responsible for what when AI systems malfunction or cause injury. This includes manufacturers, data scientists, healthcare professionals, and AI developers. The trust and use of AI in medical diagnostics are weakened by the unclear liability laws, especially in high-risk fields like skin cancer prediction.

The research points out how urgently a thorough legal framework that outlines the obligations of all parties engaged in the creation and application of AI-based medical devices must be established. In addition to guaranteeing accountability and offering patients legal protection, this system ought to handle culpability for medical errors. In addition, in order to safeguard patients and developers and encourage the responsible application of AI in healthcare, public awareness campaigns, insurance clauses, and legislative changes to the CPA, 2019 should be taken into consideration.

This study adds to the ongoing discussion on regulating AI-driven breakthroughs in healthcare by suggesting changes to current legal frameworks and establishing explicit responsibility rules. It provides practical insights to improve overall trust in AI-assisted medical procedures, developer accountability, and patient safety.

REFERENCE.

1. Shenolikar, S., & Punnen, D. (2021). The New Consumer Protection Law and Its Impact on the Medical Device Regulatory Framework. RGNUL Student Research Review, 7(1), 141-146.

2. Labani, S., Asthana, S., Rathore, K., & Sardana, K. (2021). Incidence of melanoma and nonmelanoma skin cancers in India and the global regions. Journal of Cancer Research and Therapeutics, 17(4), 906-911. doi: 10.4103/jcrt.JCRT_785_19. PMID: 34528540.

3. Panda, S. (2010). Nonmelanoma skin cancer in India: current scenario. Indian Journal of Dermatology, 55(4), 373-378. doi: 10.4103/0019-5154.74551. PMID: 21430894; PMCID: PMC3051301.

4. Chan, S., Reddy, V., Myers, B., Thibodeaux, Q., Brownstone, N., & Liao, W. (2020). Machine Learning in Dermatology: Current Applications, Opportunities, and Limitations. Dermatology Therapy, 10(3), 365-386. doi: 10.1007/s13555-020-00372-0. Epub 2020 Apr 6. PMID: 32253623; PMCID: PMC7211783.

5. Jeong, H.K., Park, C., Henao, R., & Kheterpal, M. (2022). Deep Learning in Dermatology: A Systematic Review of Current Approaches, Outcomes, and Limitations. JID Innovations, 3(1), 100150. doi: 10.1016/j.xjidi.2022.100150. PMID: 36655135; PMCID: PMC9841357.

6. Ilie, M.A., Caruntu, C., Lixandru, D., Tampa, M., Georgescu, S.R., Constantin, M.M., Constantin, C., Neagu, M., Zurac, S.A., Boda, D., et al. (2019). In vivo confocal laser scanning microscopy imaging of skin inflammation: Clinical applications and research directions (Review). Experimental and Therapeutic Medicine, 17(2), 10041011.

7. Brinker, T., Hekler, A., Utikal, J., Grabe, N., Schadendorf, D., Klode, J., Berking, C., Steeb, T., Enk, A., & von Kalle, C. (2018). Skin Cancer Classification Using Convolutional Neural Networks: Systematic Review. Journal of Medical Internet Research, 20(10), e11936. doi: 10.2196/11936.

8. Azeem, M., Kiani, K., Mansouri, T., & Topping, N. (2023). SkinLesNet: Classification of Skin Lesions and Detection of Melanoma Cancer Using a Novel Multi-Layer Deep Convolutional Neural Network. Cancers (Basel), 16(1), 108. doi: 10.3390/cancers16010108. PMID: 38201535; PMCID: PMC10778045.

9. Idakak, A., Alremeithi, A., Dahiyat, E., et al. (2024). Civil liability for the actions of autonomous AI in healthcare: an invitation to further contemplation. Humanities and Social Sciences Communications, 11(305). https://doi.org/10.1057/s41599-02402806-y