# Mapping the Regulatory Framework for Telemedicine in Zambia: A Content Analysis

Lillian Muyunda[1*], Mubanga Mpundu[2]

[1]*University of Zambia, Graduate School of Business, Great East Road Campus. Lusaka. Zambia. Email: lillianbyers@gmail.com*

[2]*University of the Western Cape, Department of Economics, Robert Sobukwe Road, Bellville 7535, Cape Town, South Africa. Email: mmpundu@uwc.ac*

**Abstracts:** This paper explores the regulatory framework for telemedicine in Zambia. Telemedicine, involving remote clinical services using technology, is a rapidly evolving field intersecting with legal, ethical, and professional domains. The primary aim is to understand Zambia's telemedicine regulatory framework through an analysis of key documents namely the Zambia E-Government Interoperability Standard (eGIF), Zambia Digital Health Strategy 2022-2026, HPCZ Guidelines for the Quality Assurance of Telemedicine Services, and Statutory Instrument 43 of 2023 (SI 43 of 2023). The study addresses the challenge of comprehensively understanding and effectively implementing telemedicine in Zambia, considering the evolving nature of technology and healthcare services. Mapping the regulatory framework is a critical exercise for ensuring legal compliance, maintaining high standards of service, protecting patients, and making informed strategic decisions in the telemedicine sector. The study conducts a detailed exploration and content analysis of the aforementioned documents. This includes examination of their contributions to establishing a strong telemedicine landscape in Zambia, focusing on aspects like interoperability, data security, and healthcare service delivery. Findings reveal each document's significant, yet varied, contributions to the telemedicine framework in Zambia. The eGIF ensures integrated, standardized, and secure digital telemedicine services. The Zambia Digital Health Strategy 2022-2026 promotes telemedicine via digital technology and global alignment, while the HPCZ Guidelines provide a detailed framework focusing on ethical and legal standards. SI. 43 of 2023 emphasizes data security, quality assurance, and collaboration in telemedicine. Comparatively, Zambia's framework, as shaped by the four documents, aligns with global standards but differs in its centralized regulation and strategic focus, lacking extensive coverage on medical device regulations and reimbursement issues seen in other countries. The study suggests the need for a unified approach to telemedicine, emphasizing standardization, legal compliance, accessibility, and inclusivity. Recommendations include improving interoperability, ensuring data security, and fostering user-centric telemedicine services for enhanced healthcare outcomes.

**Keywords:** Telemedicine, Regulatory Framework, Zambia, Content Analysis.

## 1. INTRODUCTION

Telemedicine and telehealth are often used interchangeably, leading to confusion about their precise meanings. However, there is a distinction between the two terms. Telemedicine typically refers to the use of technology to provide remote clinical services, usually involving interactions between healthcare professionals and patients. On the other hand, telehealth encompasses a broader scope, including remote non-clinical services such as provider training, administrative meetings, and continuing medical education (1). Despite the nuanced differences, the terms are frequently used interchangeably in literature and practice (2). This interchangeable use of terminology has been noted in various studies and publications, indicating a lack of consensus on the precise definitions of telehealth and telemedicine (3). The interchangeable use of these terms has also been observed in specific contexts, such as tele-emergency medicine, tele-psychiatry, teledermatology, and telestroke services, where both terms are used to refer to the same services (3). Additionally, professional organizations and researchers have also used telehealth and telemedicine interchangeably, further contributing to the lack of a universally accepted distinction between the two terms (4). Despite the interchangeable use of these terms, it is essential to recognize the nuanced differences between telehealth and telemedicine to ensure clarity in communication and understanding within the healthcare industry.

For the purpose of this paper, focus is on telemedicine, which the Health Professions Council of Zambia (HPCZ) defines as “the delivery of health-care services where distance and lack of skill set are a critical factor, by all health-care professionals using information and communication technologies for the exchange of valid information for

diagnosis, treatment and prevention of diseases and injuries all in the interests of advancing the health of individuals and their communities" (5). Literature shows that telemedicine has emerged as a very important component in modern healthcare, offering timely and accessible medical services, particularly in resource-constrained settings like Zambia. It is a rapidly evolving field that intersects with various legal, ethical, and professional domains and saw the COVID-19 global pandemic increasing its prominence in modern healthcare. This paper explores the existing regulatory framework for telemedicine in Zambia

A regulatory framework is a structured set of guidelines or rules developed by authorities or regulatory bodies (6) to supervise and control activities within a specific sector, ensuring compliance, safety, and standardization. It consists of legislations, regulations, guidelines, and policies that set out the principles, procedures, and responsibilities governing the conduct of entities within a sector (7,8). Regulatory frameworks can be voluntary, such as integrity pacts, codes of conduct, and arms control agreements, or required and coercive, such as national laws and regulations, contractual responsibilities, and so on (6).

In the context of telemedicine, a regulatory framework plays a crucial role in managing and guiding the deployment of telehealth services. To gain an understanding of Zambia's telemedicine regulatory framework, the paper examines four key documents namely the Zambia E-Government Interoperability Standard (eGIF) (9), the Zambia Digital Health Strategy 2022 - 2026 (10), the newly developed HPCZ Guidelines for the Quality Assurance of Telemedicine Services (5) and Statutory Instrument 43 of 2023 (11).

## 2. MATERIEL AND METHODS

In this analysis, the authors embarked on a detailed exploration of the regulatory framework guiding telemedicine deployment in Zambia, a crucial step in understanding and enhancing healthcare delivery in the country. The authors carefully examined four key documents: the Zambia Electronic Government Interoperability Framework (eGIF) (9), the Zambia Digital Health Strategy 2022-2026 (10), the newly developed and yet to be disseminated HPCZ Guidelines for Telemedicine Services (5), and the Statutory Instrument 43 of 2023 (11). This approach is rooted in the principles of policy analysis and healthcare research (12–14), aiming to dissect and understand each document's contribution to establishing a strong, efficient, and inclusive telemedicine landscape in Zambia. The eGIF, established under the Electronic Government Act, 2021, is designed to enhance management and promote electronic government services, facilitating access to improve service delivery and productivity (9). The Zambia Digital Health Strategy 2022-2026 emphasizes reforming digital health governance and developing digital workforce capabilities, with a focus on enhancing healthcare service deliver (10). Furthermore, the HPCZ, as a statutory regulatory body under the Health Professions Act No. 24 of 2009, sets guidelines for the registration and regulation of health practitioners and facilities, crucial for telemedicine services. The HPCZ recently developed the "Guidelines for the Quality Assurance of Telemedicine services" whose aim is to ensure that that telemedicine services are dispensed in a manner that is safe, effective, and equitable (5). Lastly, the Statutory Instrument 43 of 2023, recently signed by Zambian president, aims to strengthen the role of the Electronic Government Division and promote the adoption and uptake of ICT in public bodies (11). By scrutinizing these frameworks, the study not only assessed their individual impact on telemedicine deployment but also how they collectively shape the trajectory of digital healthcare in the nation. The approach is grounded in a methodical and evidence-based analysis, drawing parallels with existing literature and studies in the field of telemedicine, thereby ensuring a comprehensive and insightful exploration of this evolving sector (1)

In the study, the authors begun by analyzing the detailed provisions and principles outlined in the Zambia eGIF. Each aspect of the standard is examined to understand its contribution to the telemedicine implementation framework. The analysis focuses on the standard's role in ensuring standardized ICT systems, promoting data sharing and interoperability, enhancing security and trust, and fostering user-centric and inclusive services. The examination of eGIF's role in standardizing ICT systems and promoting interoperability is consistent with recommended approaches in telemedicine literature. Existing literature (15–18) highlights the importance of interoperability standards in telemedicine, emphasizing that effective telemedicine deployment relies on the integration of various technology platforms. This aligns with the paper's approach of analyzing the eGIF's

contribution to telemedicine implementation.

