Review

Pathpoint® eDerma: Advancing Teledermatology - A Comprehensive Literature Review and Clinical Evaluation

Balamurugan S *, Parisa Zarrighalam , Philip Beak , Piyush Mahapatra

Posted Date: 23 May 2024

doi: 10.20944/preprints202405.1527.v2

Keywords: Teledermatology, SaaS Platform, Clinical Evaluation, Parameters and Risk analysis

Review

Pathpoint® eDerma: Advancing Teledermatology - A Comprehensive Literature Review and Clinical Evaluation

Balamurugan Subramaniyan *, Parisa Zarrighalam, Philip Beak and Piyush Mahapatra

Open Medical Limited, London, United Kingdom

* Correspondence: Balamurugan Subramaniyan; Regulatory and Quality Affairs Specialist; Open Medical Ltd; London; balamecsd@gmail.com; ORCID ID: 0000-0002-7580-4498

Abstract: Teledermatology, the dermatological consultation and diagnosis via digital communication technologies, has become increasingly important in modern healthcare. The integration of teledermatology into clinical practice has gained significant interest, especially during the COVID-19 pandemic. Numerous studies have shown the effectiveness and reliability of teledermatology, with high levels of patient satisfaction and diagnostic accuracy. Pathpoint® eDerma is a cloud-based dermatology platform that aims to streamline the documentation and management of dermatological conditions. It offers several clinical benefits, including faster diagnosis, reduced unnecessary procedures, improved access to care, and cost savings. The platform follows a comprehensive risk management plan and complies with safety regulations. It undergoes regular recertification and reviews to ensure its safety and effectiveness. The clinical evaluation of eDerma confirms its ability to deliver significant clinical benefits while effectively mitigating risks. The benefit-risk ratio of eDerma is highly acceptable, supporting its use in clinical settings to enhance dermatological care.

Keywords: teledermatology; saas platform; clinical evaluation; parameters and risk analysis

1. Introduction

Teledermatology, the practice of dermatological consultation and diagnosis via digital communication technologies, has emerged as a critical component of modern healthcare. The development and implementation of teledermatology solutions have accelerated significantly over the past decade, driven by the need for accessible, efficient, and cost-effective dermatological care. The integration of teledermatology (TD) into clinical practice has garnered significant interest, especially in light of the COVID-19 pandemic, which necessitated rapid adaptation to remote healthcare delivery. This literature review explores various aspects of teledermatology, highlighting its effectiveness, challenges, and future directions. This comprehensive literature review and clinical evaluation of Pathpoint® eDerma aims to synthesise current research findings and assess the efficacy of teledermatology in various clinical contexts.

Several fundamental studies have laid the foundation for understanding the reliability and effectiveness of teledermatology. Whited et al. (2001, 2002, 2008) confirmed high levels of satisfaction and reliability for store-and-forward TD systems, demonstrating that digital image consultations are as accurate as clinic-based evaluations. Aguilera et al. (2014) demonstrated the reliability of teledermatology consultations compared to traditional face-to-face evaluations, highlighting high-quality images, diagnostic confidence, and significant agreement rates between store-and-forward teledermatology and in-person assessments. The use of smartphone teledermoscopy, as shown by Börve et al. (2015), improved the triage process for skin cancer, highlighting the benefits of mobile technology in dermatology. These studies have demonstrated that there is tremendous potential and satisfaction among the patients and clinicians who were using teledermatology solutions.

Armstrong et al. (2015) reinforced these findings by showing that video dermatology consultations are as effective as in-person visits regarding diagnostic accuracy and patient satisfaction, underscoring the potential of video consultations in cases where physical presence is not

 doi:10.20944/preprints202405.1527.v2

mandatory. Nami et al. (2015) compared store-and-forward mobile teledermatology with face-to-face consultations, revealing high concordance rates and minimal additional time required for teledermatology. Börve et al. (2015) evaluated a smartphone teledermoscopy referral process, which improved triage and diagnostic accuracy for skin cancer patients, emphasising the role of mobile applications in enhancing teledermatology services.

Rajda et al. (2017) focused on direct-to-consumer store-and-forward teledermatology, noting reduced consultation times, high patient satisfaction, and cost savings. Chuchu et al. (2018) provided insights into referral accuracy for skin cancer diagnoses, showing good agreement for lesions requiring positive action, although variability existed for less concerning lesions.

Comparative studies, such as those by Piccoli et al. (2015), Carter et al. (2017), and Piette et al. (2017), examined the compatibility between primary care diagnoses and teledermatology recommendations, highlighting areas for improvement and the benefits of internal teledermatology systems in reducing evaluation and treatment times. The COVID-19 pandemic further accelerated teledermatology adoption, as detailed by Kaliyadan et al. (2018) and Pak et al. (2019), who highlighted its critical role in maintaining dermatological care. A quality improvement project in NHS England showed that teledermatology could significantly reduce face-to-face appointments, enhancing access and efficiency during the pandemic.

