THE CHUTZPAH OF INNOVATION: CHARTING THE LEGAL MATRIX OF ARTIFICIAL INTELLIGENCE IN DERMATOLOGICAL DISEASES

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ABSTRACT

The field of medical science has undergone a paradigm shift in recent years, with the development of newfangled technologies and tools that have significantly transformed the healthcare delivery system across the world, including India. One such technology that has ascended to a position of conspicuousness and sparked widespread attention and interest within the medico-legal fraternity is artificial intelligence. Artificial Intelligence has tremendously revolutionized the healthcare system in different ways, and the domain of dermatology is not an exception to it. The newfangled technology has the potential to improve the clinical decision-making process, patient safety, interpretation of images, monitoring and prediction of highly contagious diseases, and mitigating the formidable challenge of workforce shortages. However, questions have been lingered among policymakers and regulators regarding the extent to which stakeholders should trust AI and whether the technology itself has earned the trust of the masses. The paper first expounds on the conceptual understanding of artificial intelligence. Through unpacking this concept, we try to encapsulate a clearer picture of it. Secondly, the paper elucidates the ongoing role of artificial intelligence in the medical diagnosis and treatment of dermatological diseases. Thirdly, the ongoing bottleneck in the development of artificial intelligence has been meticulously analyzed from a legal perspective. Finally, based on the previous meticulous examination, the paper puts forward suggestions to safeguard the interests of all stakeholders involved therein.

Keywords: Artificial Intelligence, Dermatological Diseases, Medical Diagnosis, Legal Issues and Challenges

"AI is only as good as the humans programming it and the system in which it operates. If we are not careful, AI could not make healthcare better, but instead unintentionally exacerbate many of the worst aspects of our current healthcare system." [1]

- Bob Kocher

1.1 INTRODUCTION

In the past two decades, the field of dermatology has undergone a tremendous shift by using AI powerful tools trained on vast libraries of clinic-dermoscopic histopathological image resources. The use of software, information communication technology and computerized technologies has led to widespread integration of AI in various fields of medicine, such as pathology and its subbranch dermatopathology, in that way have significantly embraced it. However, there are several limitations, issues and challenges associated therewith. The existing legal framework in India is not sufficient, which is posing challenges in the path of the widespread adoption of AI in the field of dermatology. We, therefore, must triumph over the issues and challenges that lie ahead for their successful adoption and integration.

1.2 APPLICATION OF AI IN THE DIAGNOSIS OF DERMATOLOGICAL DISEASES

AI has made major strides in the diagnosis and treatment of dermatological diseases, strikingly in general skin diseases and specific skin diseases such as acne, cold sores, blisters, hives, eczema, psoriasis, melanoma, measles, lupus, atopic dermatitis, and vitiligo. [2] Offering a range of potential applications that can prevent highly contagious diseases in the early stages, even if they are not completely curable, and consequently ameliorate the efficiency of skin diseases has always been at the heart of advocates of AI. Dermatologists usually diagnose skin diseases through visual inspection, either with the naked eye or using dermoscopic images, which is a time-consuming process because of the strong reliance on non-invasive method. The focal point of discussion is that the present health system has been in need of improvement. The existing system, however, is ringed by stumbling blocks as the diagnosis hinges upon a number of factors, such as age, color, gender, and geographical area. Another challenge is the existence of a distinct number of skin diseases with a high diversity of lesion varieties for each disease. In addition to this, another issue pertaining to the automated computerized system is that the current systems are not up to the extent of recognizing all the possible variants, whereby excludes the chance of diagnosing rare diseases. In other words, there is a dearth of appropriate