The study also conducted a thorough analysis of the HPCZ newly developed guidelines for telemedicine services (5), with a laser focus on specific provisions pertaining to service accreditation, data security, clinical standards, ethical considerations, and patient engagement. Each of these facets is critically examined to gauge their collective and individual impact on the rollout of telemedicine services, the resulting patient outcomes, and the prevailing acceptance of these services among the Zambian populace. The focus on service accreditation, data security, and clinical standards in the HPCZ Guidelines is supported by the work of Kruse and others who argue that regulatory guidelines play a crucial role in ensuring the quality and security of telemedicine services, particularly in aspects like data privacy and clinical efficacy (15).

In addition, the study examined how the Zambia Digital Health Strategy for 2022-2026 fosters inter-sectoral collaboration across health, ICT, and other sectors and promises a commitment to strengthening health systems with technology, sustainable investment, workforce development, comprehensive legislation and policy framework, development of an interoperability framework, and investment in ICT infrastructure (10). These elements collectively facilitate the deployment of telemedicine, ensuring efficient, high-quality, and accessible healthcare services in Zambia. The strategy's emphasis on inter-sectoral collaboration and strengthening health systems through technology is echoed in the work of Scott Kruse and others (16). Their research suggests that effective telemedicine strategies need to encompass comprehensive policy frameworks, workforce development, and ICT infrastructure investment, similar to the elements the paper is examining in the Zambia Digital Health Strategy (10).

Further, the study also conducted a detailed review of the provisions of SI 43.2023 (11). The instrument is scrutinized to identify specific clauses and sections relevant to the deployment and functioning of telemedicine services. The analysis also involves interpreting how these clauses contribute to the regulatory framework for telemedicine, focusing on data security, information sharing, ICT infrastructure, and the overall quality assurance of telemedicine services. The analysis of SI 43.2023 for its contribution to regulatory frameworks in telemedicine aligns with the perspectives shared by Mechael and others (17). They emphasize the importance of legislation in creating a secure and accountable environment for telemedicine, stressing on aspects like data security and quality assurance, much like the analysis presented in this paper.

All in all, the study's approach is well-founded and aligns with established methodologies and recommendations in the field of telemedicine and healthcare policy analysis as demonstrated above.

## 3. RESULTS AND DISCUSSIONS

In this section, the paper presents the outcomes of our review of the four key documents that form the core of this analysis. These documents, each significant in its own right, collectively offer a comprehensive perspective on the regulatory landscape for telemedicine in Zambia. The analysis methodically evaluates each document, scrutinizing their respective contributions to the telemedicine framework and their interrelations within the broader context of digital health implementation in the country.

Firstly, the eGIF (9) is assessed for its crucial role in establishing standardized protocols and facilitating interoperability across diverse digital platforms crucial for telemedicine. Secondly, the Zambia Digital Health Strategy 2022-2026 (10) is explored, with particular emphasis on its strategic vision for integrating digital technologies into healthcare delivery and its alignment with global health initiatives. The third document, the HPCZ Guidelines for the Quality Assurance of Telemedicine Services (5), is critically reviewed to understand its impact on service quality, ethical considerations, and patient engagement in telemedicine. Lastly, Statutory Instrument 43 of 2023 (11) is examined to discern its implications in creating a secure and transparent regulatory framework for telemedicine services.

This section, therefore, synthesizes the findings from these documents, offering insightful perspectives on how they collectively shape the telemedicine landscape in Zambia. The interplay of these documents is crucial in understanding the current state and potential future advancements in telemedicine within the country, providing a

nuanced understanding of the regulatory, operational, and ethical dimensions of telemedicine deployment.

### 3.1. Zambia E-Government Interoperability Standard

The Zambia e-Government Interoperability Framework (eGIF) is an initiative developed by the Electronic Government Division, responsible for formulating and enforcing standards in Information and Communication Technology (ICT) across all Ministries, Provinces, and Spending Agencies (MPSAs) in Zambia. Its primary purpose is to facilitate the transition into a Digital Society. The eGIF provides guidelines for implementing ICT systems to guarantee efficiency and cost-effectiveness (9).

The major objective of the eGIF is to enable seamless interconnection and data/information exchange between various government information systems and applications owned by different public service institutions. By adhering to international standards and taking into account the requirements of the government and stakeholders, the eGIF aims to eliminate unnecessary duplication and reduce the cost-of-service delivery through improved efficiency. It serves as the basic guideline for achieving interoperability in the public service and promotes data sharing and reuse, ensuring that information systems and applications in the public service are compliant with set standards for integration into the Government's ICT infrastructure (9).

The authors conducted a thorough review of the Zambia eGIF. The review revealed that the eGIF, while not explicitly referencing telemedicine, lays down principles that could significantly support telemedicine implementation and contribute to its regulatory environment through various provisions and strategies which are itemized and examined in detail below;

*Provision of Standardized ICT Systems:* One way the eGIF (9) contributes to the regulatory framework for telemedicine in Zambia is by ensuring that ICT systems are developed and maintained in a standardized manner, promoting consistency and secure exchange of medical data across different platforms and providers crucial for integrating telemedicine services. The eGIF goal for standardized ICT systems is also complemented by the HPCZ guidance on telemedicine equipment that emphasizes the need for high-quality video and audio equipment as essential for effective communication (5).

*Interoperability and Data Sharing:* One of the key features of the eGIF standard is its emphasis on interoperability and data sharing (9). This is validated by the standard’s focus on interoperability within the Zambian public service delivery context, emphasizing the sharing of information and knowledge between organizations, an element which is central to telemedicine. The authors note that, in the context of telemedicine, this would include the seamless exchange of patient data, medical records, and other vital information between different healthcare providers and institutions aligning well with HPCZ guidelines on the need for reliable and high-speed internet connectivity (5).

*Reduced Costs and Increased Flexibility:* By introducing flexible, reusable, and interoperable ICT resources, the eGIF helps reduce the cost burden of technology investments, making the implementation of telemedicine solutions more feasible.

*Coordinated Efforts at National Level:* The standard encourages well-coordinated digitization efforts, preventing fragmentation of services and data, which is crucial for creating a unified telemedicine network.

*Shared and Reusable ICT Assets:* Availability of shared and reusable ICT assets can expedite the development and implementation of telemedicine services, reducing the need for creating new solutions from scratch.

*User-Centric Services:* eGIF promotes user-centric services, ensuring that telemedicine solutions are designed with the end-user in mind, which improves accessibility and user experience.

*Secure and Trustworthy Information Sharing:* The standard emphasizes secure and trustworthy information sharing, which is essential for maintaining patient confidentiality and trust in telemedicine services.

*Legal and Institutional Interoperability:* The eGIF also includes legal and institutional interoperability, which would ensure that telemedicine services comply with national laws and policies, establishing a secure and standardized environment.