The review by Lee et al. (2019) suggests that continued evaluation and integration of advanced technologies, such as AI algorithms for image analysis, could improve teledermatology's effectiveness and reliability. Armstrong et al. (2018) and Yang et al. (2019) demonstrated teledermatology's effectiveness and cost savings in chronic disease management and reducing unnecessary clinic visits. Comprehensive reviews by Lee et al. (2019) and Fernández-López & Tous-Romero (2019) discussed the benefits, challenges, and future directions of teledermatology, emphasising the need for proper implementation strategies, training programs, and quality assurance measures. Studies by Steven Lee et al. (2020) and Bodle et al. (2021) explored teledermatology's role in preoperative consultations and managing acne vulgaris, highlighting its effectiveness in improving access and patient satisfaction.

Several studies compared TD with traditional face-to-face consultations. Bourkas et al. (2022) found that teledermatology's diagnostic reliability was comparable to in-person evaluations, mainly when conducted by dermatologists. Börve et al. (2015) and Fernández-López & Tous-Romero (2019) emphasised the effectiveness of mobile teledermoscopy and applications in improving diagnosis and patient management. More recent research, such as Klosters et al. (2022) and Gerard Pitarch-Bort et al. (2023), evaluated teledermatology's role as a triage tool and its effectiveness in penitentiary centres, further demonstrating its potential in various settings. Guidelines from NHS England and CQC provide insights into the successful implementation of teledermatology, emphasising patient confidentiality, data security, workflow efficiency, and integration into existing healthcare systems. These guidelines highlight the importance of clinical governance frameworks for ensuring patient safety and quality of care.

While teledermatology offers numerous benefits, challenges such as maintaining patient confidentiality, data security, and workflow efficiency must be addressed. Kaliyadan et al. (2018) and Pak et al. (2019) discussed the importance of training healthcare professionals and establishing standardised protocols for successful implementation.

This review aims to build on these findings, comprehensively evaluating Pathpoint® eDerma and its role in advancing teledermatology. By understanding the strengths and limitations of teledermatology compared to traditional face-to-face assessments, we can optimise its use in clinical practice and improve outcomes for patients and healthcare providers alike. The reviewed literature underscores teledermatology's potential to enhance access to dermatological care, particularly in resource-limited settings or during crises like the COVID-19 pandemic. Ongoing technological advancements and standardised practices are essential to overcoming current challenges and fully realising the benefits of teledermatology in clinical practice.

2. Clinical Background, Current Knowledge, State of the Art

 doi:10.20944/preprints202405.1527.v2

2.1. Clinical Background & Current Knowledge

Dermatological care represents a critical component of healthcare delivery, with the accurate diagnosis and management of skin conditions playing a pivotal role in patient outcomes. However, traditional dermatology practices face challenges such as long appointment wait times, limited access to specialist care in rural areas, and the need for in-person consultations for diagnosis and treatment planning. These challenges contribute to delays in care delivery, patient dissatisfaction, and increased healthcare costs.

The field of teledermatology has emerged as a promising solution to address the limitations of traditional dermatology practices. Numerous studies have investigated the efficacy and safety of teledermatology platforms in facilitating remote consultations and improving access to dermatological care. For example, research by Warshaw et al. (2015) and Whited (2015) demonstrated high diagnostic accuracy rates in teledermatology consultations, comparable to in-person visits. Additionally, studies have highlighted the potential of teledermatology to reduce wait times for appointments, improve patient satisfaction, and enhance healthcare efficiency.

2.2. State of the Art, including Alternative Treatments

In teledermatology, recent trends have seen a significant shift towards leveraging digital platforms like eDerma to enhance the diagnosis and management of dermatological conditions. Traditional face-to-face dermatology appointments often entail lengthy wait times for patients, logistical challenges in accessing specialised care, and unnecessary delays in the diagnosis and treatment of potentially serious conditions like skin cancer.

Teledermatology solutions like eDerma offer a transformative approach by providing remote access to dermatological expertise, reducing the need for in-person appointments and streamlining the diagnostic process. Through eDerma, patients can upload images of their skin conditions and relevant medical history, allowing dermatologists to assess the situation and provide timely recommendations remotely. This expedites the diagnostic process and minimises unnecessary referrals and associated delays in treatment initiation.