datasets. To overcome these challenges, several algorithms utilizing AI have been developed based upon ML/DL models to assist in the interpretation of clinical and dermoscopic images and the classification and diagnosis of different diseases such as melanoma (skin cancer) [3] , neurofibroma (cancer predisposition disease) [4], eczema classification [5], psoriasis (chronic inflammatory disease) [6], atopic dermatitis [7], vitiligo [8], and for the prediction of HIV and sexually transmitted infections. [9] Deployment has gained extreme attention from the medical-legal fraternity because of their exceptional performance in the realm of dermatology, especially for exploring and cracking the new dimensions. The overall procedure of skin disease recognition, prediction, and classification systems, which are based upon ML/DL techniques, is illustrated in the **Fig. 1**, which is explained briefly next to the figure. In this field, as perhaps any other crucial field, deployment of AI involves a systematic procedure that includes image acquisition and dataset, image preprocessing, and image segmentation. Since what we input into the system with a view to generate output, it is vitally important to make certain that the data is accurate and reliable.

Fig. 1: *Depicts the Overall Procedure of Skin Diseases Recognition, Prediction, and Classification System by using ML/DL Techniques.*

In this field, as perhaps any other crucial field, deployment of AI involves a systematic procedure that includes image acquisition and dataset, image preprocessing, and image segmentation. Since what we input into the system with a view to generate output, it is vitally important to make certain that the data is accurate and reliable. The first step is to gather a heterogenous dataset. The data can be acquired through three modes, as shown in **Fig. 2** below: (a) use of dermoscope to capture dermoscopic image; (b) the captured dermoscopic image; and (c) a captured clinical image using normal digital camera. [10]

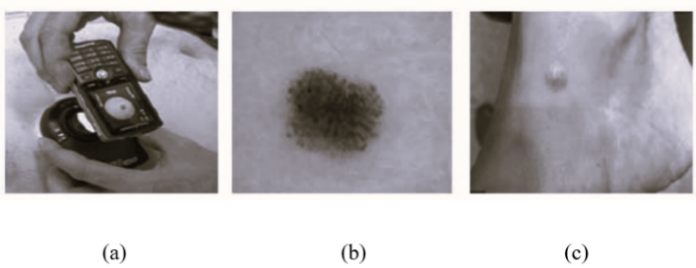

Fig. 2: *Three Ways to Acquire Data: (a) Use of Dermoscope to Capture Dermoscopic Image; (b) The Captured Dermoscopic Image; and (c) A Captured Clinical Image using Normal Digital Camera.*

After that, the data undergoes preprocessing to denoise and enhance the quality of the images. With an intent to denoise and improve the quality of the image, the **Fig. 3** depicts the various common pre-processing techniques used in this field. [11]

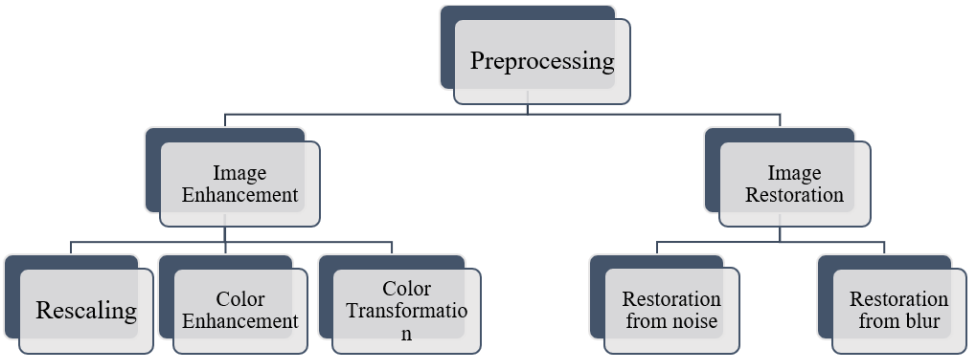

Fig. 3: *Common Pre-processing techniques used in the skin diseases recognition and classification system.*

Following this, image segmentation takes place, which aims to discern between afflicted and unaffected areas of the skin. This process essentially involves the delineation of the 'Region of Interest (ROI), which is typically the area of skin suspected to be diseased. Once pre-processed and segmented, features are extracted from the images or data to train a machine-learning model. Convolutional Neural Networks (CNNs) are a type of neural network that is particularly well-suited for image analysis. Trained on large datasets, CNNs learn to identify patterns that might be difficult for humans to see. Post-training, it can be used to classify new images. The performance of the model is evaluated using metrics like confusion matrices and Intersection-

over-Union (IoU). It is important to monitor their performance carefully in controlled settings with human intervention before widely deploying them in clinical practice.