*Accessibility for All Citizens:* The eGIF aligns with the principle of universal healthcare access due to its goal to make public services accessible to all citizens. The feasibility of both universal healthcare access and public services for all is further strengthened by the introduction of telemedicine services.

*Cross-Sectoral Interoperability:* By fostering interoperability across different sectors, the eGIF standard enables integration between healthcare and other sectors, thereby creating a suitable environment for the enhancement of the scope and effectiveness of telemedicine services.

*Openness and Transparency:* The eGIF promotes the principles of openness and transparency that support the use of open data and standards. The use of open data and standards facilitates the integration of different telemedicine platforms and solutions.

*Guidance on National Interoperability Frameworks:* eGIF ensures transparency within the administrative environment, supports interfaces with internal information systems, protects personal data, leverages existing solutions, and promotes sharing and collaboration. These aspects are critical for the successful implementation and widespread adoption of telemedicine services.

On the whole, the Zambia eGIF (9) ensures that ICT systems across different platforms are standardized, facilitating the integration of telemedicine services. It emphasizes the importance of interoperability and secure data sharing, which are central to the effective operation of telemedicine. By promoting cost reduction and increased flexibility in ICT resources, the standard makes the adoption of telemedicine solutions more feasible. Furthermore, it encourages coordinated digital efforts at the national level and provides for the availability of shared and reusable ICT assets, which are crucial for a unified and efficient telemedicine network. The standard also emphasizes the importance of secure, trustworthy information sharing, legal compliance, and accessibility for all citizens, ensuring a comprehensive and inclusive approach to telemedicine services. Further, by championing principles such as transparency, technological neutrality, and administrative simplification, alongside emphasizing the importance of security, user-centricity, and inclusive design, the standard ensures that telemedicine services are not only accessible and user-friendly but also secure and efficient. This significantly contributes to the improvement of healthcare outcomes within the country.

### 3.2. Digital Health Strategy 2022 -2026

The Digital Health Strategy of Zambia (10), developed for the period 2022-2026, plays a crucial role in the implementation and advancement of telemedicine in the country. Developed through a participatory approach involving diverse stakeholders, it fosters inter-sectoral collaboration across health, ICT, and other sectors, crucial for creating a conducive environment for telemedicine. The strategy focuses on remote healthcare delivery, aligns with global digital health trends, and builds upon the successes of its predecessor, the 2017-2021 strategy, underscoring the importance of digitalization in healthcare. It is managed by the Digital Health Technical Working Group, ensuring effective governance and technical oversight. The strategy has several provisions that would form part of the regulatory framework for telemedicine implementation in the country. The provisions that are supportive of telemedicine implementation are highlighted below;

*Recognition of Digital Technologies in Healthcare*: The strategy acknowledges the essential role of digital technologies in achieving Universal Health Coverage and enhancing healthcare service delivery, research, and education in Zambia. This recognition sets the foundation for integrating telemedicine into the healthcare system.

*Participatory Development Process:* The strategy's development involved a collaborative approach, bringing together stakeholders from both the public and private sectors, including those in healthcare and ICT. This inclusive process ensured that the strategy caters to the diverse needs and capabilities required for telemedicine

implementation.

*Inter-sectoral Collaboration:* The strategy highlights the need for collaboration across various government sectors, including health, ICT, economic science, innovation, and data privacy. This multi-sectoral approach is crucial for creating an enabling environment for digital health technologies like telemedicine.

*Focus on Remote Healthcare Delivery:* The strategy explicitly mentions using digital health to manage care provision at a distance (10), which is a fundamental aspect of telemedicine. It aims to improve coordination of care across the healthcare system and reduce duplication of tests, which are key components of effective telemedicine services.

*Support from Various Entities:* The Ministry of Health led the strategy development with support from various departments and institutions, including Smart Zambia Institute and the Ministry of Technology and Science. This support underscores the commitment at multiple levels to advance digital health initiatives like telemedicine.

*Adapting to Global Digital Health Trends:* The strategy aligns with the global shift towards virtual care and telemedicine, accelerated by the COVID-19 pandemic. It aims to transform Zambia's healthcare delivery with intelligent, digitally enhanced systems, including telemedicine (10).

*Strengthening Health Systems with Technology:* The strategy envisions using technology to make the health system more efficient, delivering high-quality care at reasonable costs, and supporting continual improvements in care - aspects that are integral to the successful deployment of telemedicine.

*Building on Previous Successes:* The strategy builds on the foundations and successes of the 2017-2021 strategy, focusing on service delivery, research, e-learning, and governance (10), all of which are relevant to the implementation of telemedicine.

*Digitalization as a Key Enabler:* It recognizes digitalization as an enabler of improvements across health systems, including better patient care, disease surveillance, and healthcare equity (10) - all essential for the effective functioning of telemedicine services.

*Governance and Technical Oversight:* The strategy is managed under a single-tier governance structure, the Digital Health Technical Working Group, which provides technical oversight, guidance, coordination, and monitoring of digital health system implementation (10), including telemedicine.

*Sustainability and Investment:* The Zambia Digital Health Strategy addresses the need for sustainable investment in digital health infrastructure and initiatives (10), ensuring continued support for telemedicine even after external funding ceases.

*Workforce Development:* The strategy acknowledges the need for developing digital healthcare skills (10), essential for adopting and effectively using telemedicine technologies.

*Legislation and Policy Framework:* A comprehensive package of legislation and policies guides digital health in Zambia, ensuring compliance and governance in the implementation of telemedicine. Examples of these include the eGovernment Act of 2021, Cyber Security and Cyber Crimes Act No. 2 of 2021 and the Data Protection Act No. 3 of 2021(10).

*Interoperability and Standards:* The strategy emphasizes the development of an interoperability framework and adherence to international standards (10), which are critical for seamless telemedicine services.

*Infrastructure Development:* Investments in ICT infrastructure, such as national networks and digital services, are vital for the successful implementation of digital health initiatives, including telemedicine.

*Digital Health Applications and Services:* The strategy promotes the use of digital health applications and services to improve healthcare quality and access, which is aligned with the goals of telemedicine.

*Guiding Principles for Strategy Development:* The strategy's development is guided by principles that focus on user-centricity, collaboration, national applicability, and alignment with healthcare and digital transformation goals in the country, which are essential for the effective implementation of telemedicine.

In summary, the Digital Health Strategy of Zambia provides a comprehensive and collaborative framework that supports the implementation of telemedicine through its focus on digital technologies, multi-sectoral collaboration, global alignment, infrastructure development, governance, and sustainability.

### 3.3. HPCZ Guidelines for the Quality Assurance of Telemedicine services 2023

The Guidelines for the Quality Assurance of Telemedicine services issued by the Health Professions Council of Zambia are designed to regulate and facilitate the delivery of healthcare services through virtual means, particularly in response to the healthcare challenges amplified by the Covid-19 pandemic (5). The major objectives of these guidelines are to provide ethical guidance and offer healthcare providers clear and specific instructions for delivering safe, effective, and high-quality care to patients using information communication technologies (ICT). The guidelines encompass both provider-to-provider and client-to-provider telemedicine, ensuring that the scope of practice for all health practitioners remains consistent with these standards (5). In this section, the paper demonstrates how the yet to be disseminated HPCZ guidelines will form the core part of the regulatory framework of telemedicine services in Zambia.