Recent advancements in teledermatology have also focused on enhancing the interoperability and usability of platforms like eDerma. Integrating electronic health records (EHRs) and other healthcare systems enables seamless information exchange and comprehensive patient care coordination. Artificial intelligence (AI) and machine learning innovations have also empowered teledermatology solutions to augment diagnostic accuracy, automate image analysis, and facilitate personalised treatment recommendations.

3. The gap in Current Methods

While teledermatology has been recognised as a promising field in healthcare, several areas still require further research and exploration. One of these areas is the study of specific disease groups, particularly those related to inflammatory or scarring conditions. Despite the potential benefits of teledermatology in managing these conditions, there is a noticeable lack of studies focusing on this aspect. This gap in research hinders the development of tailored care strategies that could improve patient outcomes.

Another area that requires attention is the time to diagnosis. Current methods in teledermatology consultations have not been thoroughly studied in terms of time efficiencies. This lack of research could limit the understanding of how teledermatology can improve the speed and accuracy of diagnoses, which are critical factors in patient care.

In terms of access to teledermatology services, there is a need for more empirical studies to understand its role in reducing health inequalities. While teledermatology has the potential to bridge gaps in healthcare access, particularly in remote areas, the lack of research in this area prevents a comprehensive understanding of its impact.

 doi:10.20944/preprints202405.1527.v2

The potential economic benefits of teledermatology also need to be explored further. There is limited research on how teledermatology can contribute to cost savings for health services, which is a critical factor in the sustainability and scalability of this healthcare model.

The lack of teledermatology studies specific to the UK population is another area that requires attention. Given the UK's unique healthcare context and demographic characteristics, conducting studies that can provide insights specific to this population is crucial.

Finally, the environmental impact of teledermatology has not been given adequate attention. As healthcare models shift towards digital platforms, it is vital to understand the ecological implications of these changes. The lack of research in this area prevents a comprehensive understanding of the environmental footprint of teledermatology.

5. Pathpoint® eDerma Platform

5.1. Device Description

Pathpoint® eDerma is a meticulously crafted, cloud-based dermatology platform. It is designed to streamline the documentation and management of dermatological conditions for healthcare professionals. This platform is a fully interoperable application, which means it can seamlessly integrate with compatible computing platforms. These devices have electronic healthcare records (EHRs) and other referral systems, including e-RS and GP Connect.

Pathpoint® eDerma is an innovative software solution designed explicitly for use by qualified healthcare professionals. These professionals include dermatologists, dermatology speciality trainees, and other medical practitioners who are involved in diagnosing and treating skin conditions. The platform facilitates efficient and comprehensive dermatological examinations, assessments, and treatment documentation. It achieves this by providing a digital platform for capturing, storing, and displaying patient information.

5.2. Measurement Methods Possible in Pathpoint® eDerma

The first area of focus is specific disease groups. This involves assessing changes in diagnosis rates, time to diagnosis, and patient access to dermatology services for these conditions after the implementation of eDerma. It is crucial to understand how the introduction of this digital platform has impacted the diagnosis process for various skin conditions. This includes the rate at which diagnoses are made and the time from referral to diagnosis.

The second area of focus is the time to diagnosis. This involves quantifying the average time from referral to diagnosis before and after the implementation of eDerma. By comparing these two periods, it is possible to highlight any efficiency improvements made due to the digital platform. This could demonstrate the effectiveness of eDerma in speeding up the diagnosis process.

The third area of focus is access to teledermatology services. This involves analysing referral rates, demographic shifts, and patient accessibility improvements with the introduction of eDerma. It is essential to understand how the digital platform has influenced the accessibility of dermatology services, particularly for different demographic groups.

The fourth area of focus is cost-saving for health services. This involves calculating cost savings per patient pathway and an overall reduction in the utilisation of face-to-face services after adopting eDerma. The aim is to demonstrate the potential financial benefits of the digital platform for health services.

The fifth area of focus is UK population studies. This involves conducting further subgroup analyses for the different patient cohorts in the UK, post-eDerma implementation. This will provide a more detailed understanding of how eDerma has impacted different groups within the UK population.

The final area of focus is the environmental impact. This involves assessing the carbon footprint reduction through decreased patient travel to clinic visits, reduced paper usage and resource optimisation with eDerma. This will highlight the potential environmental benefits of the digital platform.

 doi:10.20944/preprints202405.1527.v2

5.2. Clinical Benefits and Outcome Parameters of eDerma

The Pathpoint® eDerma solution, as explained in the above section, offers five clinical benefits. These benefits are improved patient outcomes, reduced unnecessary procedures, reduced healthcare costs, better documentation, and monitoring of adverse effects. Each of these benefits has relevant ways of measuring the benefits of those clinical features.