1.3 THE LEGAL CHALLENGES ASSOCIATED WITH ARTIFICIAL INTELLIGENCE IN THE DIAGNOSIS OF DERMATOLOGICAL DISEASES

Safety & Efficacy of AI in Diagnosis: Ensuring the precision and dependability of these algorithms is a major concern. In certain cases, dermatologists who practise in person find it difficult to accurately identify some illnesses because of their slight variance. For the application of AI, diverse range of datasets, representing a wide range of dermatological disorders ought to be used for training.

Studies have demonstrated that conflicting elements can have an adverse impact on the categorization performance of AI systems. These elements generally relate to image quality and standardisation variables. The quality of the image provided by a clinician determines several variables, including image rotation, adversarial "noise" (intended perturbations like ink spots intended to "confuse" MLA), brightness/contrast manipulation, rulers, ink markings, blurry photos, and dark corners of the tubular lens. A special focus has to be on handling specific inputs with variability or incorporating strict criteria, otherwise, these biases are inherent in these AI models. Reducing errors in diagnosis requires extensive validation and testing of AI algorithms on a variety of datasets. Stakeholders can aid the integration of AI into the clinical practice domain. This could be done by guaranteeing the reliability and authenticity of data sets, upgrading their software more often to fix bugs, including statistical biases, and implementing product transparency.

In India, medical devices are subject to regulation by the Central Drugs Standard Control Organisation (CDSCO). The MoHFW issued a notification in February 2020 that expanded the category of medical devices. [12] This makes software eligible to be classified as a medical device. However, it is crucial to point out that hardware is not covered. The fundamental point is that, despite the implementation of the MDR, medicinal products shall continue to be classified as drugs since they are subject to a definition related to those covered by the Act. This has consequences for other laws, including the Drugs Price Order 2013, as per which drugs are essential commodities. As a result, now there are restrictions on the price regulation of medical equipment that falls within the category of medicinal items. For software to be sold as a medical device in India, it must adhere to regulations, which include: (i) falling within the

ambit of the definition of a medical device; (ii) Quality Management Systems (SO 13485:2016); (iii) Application of Risk Management to Medical Devices (ISO 14971:2019). [13]

In 2021, the CDSCO issued new guidelines in respect of the classification of Software as Medical Device (SaMD), wherein it provides four distinct levels for SaMD: (i) low-risk (Class A); (ii) low- moderate risk (Class B); (iii) moderate risk (Class C), and (iv) high-risk (Class D).

The Indian government has implemented the Bureau of Indian Standards Act, 1985, allowing medical equipment to comply with guidelines set by the Bureau of Indian Standards or MoHFW. If no such standards exist, the International Electro Technical Commission (IC) or International Organisation for Standardisation (ISO) criteria must be followed. The Medical Device Rules of 2017 indicate conformity with the fifth schedule (QMS) of the MDR. It should nonetheless be mentioned that the MDR does not mandate that CLA/SLA offer a particular GMP or QMS. The government should develop a system to monitor, regulate, and identify potential hazards in AI, ML, or DL systems that often outperform oncologists and dermatologists, but their evaluation relies on archived databases, posing a problem with reliable benchmarking through randomized controlled trials (RCTs). Further RCTs are needed to ensure the clinical viability of AI solutions.