*Introduction of Telemedicine:* The guidelines recognize the crucial role of telemedicine in healthcare delivery, especially during healthcare emergencies like the COVID-19 pandemic, by allowing healthcare providers to deliver care and consult with patients remotely in real-time. This has been facilitated by advancements in medical and telecommunications technology, demonstrating the potential of telemedicine to improve access to healthcare, increase patient satisfaction, and reduce healthcare costs (5).

*Ethical Guidance and Clear Instructions:* They aim to provide ethical guidance and clear, specific instructions for healthcare providers to deliver safe, effective, and high-quality care to patients using information communication technologies. This includes covering both provider-to-provider and client-to-provider telemedicine, ensuring that the scope of practice for all health practitioners remains in force (5).

*Regulatory and Legal Considerations:* The guidelines emphasize the need for service accreditation and licensing, requiring health facilities providing telemedicine to have valid licenses and accreditation certificates as per the Health Professions Act. This ensures that staff are competent in the use of telemedicine technologies and adhere to established guidelines, maintaining the same standards of medical practice as face-to-face consultations (5).

*Technical Standards:* They outline the necessary hardware, software, and network requirements, including high-speed internet connectivity for real-time video and audio communication, which are essential for the safe, effective, and secure delivery of telemedicine services (5).

*Clinical Standards:* The guidelines define clinical standards for telemedicine providers, including the Know-Your-Client (KYC) principle, which ensures no therapeutic intervention is offered through telemedicine service to a client on the first consult if there has not been a physical interaction in the last six months (5).

*Ethical Considerations:* They highlight the importance of maintaining the healthcare practitioner-patient relationship, professional duties, malpractice, and professional liability, and ensuring informed consent from patients before delivering telemedicine services. This includes informing patients of telemedicine's limitations, benefits, potential risks, and alternative options (5).

Continuity of Care and Patient Record Management: Telemedicine providers are required to ensure continuity of

care between telemedicine visits and in-person visits. They must have access to the patient's medical history and relevant health information and ensure that a record of information exchange is maintained (5).

*Professionalism in Telemedicine:* The guidelines mandate that telemedicine providers adhere to professional standards of conduct and ethics. This includes maintaining a professional demeanor, ensuring accessibility of services to all patients, and having competencies in the use of telemedicine technologies (5)

*Emergency Telemedicine:* The guidelines detail how telemedicine technologies can be used in emergency medical situations, allowing healthcare providers to provide rapid assessment, diagnosis, and treatment of patients in critical condition regardless of their location (5).

*Patient Referral System:* They establish a patient referral system for telemedicine, where healthcare providers refer a patient to another provider for specialized care or consultation using telecommunication technologies. This includes developing clear referral guidelines, identifying referral partners, establishing communication protocols, and educating patients on the referral process (5)

All in all, the HPCZ guidelines collectively aim to enhance the implementation of telemedicine in Zambia by establishing clear standards and protocols, ensuring the safety and effectiveness of telemedicine services, and maintaining the quality of care. They address crucial elements such as establishing credibility, ensuring data protection, and upholding high standards of care. They lay down a solid foundation for building trust through service accreditation and data security protocols, while also ensuring accountability and professional integrity through stringent clinical and ethical standards. Moreover, the guidelines advocate for accessibility and inclusivity, factors that are anticipated to play a significant role in enhancing the acceptability of telemedicine services across diverse Zambian communities.

### 3.4. Statutory Instrument (SI) 43 of 2023

On October 19, 2023, the Zambian Ministry of Home Affairs announced the presidential endorsement by the Zambian President, Hakainde Hichilema, of Statutory Instrument (SI) No. 43 of 2023 (11). The ministry further stated, on its official website, that the legislative instrument is poised to bolster the Electronic Government Division, Smart Zambia Institute, in its mission to escalate the adoption and utilization of Information Communication Technology (ICT) across all public entities (18). According to the ministry’s statement, central to SI No. 43 of 2023 is its mandate for standardized and integrated digital solution deployment, characterized by security, efficiency, and cost-effectiveness. The regulation is in harmony with the government's strategic focus on digital transformation, utilizing technology to elevate citizen well-being through improved public service delivery (18). A key expectation from this legislative move is the collaboration of all public sector bodies with the SMART Zambia Institute to ensure their digital initiatives are in congruence with this regulation. This collaboration is crucial for optimizing the returns on public sector investments in technology and is instrumental in advancing a unified government approach to digital transformation nationwide (18).

In this section, the paper highlights how SI 43 of 2023 (11) will impact the implementation of telemedicine in Zambia. The key findings include:

*Data Confidentiality and Security*: The instrument, in Section 2(A)(a), emphasizes the confidentiality, integrity, and availability of data, crucial for safeguarding patient information in telemedicine interactions.

*Institutional Policy:* Section 2(A)(b) of SI 43.2023 mandates public bodies to establish policies that govern access to and sharing of information. This ensures clear guidelines on the use and distribution of patient data in telemedicine practices.

*Process Automation:* Encouraged by Section 2(A)(1), the automation of paper-based processes, such as appointment bookings, patient registrations, and e-prescriptions, is promoted, enhancing the efficiency of telemedicine operations.

*ICT Systems and Infrastructure*: The SI, particularly in Sections 2(A)(a) and 2(A)(b), mandates the use of standardized and interoperable ICT systems and infrastructure. This integration ensures that telemedicine services are seamlessly incorporated into the existing healthcare network.

*Quality Assurance and Audit*: Regular audits and quality assurance checks, as discussed in Section 14, are emphasized to ensure that telemedicine platforms maintain high standards of service delivery.

*Data Protection and Localization:* The instrument aligns with the Data Protection Act of 2021, as seen in clauses 5, 6, 7, and 8. This alignment ensures secure handling of patient data and compliance with regulatory requirements for data storage outside Zambia.

*Integration and Collaboration:* Sections 16, 27, and 28 of SI 43.2023 encourage integration with government digital infrastructure and promote collaborative data sharing among public bodies, thereby enhancing the reach and efficiency of telemedicine services.

Overall, SI 43 of 2023 significantly strengthens the regulatory framework for telemedicine in Zambia. Through its various provisions, it ensures data confidentiality and security, mandates clear institutional policies, advocates for process automation, requires standardized and interoperable ICT systems, and emphasizes quality assurance. Additionally, it fosters greater integration and collaboration in the telemedicine sector, expanding the reach and effectiveness of digital health services in Zambia.

### 3.6 Discussion

The analysis of the Zambia eGIF, the Zambia Digital Health Strategy 2022 - 2026, the HPCZ Guidelines for the Quality Assurance of Telemedicine Services, and SI 43 of 2023 to illustrate how they contribute to the regulatory framework for telemedicine in Zambia, also provides a comprehensive insight into the current state and future prospects of telemedicine regulation in the country.

The Zambia eGIF plays a critical role in ensuring the integration of telemedicine services across various digital platforms. It emphasizes the importance of standardized ICT systems, interoperability, secure data sharing, and cost-effective solutions (9). These elements are essential for the effective operation of telemedicine services (19–21) facilitating a unified and efficient telemedicine network that is accessible to all citizens. For instance, solid and reliable ICT systems are the backbone of telemedicine, supporting complex needs such as real-time communication and data management, and ensuring compatibility across various platforms (22). Interoperability is key to seamless data and medical record exchange among healthcare providers (23,24), facilitating coherent patient care and informed medical decisions. Secure data sharing is paramount in maintaining patient confidentiality and trust, critical for the acceptance of telemedicine services. Furthermore, cost-effective solutions, like reusable ICT resources, reduce the financial burden, making telemedicine more feasible and accessible, especially in resource-limited areas. These elements collectively enhance the quality, reach, and sustainability of telemedicine, significantly contributing to the transformation of healthcare delivery (16,21,25,26). This approach aligns with global trends in digital health and is crucial for creating a comprehensive and inclusive telemedicine environment in Zambia.