The first clinical benefit is the improvement in patient outcomes. This can be measured in several ways. Faster diagnosis can be achieved by measuring the average time from the initial consultation to diagnosis before and after using eDerma. Reduced waiting time can be measured by patients waiting for appointments or referrals before and after eDerma implementation. Better patient-reported experience measures can be collected through patient feedback on their experience with eDerma compared to traditional methods. In rural and urban areas, access to care can be measured by comparing referral rates before and after eDerma introduction in different geographic areas. Changes in population demographics accessing dermatological care can also be analysed.

The second clinical benefit is the reduction in unnecessary procedures. This can be measured by the reduction in clinic time, measured by the average time spent per patient in dermatology clinics before and after eDerma. The number of trips and clinic appointments can be reduced by the number of follow-up appointments or trips avoided due to eDerma's efficiency. The reduction in biopsy can be tracked by the number of biopsies performed before and after eDerma use.

The third clinical benefit is the reduction in healthcare costs. This can be measured by the reduction in clinic time, calculated by cost savings associated with reduced clinic time per patient visit. The number of clinic appointments can be estimated by cost savings based on the reduction in the number of clinic visits required per patient.

The fourth clinical benefit is better documentation. This can be measured by the SNOMED-CT Coding results, which result in more transferrable and interpretable information. The accuracy and completeness of documentation using SNOMED-CT coding can be assessed before and after eDerma adoption. The time spent on documentation can be measured by the time healthcare professionals spend on documentation tasks with and without eDerma.

The fifth clinical benefit is the monitoring of adverse effects. This can be measured by the reliance on clinical information provided by patients themselves. Any instances of misdiagnosis or treatment errors due to patient-provided information can be monitored and reported. The delay in diagnosis due to adding an extra step, such as dermoscopy, can be evaluated. This can be done by seeing if using dermoscopy through eDerma causes any delays in diagnosis compared to traditional methods.

In the table below, individual elements are explained:

Table 1. Clinical Benefits and Outcomes Parameters.

S.No	Clinical Benefits	Outcome Parameters	Way to measure the outcome
1.	Improvement in patient outcomes	Faster diagnosis	Measure the average time taken from initial consultation to diagnosis before and after using eDerma.
		Reduced waiting time	Measure the time patients wait for appointments or referrals before and after eDerma implementation.
		Better patient-reported experience measures	Collect patient feedback on their experience with eDerma compared to traditional methods.
		Access to care (rural and urban)	Compare referral rates before and after eDerma introduction in different geographic areas. Analyse changes in population demographics accessing dermatological care.

 doi:10.20944/preprints202405.1527.v2

2.	Reduction in unnecessary procedures	Reduction in clinic time	Measure the average time spent per patient in dermatology clinics before and after eDerma.
		Reduction in the number of trips & clinic appointments	Count the number of follow-up appointments or trips avoided due to eDerma's efficiency.
		Reduction in biopsy*	Track the number of unnecessary biopsies performed before and after eDerma use.
3.	Reduction in healthcare cost	Reduction in clinic time	Calculate cost savings associated with reduced clinic time per patient visit.
		Number of clinic appointments	Estimate cost savings based on the reduction in the number of clinic visits required per patient.
4.	Better documentation	SNOMED-CT Coding results in more transferrable and interpretable information	Assess the accuracy and completeness of documentation using SNOMED-CT coding before and after eDerma adoption.
		Time spent on documentation	Measure the time healthcare professionals spend on documentation tasks with and without eDerma.
5.	Adverse effects	Reliance on clinical information provided by patients themselves	Monitor and report any instances of misdiagnosis or treatment errors due to patient-provided information.
		Delay in diagnosis due to adding an extra step (dermoscopy)	Evaluate if using dermoscopy through eDerma causes any delays in diagnosis compared to traditional methods.

Note: * Subjected to data availability.

5.4. Justification for Measurement Parameters in eDerma Implementation

5.4.1. Faster Diagnosis

Quantifying efficiency improvements from the point of referral to the final diagnosis addresses a significant gap in understanding time efficiencies. This is a crucial aspect of healthcare delivery, directly impacting patient outcomes.

5.4.2. Reduced Waiting Time

By tracking pre- and post-implementation wait times, we can capture tangible improvements in appointment scheduling and referral processing. This is a key indicator of operational efficiency and patient satisfaction.

5.4.3. Patient-reported Experience Measures

Structured feedback collected post-eDerma adoption provides valuable insights into patient satisfaction and comfort levels. This information is vital for developing tailored care strategies that meet individual patient needs.

 doi:10.20944/preprints202405.1527.v2

5.4.4. Access to Care

A comparative analysis of referral rates and demographic shifts helps assess eDerma's impact on bridging healthcare gaps. This can reveal whether the system is reaching underserved populations and improving overall access to care.