Data Protection and Privacy: Privacy is critical in the following contexts: (i) collecting vast quantities of health data to train algorithms, and (ii) sharing that data to track how it is used. Data from several sources must be assembled by algorithm developers to train machine learning algorithms. To ascertain how effectively algorithms perform in real-world medical contexts, these data may then be shared with other organisations within the healthcare system for evaluation and validation. Therefore, patient privacy about their personal information is a concern in both cases. Dermatological diagnosis frequently entails gathering and analysing private patient information, such as demographics, medical history, genetic information, and photos of skin lesions. Obtaining patients' informed consent before to the collection, use, and disclosure of any dermatological data is a fundamental need. It is clear from a cursory review of the law that this nation has very inadequate data protection regulations. It has taken more than 70 years for India's constitutional courts to acknowledge and embrace a unique right to privacy within the confines of the Indian Constitution.

The DPDP Act aims to protect personal data in light of the increase in internet usage and information creation. It reflects India's contemporary position on data protection and was reinforced after extensive consultations. The Act covers methods for managing data complaints, information handling policies, breach prevention techniques, and data protection for children. However, the Act does not discriminate between personal and sensitive data, which begs the question of the rules pertaining to permission. In the event of an epidemic, disease outbreak, or threat to the public health, data fiduciaries may handle personal data for medical treatment or health services without obtaining express consent. Apart from the implementation-related challenges, there are concerns over the numerous sections of the law and their potential to undermine the protection it purports to give. First of all, the state is allowed to prioritise state imperatives over private interests and wield enormous powers because of the exemption granted to consent. [14] Secondly, the government has the authority to enact regulations in compliance with the law, which in some situations may jeopardise the protections afforded by that legislation. Thirdly, there are issues with the composition, power, and functions of the Data Protection Board. Furthermore, the Information Technology Act of 2000 implicitly regulates and oversees Al-related activities in India. Section 43A of the Act, which offers compensation in situations of careless handling of sensitive personal data or information (SPDI) resulting in a data protection breach, is specifically concerned with such activities. There are certain provisions of the rules notified under this act that are in direct conflict with the DPDP Act. The conventional way of machine learning has been to use a Blackbox model to link these rules with Al in medical diagnosis. This paradigm just provides the conclusion of reasoning, concealing all the complex procedures. Experts or practitioners have therefore been unable to support the reasoning process in the medical diagnosis since they are unable to comprehend the reasons that were considered throughout that process. Therefore, it is crucial that these challenges be thoroughly studied in order to optimise the use of medical data generally.

Liability: Though AI systems can process and analyse large quantities of data and offer potential solutions, these systems are not infallible. Attributing liability can become a prolonged legal struggle if such a tool misidentifies a malignant melanoma as benign, thus, delaying treatment and harming patients. While the developers may counter that their system was designed to assist rather than be definitive, the doctor may argue that there is too much reliance on AI technology. This could result in *"liability dilution"*, which makes it more difficult for the victim to get justice because no one is held solely accountable.

Therefore, liability concerns arise, and it becomes difficult to assign blame - whether it lies with the system's creator, the health care provider using it, or both. Mezrich believes that the tort law for artificial intelligence is still developing, and malpractice can arise from breaches of duty of care, deviations from the standard of care, errors in programming, doctor's actions, or the algorithm itself. [15] Barlett stipulated that there is no clear-cut solution to AI accountability, highlighting that the developers are often small actors - individuals or small companies - who may be the most culpable when their creations cause harm. The tangible weight of confronting lawful consequences each time their system leads to adverse outcomes could understandably cause them to be excessively careful about presenting their creations to the general population. Currently, it seems that physicians may still be held accountable even if they trusted the *"Blackbox"* machine learning algorithm in good faith. But the relevant point is, does this still be true when the software's functioning prevents the medical expert from independently reviewing the recommendations?

When it comes to liability issues, defining the scope of control is essential. Sung and Poon contend that the creators of AI should bear some of the responsibility when devices use self-learning algorithms to diagnose without a doctor's clearance. However, according to the same authors, developers should not be held accountable only because their AI systems can't guard against all possible harm. Mezrich also makes the point that the level of autonomy that the software exercises will determine how the law treats AI liability. The onus of liability shifts to the radiologist who makes the final diagnosis when AI is used exclusively as a decision-support tool.