The Zambia Digital Health Strategy 2022-2026 (10) indeed significantly supports telemedicine implementation through its focus on integrating digital technologies, fostering inter-sectoral collaboration, and aligning with global digital health trends. As such, the strategy's recognition of digital technologies in healthcare sets the foundation for integrating telemedicine into the healthcare system. It also underscores the importance of remote healthcare delivery, which is fundamental to telemedicine. The participatory development process and emphasis on sustainable investment, workforce development, and compliance with international standards and guidelines ensure the strategy is comprehensive and supports the effective functioning of telemedicine services.

The HPCZ Guidelines for the Quality Assurance of Telemedicine Services (5) provide a strong framework to enhance telemedicine implementation in Zambia. These guidelines focus on ethical guidance, regulatory and legal considerations, technical and clinical standards, and the importance of maintaining the healthcare practitioner-

patient relationship. They emphasize service accreditation, data security, and the need for high-speed internet connectivity for real-time communication, which are vital for the safe, effective, and secure delivery of telemedicine services. The guidelines also advocate for accessibility and inclusivity, ensuring that telemedicine services are user-friendly and accessible to diverse communities across Zambia.

SI 43 of 2023 (11) significantly contributes to the regulatory framework for telemedicine in Zambia by addressing key aspects crucial for the effective implementation of telemedicine services. The instrument emphasizes data confidentiality and security, institutional policy, process automation, ICT systems and infrastructure, quality assurance and audit, data protection and localization, as well as integration and collaboration. These provisions align with the strategic focus on digital transformation and the utilization of technology to enhance public service delivery in Zambia (9). Furthermore, the regulatory framework established by SI 43 of 2023 is in line with the government's mission to escalate the adoption and utilization of ICT across all public entities (9), emphasizing standardized and integrated digital solution deployment characterized by security, efficiency, and cost-effectiveness. The regulatory framework outlined in SI 43 of 2023 is consistent with the experiences of telemedicine implementation in other countries, such as Brazil, where a mapped regulatory framework has been instrumental in shaping the telemedicine landscape (27). Additionally, existing literature also highlights the importance of demonstrating the clinical effectiveness of telemedicine to encourage reimbursement for these services in the long term (28), which aligns with the quality assurance and audit provisions in SI 43 of 2023. In conclusion, SI 43 of 2023 significantly strengthens the regulatory framework for telemedicine in Zambia by addressing critical components necessary for the successful implementation of telemedicine services. The alignment of this statutory instrument with the experiences of telemedicine regulation in other countries underscores its potential to enhance the reach and effectiveness of digital health services in Zambia.

**Table 1. Summary comparative analysis of the four documents that contribute to the regulatory frameworks for Telemedicine in Zambia (5) (9-11)**

| Document | Similarities | Contrasts |
|---|---|---|
| Digital Health Strategy | Focuses on the broader strategy for digital health in Zambia, including telemedicine. Emphasizes the importance of data security, interoperability, and the use of technology in healthcare. | More general in scope, covering various aspects of digital health beyond just telemedicine. Lays out strategic plans and objectives for the overall digital transformation of healthcare in the country. |
| eGovernment Interoperability Standard | Addresses the standards for interoperability in eGovernment, which is crucial for telemedicine in ensuring seamless integration of various health information systems. | Specifically targets the interoperability aspect of eGovernment services, not exclusively healthcare or telemedicine. |
| Health Professions Council of Zambia Telemedicine | Directly focused on the regulations and guidelines specific to telemedicine practice, set by the Health Professions Council of Zambia. | Very specific to telemedicine, detailing professional standards, ethical considerations, and regulatory requirements for practitioners. |
| SI 43 of 2023 | Provides regulations under the Electronic Government Act 2021, impacting telemedicine by stipulating data security, ICT infrastructure standards, and digital service delivery mechanisms. | While it influences telemedicine, its scope is broader, covering all eGovernment services. Discusses specific clauses relevant to data security and digital platform security which are pertinent to telemedicine. |

But when further assessed against some of the key elements of an effective regulatory framework, the authors found that each document contributes differently to the framework, with some providing comprehensive coverage and others focusing on specific areas. Table 2. Below summarizes the findings;

**Table 2: Assessing key study documents against the main elements of an effective telemedicine regulatory framework (5) (9-11)**

| Main Elements | eGovernment-interoperability-Standard | Zambia Digital Health Strategy 2022-2026 | HPCZ Telemedicine Guidelines | SI 43 of 2023 |
|---|---|---|---|---|
| **Licensing and Credentialing** | No | Yes | Yes | Partial (Indirect mention of data handling by public bodies) |
| **Quality and Standard of Care** | No | Yes | Yes | No |
| **Patient Privacy and Data Security** | Yes, emphasizes data security | Yes | Yes | Yes (Strong emphasis on data security and protection) |
| **Reimbursement Policies** | No | Yes | Partially (Billing mentioned) | No |
| **Cross-State and International Practice** | No | Yes | Yes (for outsourced services) | Partial (Addresses data storage outside Zambia) |
| **Technology and Infrastructure Standards** | Yes, focuses on interoperability standards | Yes | Yes | Yes (Detailed provisions on ICT systems and infrastructure) |
| **Ethical Considerations** | No | Yes | Yes | Partial (Data protection and security) |
| **Emergency Protocols** | No | Yes | Yes | No |
| **Continuing Education and Training** | No | Yes | Yes | No |
| **Monitoring and Evaluation** | Yes, in the context of ICT standards | Yes | Partial (Quality assurance) | Yes (Quality assurance and audit of electronic services) |

As can be seen from the Table 2 above, the Zambia Digital Health Strategy 2022-2026 and HPCZ Telemedicine Guidelines are comprehensive, addressing all key elements except reimbursement policies and monitoring and evaluation, respectively. The eGIF focuses on patient data security and technology standards but lacks coverage in other areas whereas the SI 43 of 2023 provides strong data security, partial consideration of cross-state/international practice and ethical considerations, and detailed technology standards but omits several other elements.

Therefore, taken together, these documents complement each other to provide a regulatory framework that appears to be adequately addressing the key aspects necessary for the effective implementation of telemedicine services in Zambia. For instance, the HPCZ guidelines (5) and the eGIF (9) exhibit a complementary relationship, synergistically enhancing telemedicine services in Zambia. The HPCZ guidelines mandate reliable and high-speed internet connectivity with a minimum bandwidth of 2 Mbps, resonating with the eGIF's emphasis on interoperability and data sharing, crucial for real-time video and audio communication in telemedicine. Additionally, the requirement for high-quality video and audio equipment supports effective patient-provider communication, aligning with the eGIF's objective for standardized, interoperable ICT systems. Furthermore, the guidelines stipulate that Electronic Health Record (EHR) systems must adhere to principles such as usability, interoperability, and data privacy, echoing the eGIF's focus on secure and standardized ICT resources. Importantly, telemedicine services are required to comply with Zambia's privacy and security regulations, consistent with the eGIF's emphasis on secure and trustworthy information sharing. Lastly, the necessity for telemedicine platforms to support interoperability with other healthcare systems strengthens the eGIF's goal of seamless data and information exchange across government information systems and applications. These aligned standards and requirements underscore a collaborative effort to integrate and enhance telemedicine services within Zambia's broader ICT infrastructure, promoting efficiency, security, and comprehensive healthcare delivery.