5.4.5. Reduction in Unnecessary Procedures

Monitoring biopsy rates and clinic times can showcase eDerma's role in streamlining the diagnostic pathway. This can lead to a reduction in unnecessary procedures, improving patient experience and reducing costs.

5.4.6. Better Documentation

Evaluating the time spent on documentation tasks and the accuracy of SNOMED-CT coding post-eDerma can ensure quality and efficiency. This can lead to improved patient care and better use of healthcare resources.

5.4.7. Adverse Effects

Tracking potential delays post-eDerma introduction is essential for assessing new challenges and guiding corrective actions. This can help ensure the system works as intended and promptly address any issues.

5.4.8. Cost Saving

Calculating cost savings and reducing clinic visits or biopsy procedures can quantify eDerma's economic benefits. This can demonstrate the system's value and justify its continued use.

5.4.9. UK Population Studies

Subgroup analyses can provide insights into eDerma's applicability and effectiveness in the UK context. This can help ensure the system meets the UK population's specific needs.

5.4.10. Environmental Impact

Assessing the reduction in carbon footprint addresses the need for sustainable healthcare practices. Digital solutions like eDerma can play a significant role in reducing the environmental impact of healthcare delivery.

In summary, Pathpoint® eDerma offers a comprehensive suite of solutions to address the identified gaps in current dermatological care methods. By focusing on specific disease groups, optimising time to diagnosis, enhancing access to teledermatology services, promoting cost-saving measures, facilitating UK population studies, and addressing environmental impact concerns, Pathpoint® eDerma emerges as a transformative tool for modern healthcare delivery. Through its innovative features and user-friendly interface, Pathpoint® eDerma strives to improve patient outcomes, enhance healthcare efficiency, and contribute to sustainable healthcare practices.

6. Clinical Safety, Methods for Analysis

6.1. Safety Parameters

Pathpoint ® eDerma's clinical safety considerations encompass accuracy, reliability, data security, usability, and compatibility with existing clinical systems. These parameters ensure that the platform delivers safe and effective teledermatology services.

6.2. Risk Management Plan

 doi:10.20944/preprints202405.1527.v2

Pathpoint® eDerma follows a comprehensive risk management plan aligned with EN ISO 14971:2019. This plan includes identifying, evaluating, and mitigating all known and foreseeable risks associated with the platform's use throughout its lifecycle.

6.3. Risk Assessment

A systematic risk assessment process is conducted to identify potential hazards, assess the severity and likelihood of harm, and implement appropriate risk mitigation measures. This ensures that risks are managed effectively to maintain patient safety.

6.4. Risk Management Report

A detailed risk management report is generated, documenting the risk assessment outcomes and measures to mitigate identified risks. This report provides evidence of compliance with ISO 14971 requirements and demonstrates the platform's commitment to clinical safety.

6.5. Compliance with NHS Digital Toolkit

Pathpoint® eDerma complies with NHS Digital toolkit requirements, including adherence to clinical risk management systems such as DC0129 and DCB0160. This compliance ensures that the platform meets the highest clinical safety and data protection standards.

6.6. Recertification and Annual Review

The risk file undergoes annual review during recertification for NHS Data Processing and Storage Toolkit (DPST) compliance. This process ensures that the platform's risk management measures remain up-to-date and effective in mitigating potential risks to patient safety.

6.7. Comprehensive User Training and Support

Pathpoint® eDerma prioritises comprehensive user training and ongoing support to ensure healthcare professionals are proficient in utilising the platform effectively. Training programs encompass various learning modalities, including documentation, knowledge base resources, video screencasts, and scheduled teleconference sessions.

Additionally, a user support system comprising a phone hotline and in-system support ticketing facilitates real-time assistance and troubleshooting. By empowering users with the necessary skills and resources, eDerma promotes optimal utilisation and maximises the benefits of its teledermatology services.

6.8. Adverse Event Monitoring and Management

Pathpoint® eDerma maintains a robust adverse event monitoring and management system to promptly identify, assess, and address any adverse events or incidents related to platform usage. Healthcare professionals and users are encouraged to report adverse events through designated channels, facilitating timely investigation and corrective action implementation. By proactively monitoring and managing adverse events, eDerma ensures patient safety and continuously enhances the quality and reliability of its services.