The CPA 2019 in India includes regulations pertaining to product liability. Chapter VI outlines when people can claim compensation for any harm from a faulty product. S. 72 says it applies "to every claim for compensation under a product liability action by a complainant for any harm caused by a defective product manufactured by a product manufacturer or serviced by a product service provider or sold by a product seller." Although taking legal action against defective items is a valuable tool, it is quite challenging as the burden of evidence is on the complainant. For the remedies outlined in the CPA 2019 to take effect, the AI must be transparent about the reasoning behind its decisions. If not, the statute doesn't offer many useful alternatives.

Courts, however, have shown little appetite to extend the applicability of product responsibility

laws to developers. A detailed analysis of the circumstances, including the acts or inactions of all parties involved, the standard of care that applies in the situation, and the degree to which the AI system contributed to or failed to prevent the harm, is necessary to determine liability in cases of medical negligence involving AI in dermatology.

Intellectual Property Law

Interesting nuggets of issues and challenges have emanated from this study about the altering AI and large-scale data used in "real-world" applications, services, and procedures, which entangle major costs and risks. As is often the case in other medical fields, several studies have pinpointed that the commercial safeguarding of AI and data-centric healthcare/life science technologies would require careful consideration. Meanwhile, it is too early to judge in a subjective way the merits of these tools. In the time to come, they may well be seen as harbingers of change in this field, but, as of now, familiar concerns about open science and innovation focus on enhancing data sharing and access to these technologies and their associated data loom large. The protection of AI and its underlying data is most of the part ensured through a variety of IPRs, which commonly include extensive agreements, copyright, trade secrets, and database rights. This has led to a curious paradox here. Conspicuously, pressing issues is arising regarding data accessibility and ownership, exceptionally within the orbit of data mining and analytics. The application of IPRs to these activities, including copyrights on the software which is utilized for data collection and processing, has been subject to critical scrutiny. This scrutiny springs from the unique characteristics of big data, such as its unstructured nature and the non-relational databases is often employed to store it, which challenge the traditional scope and applicability of existing copyright protections, including the sui generis database right in India. In addition to this, within the pharmaceutical sector incorporation of AI is characterized by a multifaceted array of IP obstacles. Although pharmaceutical firms will more likely to embrace AI to enhance their patent collections, these identical systems could be utilized by rivals or patent inspectors to challenge the legitimacy of patents. In this context, the safeguarding of innovations produced by AI, encircling algorithms and datasets, is significantly dependent on a blend of proprietary information, technological protections, and contractual arrangements.

Biasness: Fairness, prejudice, and discrimination are concerns that recur often and have been seen as a significant obstacle in the use of algorithms and automated decision-making systems.

These models are conventionally trained on voluminous datasets which consist of information on the patient and medical images. If there is lack of diversity in these datasets, bias may be demonstrated on the basis of age, gender, race, skin type etc leading to vital repercussions such as misdiagnosis or delayed treatment for underrepresented patient populations. Detection of skin cancer, especially melanoma, is one of the glaring examples in this issue.The AI algorithms that were trained on lighter skin tones demonstrate less accuracy in identifying melanoma in skin of colour. Air bubbles, hair, skin disorders with a history, sun-damaged skin, and unusual anatomical locations are examples of confounding variables that affect CNN function.

At the "17th Annual Skin of Colour Society Scientific Symposium"[1], a presented poster revealed a notable discrepancy in the performance of AI systems in distinguishing between melanoma and basal cell carcinoma (BCC) in individuals with darker skin compared to those with lighter skin.

The apps used for commercial purposes which claim to identify the disease on the basis of pictures taken from smartphones have also been controversial as these work better on people who have a lighter skin tone. This prejudice results in legal as well as ethical issues.

These biased results violate the Right to Equality as guaranteed by the Indian Constitution. Moreover, the Right to Equality is guaranteed by the Indian Constitution. However, the discriminatory results of AI systems, particularly in case of people with darker skin tones violates their right to equality in healthcare. Moreover, this issue resonates with the right to health as guaranteed under Article 21, which ensures adequate healthcare. It could be argued that the discriminatory results in the case of specific demographic groups indicates unintentional perpetuation of inequality in medical treatment also.