All in all, the emphasis on standardization, interoperability, security, user-centricity, and inclusivity in the eGIF, coupled with the strategic and comprehensive approach of the Digital Health Strategy and the detailed guidelines from the HPCZ, collectively create a strong environment for the deployment and operation of telemedicine services in Zambia. These frameworks, when properly implemented, would ensure that telemedicine services are not only efficient and secure but also tailored to the unique needs of the Zambian healthcare context, promoting universal health coverage and enhancing healthcare service delivery.

### 3.7 Zambia Telemedicine Regulatory Framework in Comparison to Frameworks in other Countries

The regulatory framework for telemedicine in Zambia, as outlined in the four pivotal documents highlighted above can be compared with frameworks from other countries on several key aspects.

When Zambia's four cornerstone documents are considered together, there emerges an emphasis on integrating technology into healthcare which aligns with global trends, with a focus on improving healthcare delivery and access. However, while global trends (29) highlight a variety of digital health technologies, Zambia's documents (5,9–11) are more focused on specific applications like telemedicine and creating a comprehensive digital ecosystem.

The global perspective illustrates a complex, evolving legal landscape often adapting to new technologies (29), while Zambia's guidelines and strategies provide focused approaches tailored to telemedicine and digital health within the country. For instance, the Zambia's eGIF emphasizes standardized ICT systems and interoperability, similar to the European Union's eHealth Action Plan 2012-2020 (30), which also focuses on interoperability of eHealth services (10). This alignment with international standards is crucial for ensuring seamless telemedicine services across borders. It illustrates the common aspects in terms of standardization and interoperability. However, in contrast with the broader scope of global trends that encompass regulatory challenges specific to digital health technologies.

Both global trends and Zambia's guidelines stress the importance of data privacy and security in digital health. Zambia mandates adherence to local acts, similar to global trends like HIPAA in the US (29), which regulate the use and disclosure of sensitive health information.

Global trends highlight the complexities of medical device regulations and coverage/reimbursement issues, particularly in the US and EU(29). In contrast, Zambia's documents do not delve deeply into these aspects, focusing more on the strategic application and delivery of digital health services.

Globally, telehealth regulation often varies by region, as seen in the US where it's regulated at state level (29). In contrast, Zambia's Telemedicine Guidelines provide a centralized framework under the Health Professions Council, offering a more uniform approach within the country.

Zambia's Digital Health Strategy includes a detailed implementation and evaluation plan, focusing on continuous improvement and stakeholder engagement (10). This mirrors the global emphasis on strategic planning and assessment in digital health initiatives, although the global perspective tends to be broader in scope. Further, the Zambia Digital Health Strategy's development through a participatory approach and its emphasis on inter-sectoral collaboration is mirrored in the Australian National Digital Health Strategy. Australia's strategy also involved a wide range of stakeholders and stressed collaboration across different sectors for successful digital health implementation (11).

Coverage and Reimbursement appears to be a major focus in global trends, especially in the US, where it's often determined on a payor-by-payor basis (29). In Zambia, the recently developed HPCZ Telemedicine Guidelines do address aspects of coverage and reimbursement. Specifically, they mention that the healthcare provider's office generates an invoice or bill for telemedicine services rendered, and the patient may settle the payment through various methods such as online payment platforms or insurance reimbursement (5). Moreover, there are also similarities arising from ethical and legal considerations. Particularly, the HPCZ Guidelines resemble the American

Telemedicine Association (ATA) guidelines in terms of providing ethical guidance, professional standards, and legal considerations for telemedicine services (9) (31). Both sets of guidelines underscore the importance of maintaining quality and standards in telemedicine practice.

The authors also examined the specific guidelines for telemedicine in Zambia in comparison to those of other countries. Specifically, they compared the HPCZ guidelines to the Indian “Telemedicine Practice Guidelines: Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine of 2020”(32) and South Africa’s “General Ethical Guidelines for Good Practice in Telehealth” (33) guidelines. They compared the telemedicine guidelines from South Africa and India to the HPCZ guidelines, paying close attention to four factors: the regulatory framework, the technical standards, the clinical standards, and the ethical considerations. On the regulatory framework they noted that the Zambian guidelines detailed service accreditation, equipment requirements, and data security compliance while the South African guidelines for telehealth emphasized ethical guidelines, patient consent, and data protection under POPIA. India’ comprehensive guidelines focus on Registered Medical Practitioners (RMPs) and technology use, along with legal and ethical aspects.

The table below summarizes the main provisions of the telemedicine guidelines for each country, highlighting their focus areas and approach to telemedicine.

**Table 3: Summary provisions of telemedicine guidelines for Zambia, South Africa and India (5) (32) (33)**

| Criteria | Zambia | South Africa | India |
|---|---|---|---|
| **Regulatory Framework** | Detailed service accreditation, equipment requirements, and data security compliance. | Emphasis on ethical guidelines, patient consent, and data protection under POPIA. | Comprehensive guidelines focusing on RMPs and technology use, along with legal and ethical aspects. |
| **Technical Standards** | Emphasis on connectivity, bandwidth, and EHR systems. | Acknowledges diverse ICT platforms, ensuring secure and effective communication. | Focuses on various communication modes and technology strengths. |
| **Clinical Standards** | Provider-client workflows for telemedicine services, with stress on no therapeutic intervention for new clients without prior physical interaction. | Concentration on maintaining practitioner-patient relationship and informed consent. | Professional judgment of RMPs guiding telemedicine practices, including patient evaluation and management. |
| **Ethical Considerations** | Healthcare practitioner-patient relationship, professional duties, malpractice, liability, and patient privacy. | Ethical responsibilities in telehealth, including patient dignity, privacy, and quality of care. | Highlights medical ethics, patient privacy, and confidentiality, with guidelines for RMPs. |
| **Other Notable Aspects** | Specific acts like the Data Protection and Privacy Act referenced. | - | Includes guidelines for technology platforms enabling telemedicine. |

The authors observed that the telemedicine guidelines of Zambia, South Africa and India reflect diverse approaches to integrating technology in healthcare, each tailored to their unique healthcare landscapes and legal frameworks.

Zambia's guidelines are notably detailed, focusing on service accreditation, technical equipment, and data security, reflecting a strong regulatory approach. When the guidelines are fully implemented, they will ensure a high standard of telemedicine services, addressing both infrastructural and legal aspects. The emphasis on connectivity and bandwidth, alongside electronic health records systems, underlines a commitment to technical excellence and data integrity in telehealth services (5).

South Africa's guidelines, while less detailed in technical and regulatory specifics, place a strong emphasis on ethical guidelines, patient consent, and data protection. The focus on maintaining the practitioner-patient relationship and informed consent underlines the patient-centred approach in telehealth. This reflects a more

principles-based approach, prioritizing ethical considerations and patient rights within the telemedicine framework (33).