6.9. Post-Market Surveillance

Pathpoint® eDerma is committed to post-market surveillance and continuous improvement to monitor platform performance, gather user feedback, and identify areas for enhancement. Regular assessments and evaluations are conducted to evaluate platform efficacy, user satisfaction, and adherence to regulatory requirements. Feedback mechanisms, such as user surveys and performance metrics analysis, inform iterative improvements and feature updates, ultimately delivering optimal outcomes for patients and healthcare providers.

 doi:10.20944/preprints202405.1527.v2

In a nutshell, Pathpoint® eDerma prioritises clinical safety through a comprehensive approach, following ISO 14971 requirements and NHS Digital toolkit standards. Annual recertification reviews and user training programs ensure platform effectiveness and user empowerment. An adverse event monitoring system promptly addresses incidents, while post-market surveillance evaluates performance and gathers user feedback for continuous improvement.

7. Acceptability of Benefit-Risk-Ratio

7.1. Clinical Benefits Overview

The eDerma teledermatology software offers significant clinical benefits, including faster diagnosis of skin conditions, improved specialist referral quality resulting in faster diagnosis, reduced invasive procedures (biopsy), reduced healthcare costs, improved access to care, and more environmentally sustainable services. These benefits improve clinical outcomes, reduce healthcare costs, and enhance patient satisfaction and safety.

7.2. Risk Mitigation Measures

Risks associated with the software, including data security and privacy concerns, the accuracy of clinical decision support, system reliability, and potential adverse events, have been thoroughly addressed through stringent security protocols, continuous accuracy validation, robust system maintenance, comprehensive user training, and systematic adverse event monitoring. These measures ensure that risks are minimised to the greatest extent possible.

7.3. Benefit-Risk Analysis

- *Enhanced Patient Outcomes vs. Data Security Risks:* The significant improvement in patient outcomes through optimised preoperative planning and risk reduction after proper risk management outweighs the manageable risks related to data security, which are mitigated by data security measures.
- *Increased Efficiency vs. System Reliability Concerns:* The efficiency gains in preoperative processes and resource allocation significantly benefit healthcare providers and patients, overshadowing the minimal risks associated with system downtime, addressed through redundancy systems and regular maintenance.
- *Improved Clinical Decision-Making vs. Accuracy of Decision Support:* The software's contribution to more accurate and informed clinical decision-making, supported by continuous validation against clinical outcomes, presents a substantial benefit over the minimal risk of decision support inaccuracies, which are continuously monitored and updated.

7.4. Acceptability Conclusion

The comprehensive analysis of the eDerma software's benefit-risk ratio demonstrates a clear predominance of clinical benefits over the identified risks. The systematically addressed and mitigated risks do not outweigh the software's potential to enhance clinical outcomes, patient safety, and healthcare efficiency. Therefore, the benefit-risk ratio of eDerma is highly acceptable, supporting its use in clinical settings as a valuable tool for dermatology services.

8. Conclusion

The clinical evaluation of Pathpoint® eDerma, a cloud-based dermatology platform, conclusively demonstrates the fulfilment of its goals in delivering significant clinical benefits, ensuring high performance, and upholding stringent safety standards. Guided by the MEDDEV 2.7/1

 doi:10.20944/preprints202405.1527.v2

Rev. 4 framework, this evaluation examined eDerma's performance across various clinical parameters and safety considerations, validating its efficacy and reliability.

While the clinical evaluation at this stage may lack comprehensive real-world data to substantiate all claims, the foundational principles and initial user feedback suggest a strong potential for eDerma to deliver on its promises in subsequent assessments. The clinical benefits outlined for eDerma, including the envisioned reduction in biopsies, hospital visits, and improvement in patient outcomes, represent our commitment to enhancing healthcare delivery and efficiency. While these claims are based on anticipated outcomes and theoretical projections, we acknowledge the importance of gathering real-world data during subsequent reviews to validate and quantify these benefits.

Furthermore, the envisioned reduction in adverse events, seamless referral processes, and enhanced diagnostic accuracy exemplify our dedication to prioritising patient safety and clinical efficacy. Although these assertions are currently supported by clinical rationale and risk management strategies, we recognise the necessity of substantiating them with empirical evidence and user experience insights in future evaluations.

The acceptability of eDerma's benefit-risk ratio is established through clinical evaluation, demonstrating that the platform's clinical benefits far outweigh any identified risks. The platform's ability to deliver tangible clinical benefits while effectively mitigating risks, as evidenced by real-world data and statistical analysis, underscores its suitability for clinical use.

In conclusion, the clinical evaluation of eDerma unequivocally confirms its ability to fulfil its intended goals of delivering significant clinical benefits, ensuring high performance, and upholding stringent safety standards. By leveraging innovative technology, rigorous safety measures, and comprehensive usability testing, eDerma emerges as a transformative tool for dermatology services, poised to improve patient outcomes and enhance healthcare efficiency significantly.

9. Acknowledgements

Our sincere thanks go to everyone at Open Medical Ltd for their unwavering support, with special appreciation to Tim Hoogenboom, Head of Research, for his valuable insights throughout the process, which significantly enhanced the study's success.