In order to minimise these risks, it is essential that these systems are rigourously tested before their application in healthcare. First, in order to represent the diversity of the broader population, we must increase the size of CNN training sets. The necessity for physicians to evaluate patient groups with whom they are less familiar and less able to appraise is rooted in the immigrant waves. Thus, having a trained algorithm will be beneficial. The majority of

[1] P. Aggarwal, "Artificial Intelligence (AI) image recognition of dermatological diseases in people with skin of color". Poster presented at "17th Annual Skin of Color Society Scientific Symposium" on March 13, 2021, virtual. *Available at:* https://socs2021-trexperts.ipostersessions.com/?s=20-91-5B-ED-F6-46-5B-8B-25-13-D3-B5-F8-A7-F2-AA. (Visited on August 12, 2024).

algorithms are trained on patients who are Caucasian or Asian, although early screening for individuals with skin colour differences may be more advantageous because delayed diagnosis has been linked to more severe illness and shorter survival rates in this population. When algorithms are given data from populations other than the ones in the dataset, they often perform worse. This emphasises how important it is to train the same algorithm using a wider variety of photos from various ethnic backgrounds.

1.4 CONCLUSION AND SUGGESTIONS

As things stand, the present study sketches the application of AI in the diagnosis of dermatological diseases as sites of rays of hope in highly intricate diseases, navigating the various dimensions from a legal perspective and dissecting the challenges that lie ahead. The use of AI has exploded over the last decades, prompting a broader debate among the medico-legal fraternity about the integration, adoption, and acceptance of artificial intelligence within the healthcare system, including in the realm of dermatology. Different jurisdictions around the world are taking note of the application and its implications. With effective oversight, the various actors can build a multifaceted approach to addressing these challenges of this newfangled technology and provide a future pathway that is accessible to all. To achieve the objectives of this technology in the field of dermatology, the author would like to present the following suggestions:

- The stakeholders must assess either short-term usage or long-term usage. On the basis of this assessment, clear legal and ethical rules can effectively be devised. It must include, *inter-alia,* providing a conceptual model of AI, consultation with various key actors, and promotion of research and development, as the efficacy of the model absolutely depends upon the training and its accuracy.

- As far as the safety and efficacy of AI are concerned, the developers must rely on highly reliable and valid data. The model must be trained with refined data in order to achieve the better performance of it. It is necessary to chalk out the statutory measures in order to ensure the protection of users, healthcare professionals, and patients.

- To maintain the privacy of the patient's data, privacy-aware ML/DL models would eventually be helpful. The federated learning model is helpful and allows decentralization which keeps the data at its origin. It doesn't allow the local data to be processed by a central

coordinator rather processes it locally with its own data.

- In cases of liability, it is always expected on part of the healthcare professional to exercise reasonable care. Presently, the development of AI is in its nascent stage, and the question of liability is also in the pipeline among various stakeholders. To avoid liability, the healthcare professional can use it as a confirmatory tool in the process of diagnosis.

- The laws with respect to intellectual property rights are not very effective. More regulations regarding internet data giants will need to be devised. Issues with regard to intellectual property law can only be addressed after the full effect and purpose of the models. Without analyzing the purpose and its effect, the law wouldn't be effective enough to tackle the issues.

- In order to overcome the bias, the application of active ML/DL models will be helpful to uptake AI in the realm of dermatology.

- A new Intellectual Framework is the need of the hour in order to address the issues of ownership in AI-assisted healthcare. It must have provisions regarding the rights of patients whose data is being used for training purposes, healthcare institutions as well as AI developers.

- Rather than being treated as decision maker, AI tools should be treated as "decision-support" tools. A global framework which provides guidelines for the clinicians on how to interpret AI diagnosis with clinical empathy.

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