India's comprehensive guidelines revolve around RMPs, technology use, and encompassing legal and ethical issues. This holistic approach balances the technological aspects with the critical role of RMPs in decision-making, patient evaluation, and management. By covering a spectrum of communication modes and technological strengths, India's guidelines demonstrate flexibility and adaptability to various telemedicine contexts(32).

Hence, each set of guidelines illustrates the delicate balance between technology, healthcare delivery, and regulatory oversight. They collectively underscore the importance of ethical considerations, patient safety, and data security in the rapidly evolving domain of telemedicine.

In summary, Zambia's guidelines are highly detailed in technical and regulatory aspects, India's guidelines are extensive, covering various aspects of telemedicine practice including technology and ethical considerations, and South Africa's guidelines put a strong emphasis on legal and ethical considerations.

Overall, Zambia’s regulatory framework for telemedicine shows a strong alignment with global trends and best practices, reflecting a similar emphasis on interoperability, stakeholder engagement, ethical and legal considerations, infrastructure development, and comprehensive regulatory oversight. These similarities suggest that Zambia’s approach is well-aligned with international efforts to establish effective and sustainable telemedicine services.

### 3.8 Potential Gaps and Inconsistencies

The four documents collectively cover a broad range of aspects crucial for telemedicine, including governance, legal and ethical standards, technological infrastructure, and interoperability. They are well-aligned in their objectives to enhance digital healthcare. However, there are still a few areas that represent an opportunity for improvement. In this section, the authors highlight these potential gaps and inconsistencies.

*Explore and document case studies of framework implementation:* Future research endeavours should consider exploring and documenting of practical application pertaining to the strategies, standards, and guidelines evaluated within this study. Such scholarly inquiry could concentrate on the modalities of their execution within Zambia, particularly in relation to the provision of telemedicine services. This examination would provide valuable insights into the operationalization of theoretical frameworks in real-world settings, contributing to an enhanced understanding of their effectiveness and the identification of further potential areas for improvement.

*Data Protection and Privacy:* While the documents emphasize data security and patient confidentiality, there might be a need for more detailed guidelines specifically tailored to telemedicine practices, especially regarding data sharing across different platforms and international borders.

*Resource Allocation and Infrastructure:* The documents mention infrastructure development, but there may be a lack of detailed strategies for resource allocation, particularly in rural or under-resourced areas.

*Healthcare Workforce Training:* While there is mention of developing digital workforce capabilities, specific strategies for training healthcare workers in telemedicine technologies and practices could be further elaborated.

*Patient-Centred Approach:* While user-centricity is mentioned, more emphasis on patient engagement and feedback in the development and implementation of telemedicine services could enhance the effectiveness and acceptance of these services.

*Monitoring and Evaluation:* The documents could benefit from more detailed frameworks for the continuous monitoring, evaluation, and updating of telemedicine policies and practices to ensure they remain effective and relevant.

## CONCLUSIONS

The content analysis of the four documents considered in this study has revealed that each document contributes differently to the regulatory landscape for telemedicine in the country.

The Zambia Electronic Government Interoperability Framework (eGIF) plays an essential role in ensuring the seamless integration of telemedicine services across various digital platforms. Its emphasis on standardized ICT systems, interoperability, secure data sharing, and cost-effective solutions is essential for the effective operation of telemedicine. This approach facilitates a unified and efficient telemedicine network accessible to all citizens, enhancing the quality, reach, and sustainability of telemedicine, thus significantly contributing to the transformation of healthcare delivery in Zambia (9).

The Zambia Digital Health Strategy 2022-2026 significantly supports telemedicine implementation through its focus on digital technologies, multi-sectoral collaboration, and alignment with global digital health trends. Recognizing the role of digital technologies in healthcare, the strategy sets the foundation for integrating telemedicine into the healthcare system. It emphasizes remote healthcare delivery, sustainable investment, workforce development, and compliance with international standards, ensuring a comprehensive and supportive environment for effective telemedicine services (10).

The HPCZ Guidelines for the Quality Assurance of Telemedicine Services 2023 provide a robust framework for telemedicine in Zambia. These guidelines focus on ethical guidance, regulatory and legal considerations, technical and clinical standards, and the importance of maintaining the healthcare practitioner-patient relationship. They advocate for service accreditation, data security, high-speed internet connectivity, accessibility, and inclusivity, ensuring that telemedicine services are user-friendly and accessible across diverse communities in Zambia (5).

Statutory Instrument 43 of 2023 contributes significantly to the regulatory framework for telemedicine by addressing key aspects crucial for its effective implementation. This includes data confidentiality and security, institutional policy, process automation, ICT systems, and infrastructure. It also emphasizes quality assurance, data protection, and integration and collaboration in the telemedicine sector, thereby expanding the reach and effectiveness of digital health services in Zambia (11).

Further, the regulatory framework for telemedicine in Zambia can be compared with those of other countries across several key dimensions. Zambia's approach, encapsulated in its four cornerstone documents, exhibits a strong alignment with global trends in integrating technology into healthcare. Collectively, these documents provide a strong foundation for the effective implementation of telemedicine and the creation of a comprehensive digital ecosystem. This emphasis is in line with international standards, particularly regarding interoperability and standardized ICT systems, similar to the European Union's eHealth Action Plan (30). Additionally, Zambia's framework, as provided by the four essential documents considered in this paper, like many global trends, underscores the importance of data privacy and security, paralleling regulations such as the HIPAA (34) in the United States.

However, there are notable differences in focus and scope when comparing Zambia’s telemedicine regulations with global practices. Unlike broader global trends that delve into medical device regulations and coverage/reimbursement issues, Zambia’s framework is more concentrated on the strategic application and delivery of digital health services. For instance, while the US and EU face complexities in medical device regulations and reimbursement issues (29), Zambia's framework does not extensively cover these areas. Another contrast is seen in the regulatory approaches: the US regulates telehealth at the state level (29), whereas Zambia provides a more centralized framework under the Health Professions Council (5).

Furthermore, the comparison of Zambia's telemedicine guidelines (5) with those of South Africa (33) and India (32) further highlights the diverse approaches to integrating technology in healthcare. Zambia’s HPCZ guidelines are detailed, focusing on service accreditation, technical equipment, and data security, signifying a strong regulatory approach geared towards high standards in telemedicine services. In contrast, South Africa’s guidelines are less

detailed in technical and regulatory specifics but emphasize ethical guidelines, patient consent, and data protection, reflecting a more principles-based approach. India's guidelines offer a comprehensive perspective, balancing technological aspects with the role of RMPs in decision-making and patient management. This comparison elucidates each country's unique approach to telemedicine, balancing technological integration with healthcare delivery and regulatory oversight.

Hence, it can be concluded that Zambia's telemedicine regulatory framework, while aligning with global trends in several respects, also exhibits unique focuses and approaches. Its detailed technical and regulatory guidelines ensure high standards in telehealth services, resonating with international efforts to establish effective and sustainable telemedicine services. This comparison underscores the global diversity in telemedicine regulations, each tailored to the specific healthcare landscapes and legal frameworks of the respective countries.