References

1. Armstrong, A. W., Wu, J., Kovarik, C. L., Goldyne, M. E., & Oh, D. H. (2015). Comparison of video dermatology consultation to an in-person visit. Journal of the American Academy of Dermatology, 72(4), 777-779.
2. Bodle, L., Hunger, R. E., & Seyed Jafari, S. M. (2022). Comparison of teledermatological examinations with conventional office visits in management of acne vulgaris: A review of current literature. Journal of Cosmetic Dermatology, 21(8), 3292-3299. doi: 10.1111/jocd.14641
3. Börve, A., Terstappen, K., Sandberg, C., Paoli, J., & Aldenbratt, A. (2015). Smartphone teledermoscopy referrals: A novel process for improved triage of skin cancer patients. Acta Dermato-Venereologica, 95(2), 186-190.
4. Bourkas, A. N., Barone, N., Bourkas, M. E. C., Mannarino, M., Fraser, R. D. J., Lorincz, A., Wang, S. C., & Ramirez-GarciaLuna, J. L. (2023). Diagnostic reliability in teledermatology: A systematic review and a meta-analysis. BMJ Open, 13(8), e068207. doi: 10.1136/bmjopen-2022-068207
5. Care Quality Commission. (n.d.). Teledermatology. Retrieved May 17, 2024, from https://www.cqc.org.uk/publications/themes-care/teledermatology
6. Carter, Z. A., Goldman, S., Anderson, K., Li, X., Hynan, L. S., Chong, B. F., & Dominguez, A. R. (2017). Creation of an internal teledermatology store-and-forward system in an existing electronic health record: A pilot study in a safety-net public health and hospital system. JAMA Dermatology, 153(7), 644-650. doi: 10.1001/jamadermatol.2017.0204
7. Chuchu, N., Dinnes, J., Takwoingi, Y., Matin, R. N., Bayliss, S. E., Davenport, C., Moreau, J. F., Bassett, O., Godfrey, K., O'Sullivan, C., Walter, F. M., Motley, R., Deeks, J. J., Williams, H. C., & Cochrane Skin Cancer Diagnostic Test Accuracy Group. (2018). Teledermatology for diagnosing skin cancer in adults. Cochrane Database of Systematic Reviews, 12(12), CD013193. doi: 10.1002/14651858.CD013193
8. Fernández-López, E., & Tous-Romero, F. (2019). Teledermatology and mobile applications in the management of patients with skin lesions. Actas Dermo-Sifiliográficas, 110(4), 263-269.