## REFERENCES


1. Telemedicine and telehealth: principles, policies, performance, and pitfalls. Choice Rev Online. 2000 Sep 1;38(01):38-0318-38–0318.
2. Fatehi F, Wootton R. Telemedicine, telehealth or e-health? A bibliometric analysis of the trends in the use of these terms. J Telemed Telecare. 2012 Dec;18(8):460–4.
3. Sikka N, Gross H, Joshi AU, Shaheen E, Baker MJ, Ash A, et al. Defining emergency telehealth. J Telemed Telecare. 2021 Sep;27(8):527–30.
4. Suzuki H, Shealy SC, Throneberry K, Stenehjem E, Livorsi D. Opportunities and challenges in improving antimicrobial use during the era of telehealth expansion: A narrative review. Antimicrob Steward Healthc Epidemiol. 2021;1(1):e26.
5. Health Professions Council of Zambia. Guidelines for Quality Assurance of Telemedicine Services. 2023.
6. Security Sector integrity [Internet]. [cited 2023 Dec 4]. Regulatory Framewroks. Available from: https://securitysectorintegrity.com/standards-and-regulations/procurement-monitoring-evaluation/
7. Musazzi UM, Di Giorgio D, Minghetti P. New regulatory strategies to manage medicines shortages in Europe. Int J Pharm. 2020 Apr;579:119171.
8. Jones A, Neal B, Reeve B, Ni Mhurchu C, Thow AM. Front-of-pack nutrition labelling to promote healthier diets: current practice and opportunities to strengthen regulation worldwide. BMJ Glob Health. 2019 Dec 14;4(6):e001882.
9. E-Governement Division. Public Service Information Communication Technology Standard: E-Government Interoperability Standard [Internet]. Governement of Zambia; 2019 [cited 2023 Dec 24]. Available from: https://doi.org/10.1016/j.ijpharm.2020.119171
10. Ministry of Health. Digital Health Strategy 2022-2026 [Internet]. 2022 [cited 2023 Dec 24]. Available from: https://www.moh.gov.zm/?wpfb_dl=144
11. Government of the Republic of Zambia. Statutory Instrument No.43 of 2023 [Internet]. Smart Zambia Institute; 2023 [cited 2023 Dec 24]. Available from: https://www.szi.gov.zm/wp-content/uploads/2023/10/SI-No.-43-of-2023-Latest.pdf
12. Carol Cardno. Policy Document Analysis: A Practical Educational Leadership Tool and a Qualitative Research Method. Educ Adm Theory Pract. 2018;Volume 24(Issue 4):623–40.
13. Evolution of public health policy on healthcare self-management: the case of ontario, canada.
14. Trauma-informed care in the UK: where are we? A qualitative study of health policies and professional perspectives - PMC [Internet]. [cited 2023 Dec 26]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9473455/
15. Kruse CS, Krowski N, Rodriguez B, Tran L, Vela J, Brooks M. Telehealth and patient satisfaction: a systematic review and narrative analysis. BMJ Open. 2017 Aug 3;7(8):e016242.
16. Scott Kruse C, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: A systematic review. J Telemed Telecare. 2018 Jan;24(1):4–12.
17. [PDF] Barriers and Gaps Affecting mHealth in Low and Middle Income Countries: Policy White Paper | Semantic Scholar [Internet]. [cited 2023 Dec 26]. Available from: https://www.semanticscholar.org/paper/Barriers-and-Gaps-Affecting-mHealth-in-Low-and-Mechael-Batavia/c8aaef9f5b587a0b481bffc6a32056ae7188b539
18. Editor C. Zambia : President Hichilema signs Electronic Governement Regulations SI [Internet]. 2023 [cited 2023 Dec 4]. Available from: https://www.lusakatimes.com/2023/10/19/president-hichilema-signs-electronic-governement-regulations-si/
19. Almathami HKY, Win KT, Vlahu-Gjorgievska E. Barriers and Facilitators That Influence Telemedicine-Based, Real-Time, Online Consultation at Patients' Homes: Systematic Literature Review. J Med Internet Res. 2020 Feb 20;22(2):e16407.
20. Rabeifar F, Radfar R, Toloie Eshlaghy A. Cloud-Based Smart Telemedicine. Int J Basic Sci Med. 2022 Sep 29;7(3):96–7.
21. Venkataraman A, Fatma N, Edirippulige S, Ramamohan V. Facilitators and Barriers for Telemedicine Systems in India from Multiple Stakeholder Perspectives and Settings [Internet]. Health Policy; 2023 Apr [cited 2023 Dec 4]. Available from: http://medrxiv.org/lookup/doi/10.1101/2023.04.23.23288980
22. Bashshur RL, Shannon GW, Smith BR, Alverson DC, Antoniotti N, Barsan WG, et al. The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management. Telemed J E Health. 2014 Sep 1;20(9):769–800.
23. Gordon WJ, Catalini C. Blockchain Technology for Healthcare: Facilitating the Transition to Patient-Driven Interoperability. Comput Struct Biotechnol J. 2018;16:224–30.
24. De Mello BH, Rigo SJ, Da Costa CA, Da Rosa Righi R, Donida B, Bez MR, et al. Semantic interoperability in health records standards: a systematic literature review. Health Technol. 2022 Mar;12(2):255–72.
25. Sun R, Blayney DW, Hernandez-Boussard T. Health management via telemedicine: Learning from the COVID-19 experience. J Am Med

Inform Assoc. 2021 Nov 1;28(11):2536–40.

26. Shaikh A, Al Reshan MS, Sulaiman A, Alshahrani H, Asiri Y. Secure Telemedicine System Design for COVID-19 Patients Treatment Using Service Oriented Architecture. Sensors. 2022 Jan;22(3):952.
27. Silva AB, Da Silva RM, Ribeiro GDR, Guedes ACCM, Santos DL, Nepomuceno CC, et al. Three decades of telemedicine in Brazil: Mapping the regulatory framework from 1990 to 2018. Makkar A, editor. PLOS ONE. 2020 Nov 25;15(11):e0242869.
28. Hilgart JS, Hayward JA, Coles B, Iredale R. Telegenetics: a systematic review of telemedicine in genetics services. Genet Med. 2012 Sep;14(9):765–76.
29. Group GL. International Comparative Legal Guides International Business Reports. Global Legal Group; [cited 2023 Dec 31]. International Comparative Legal Guides. Available from: https://iclg.com/practice-areas/digital-health-laws-and-regulations/05-emerging-trends-in-the-global-regulation-of-digital-health
30. eHealth Action Plan 2012-2020 - European Commission [Internet]. [cited 2023 Dec 24]. Available from: https://health.ec.europa.eu/publications/ehealth-action-plan-2012-2020_en
31. ATA [Internet]. [cited 2024 Jan 2]. Credentialing By Proxy: A Guidebook. Available from: https://www.americantelemed.org/resources/credentialing-by-proxy-a-guidebook/
32. Board of Govenors, NITI Aayog. Telemedicine Practice Guidelines: Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine [Internet]. 2020. Available from: https://www.mohfw.gov.in/pdf/Telemedicine.pdf
33. Health Professions Council of South Africa. General Ethical Guidelines for Good Practice in Telehealth [Internet]. 2021 [cited 2024 Feb 1]. Available from: https://www.hpcsa.co.za/Uploads/professional_practice/ethics/Booklet_10_Telehealth_Dec_2021_v2.pdf
34. Health Insurance Portability and Accountability Act of 1996 (HIPAA) | CDC [Internet]. 2022 [cited 2024 Jan 5]. Available from: https://www.cdc.gov/phlp/publications/topic/hipaa.html

DOI: https://doi.org/10.15379/ijmst.v10i3.3382