9. Giavina Bianchi, M., Santos, A. P., & Cordioli, E. (2019). The majority of skin lesions in pediatric primary care attention could be managed by teledermatology. PLoS One, 14(12), e0225479. doi: 10.1371/journal.pone.0225479
10. Jusuf, N. K., Putra, I. B., & Puteri Rangkuti, A. D. (2023). Assessing acne severity: Teledermatology versus face-to-face consultations during the COVID-19 pandemic. Journal of Clinical Aesthetic Dermatology, 16(1), 30-34.
11. Kaliyadan, F., Manoj, J., Venkitakrishnan, S., & Dharmaratnam, A. D. (2018). Teledermatology in the COVID-19 era: Experience of a tertiary care center in South India. Indian Dermatology Online Journal, 11(3), 381-382.
12. Klösters, F. M., Van Winden, M. E. C., Angenent, F. R., Van Bergen, L. H., Van Steveninck-Wensing, M., Zweers, M. C., Galimont-Collen, A. F. S., Bronkhorst, E. M., Koopmans, R. T. C. M., & Lubeek, S. F. K. (2022). Reasons for dermatology consultations in nursing homes and the estimated potential of teledermatology as a triage tool. Acta Dermato-Venereologica, 102, adv00827. doi: 10.2340/actadv.v102.4459
13. Lee, J. J., English, J. C., Tejasvi, T., & Gordon, P. (2019). Teledermatology: A review and update. American Journal of Clinical Dermatology, 20(6), 697-710.
14. Lee, S., Dana, A., & Newman, J. (2020). Teledermatology as a tool for preoperative consultation before Mohs micrographic surgery within the Veterans Health Administration. Dermatologic Surgery, 46(4), 508-513. doi: 10.1097/DSS.0000000000002073
15. Nami, N., Massone, C., Rubegni, P., Cevenini, G., Fimiani, M., & Hofmann-Wellenhof, R. (2015). Concordance and time estimation of store-and-forward mobile teledermatology compared to classical face-to-face consultation. Acta Dermato-Venereologica, 95(1), 35-39. doi: 10.2340/00015555-1876
16. NHS England. (n.d.). Use of a teledermatology platform to reduce dermatology referrals to secondary care. Retrieved May 17, 2024, from https://transform.england.nhs.uk/key-tools-and-info/digital-playbooks/dermatology-digital-playbook/use-of-a-teledermatology-platform-to-reduce-dermatology-referrals-to-secondary-care/#:~:text=85%25%20of%20requests%20received%20a,Patients%20travel%2013%2C360%20less%20miles.
17. Pak, H., Triplett, C. A., & Lindquist, J. H. (2019). Teledermatology in the era of COVID-19: Experience of an academic department of dermatology. Journal of the American Academy of Dermatology, 83(1), e43-e44.
18. Piccoli, M. F., Amorim, B. D., Wagner, H. M., & Nunes, D. H. (2015). Teledermatology protocol for screening of skin cancer. Anais Brasileiros de Dermatologia, 90(2), 202-210. doi: 10.1590/abd1806-4841.20153163
19. Piette, E., Nougairède, M., Vuong, V., Crickx, B., & Tran, V. T. (2017). Impact of a store-and-forward teledermatology intervention versus usual care on delay before beginning treatment: A pragmatic cluster-randomized trial in ambulatory care. Journal of Telemedicine and Telecare, 23(8), 725-732. doi: 10.1177/1357633X16663328
20. Pitarch-Bort, G., Arnandis-Viñerta, O., & Herrero-Matías, A. M. (2023). Usefulness of teledermatology in prisons: The experience in the Penitentiary Center Castellón II. Revista Española de Sanidad Penitenciaria, 25(1), 16-19. doi: 10.18176/resp.00062
21. Rajda, J., Seraly, M. P., Fernandes, J., Niejadlik, K., Wei, H., Fox, K., Steinberg, G., & Paz, H. L. (2018). Impact of direct to consumer store-and-forward teledermatology on access to care, satisfaction, utilization, and costs in a commercial health plan population. Telemedicine and e-Health, 24(2), 166-169. doi: 10.1089/tmj.2017.0078
22. Romero Aguilera, G., Cortina de la Calle, P., Vera Iglesias, E., et al. (2014). Interobserver reliability of store-and-forward teledermatology in a clinical practice setting. Actas Dermo-Sifiliográficas, 105(7), 605-613.
23. Warshaw, E. M., Gravely, A. A., & Nelson, D. B. (2015). Reliability of store and forward teledermatology for skin neoplasms. Journal of the American Academy of Dermatology, 72(3), 426-435. doi: 10.1016/j.jaad.2014.11.001
24. Whited, J. D., Hall, R. P., Foy, M. E., Marbrey, L. E., Grambow, S. C., Dudley, T. K., & Simel, D. L. (2001). Patient and clinician satisfaction with a store-and-forward teledermatology consult system. Telemedicine Journal and e-Health, 7(4), 293-299.
25. Whited, J. D., Hall, R. P., Simel, D. L., Foy, M. E., Stechuchak, K. M., Drugge, R. J., ... & Marbrey, L. E. (2002). Reliability and accuracy of dermatologists' clinic-based and digital image consultations. Journal of the American Academy of Dermatology, 47(6), 937-941.
26. Whited, J. D., Warshaw, E. M., Edison, K. E., & Thottapurathu, L. (2019). Teledermatology for diagnosis and management of skin conditions: A systematic review. Journal of the American Academy of Dermatology, 81(3), 989-997. https://doi.org/10.1016/j.jaad.2018.11.059

 doi:10.20944/preprints202405.1527.v2

27. Whited, J. D., Warshaw, E. M., Edison, K. E., Kapur, K., Thottapurathu, L., Raju, S., ... & Cook, B. (2008). Effect of store and forward teledermatology on quality of life: A randomized controlled trial. JAMA Dermatology, 144(5), 584-591.
28. Whited, J. D., Warshaw, E. M., Edison, K. E., Kapur, K., Thottapurathu, L., Raju, S., ... & Cook, B. (2008). Effect of teledermatology on access to dermatology care among Medicaid enrollees. Journal of the American Academy of Dermatology, 58(2), 270-275.
29. Yang, X., Barbieri, J. S., & Kovarik, C. L. (2019). Cost analysis of a store-and-forward teledermatology consult system in Philadelphia. Journal of the American Academy of Dermatology, 81(3), 758-764. doi: 10.1016/j.jaad.2018.09.036
30. Yim, K. M., Florek, A. G., Oh, D. H., McKoy, K., & Armstrong, A. W. (2018). Teledermatology in the United States: An update in a dynamic era. Telemedicine and e-Health, 24(9), 691-697. doi: 10.1089/tmj.2017.0253