

Exploring the Telemedicine Landscape in India and Germany: A Comparative Study of Legal and Policy Frameworks

Anmol Rattan Singh

Assistant Professor teaching Public Administration at Sri Guru Gobind Singh College, Sector 26, Chandigarh, India

Abstract

Over the past decade, healthcare systems across the globe have integrated digital technology into various functional areas, adopting electronic health record systems, building apps, and experimenting with disruptive technologies such as artificial intelligence. The Covid-19 pandemic has accelerated the need for digital transformation in healthcare systems, which has expanded beyond technology investments to encompass changes in organisational culture and consumer participation. In response, India has taken instinctual steps to promote telemedicine/telehealth projects to enhance information transmission. On March 25, 2020, the Indian government issued telemedicine practice guidelines for Registered Medical Practitioners, marking a significant shift in the country's approach to telemedicine. In contrast, Germany, a parliamentary democracy and a federal republic, has benefited from an established framework of telemedicine/telehealth laws, regulations, and guidelines, as well as new policy interventions, such as the Digital Healthcare Act (2019), which boosts the uptake of digital health applications. As a result, Germany is now recognized globally for its robust policy planning and digital health growth. This paper aims to comparatively assess the legal and policy aspects of India and Germany, with the goal of understanding their respective telemedicine healthcare infrastructures. Ultimately, this paper seeks to contribute to the ongoing global conversation on digital health and inform efforts to establish a sustainable and equitable digital healthcare infrastructure in India.

Keywords: Telemedicine, Healthcare, Data, India, Germany

Introduction

Over the past decade, health systems worldwide have incorporated digital technology into various functional areas, although often in a fragmented and siloed manner. These initiatives have ranged from the implementation of electronic health record (EHR) systems to the development of mobile applications and experimentation with emerging technologies such as artificial intelligence (AI). Despite the adoption of these technologies, healthcare organisations have remained focused on status-quo business-customer paradigms.

However, the emergence of the COVID-19 pandemic has accelerated the need for digital transformation in the healthcare industry, with digital technologies becoming a critical means of delivering care, optimising operations, and meeting consumer demands for overall wellness. This transformation is not merely a matter of

technological expenditure; but one that entails a cultural shift within organisations and increased employee engagement to achieve operational and financial savings. As a result, healthcare organisations are now being forced to rethink traditional models of care and delivery, as digital transformation is becoming an integral component of future healthcare strategies.

As organisations increasingly rely on digital technologies, the emphasis is shifting from a focus on specific programmes to a more comprehensive and integrated approach to digital transformation. By embracing a culture of innovation and adopting emerging technologies, healthcare organisations can optimise care delivery, enhance operational efficiency, and improve overall patient outcomes.

The global importance of digital health is recognized by the World Health Organization (WHO), which has called on member states to develop policies and legislative mechanisms related to national eHealth strategies. In 2013, the Health Assembly passed resolution WHA66.24, which emphasised the need for eHealth standardisation and interoperability, and urged member states to consider implementing these practices. The WHO has also endorsed the global strategy on digital health for 2020-2025 in decision WHA73(28) (2020), highlighting the potential of digital technology in healthcare.

Advancements such as the Internet of Things (IoT), virtual care, remote monitoring, artificial intelligence, big data analytics, blockchain, smart wearables, platforms, and tools for data exchange and storage have shown to significantly improve health outcomes. By enabling the exchange of data and sharing of relevant information across the health ecosystem, these technologies can create a continuum of care that improves medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, and self-management of care. They can also promote person-centred care and support the creation of evidence-based knowledge, skills, and competencies for healthcare professionals. However, to fully realise the potential of these digital technologies, countries must commit to implementing national eHealth strategies and invest in the resources and capabilities required to do so.

Although many countries have made significant progress in adopting digital health, others still require institutional support to develop and implement national eHealth and digital health strategies requiring additional resources and capabilities to implement action plans effectively.

For the purpose of this paper, in the case of India, the healthcare landscape has been evolving with the introduction of various initiatives aimed at digitising healthcare services. Two key milestones in this regard are the 2016 introduction of Electronic Health Record (EHR) standards¹ and the 2017 National Health Policy, which aimed to establish a digital health ecosystem. These developments paved the way for the establishment of the Ayushman Bharat Digital Mission and Health Data Management Policy², with the National Institution for Transforming India also launching the

¹ The EHR standards were first introduced by the Ministry of Health and Family Welfare in 2013, after which a revision of the standards was done after successive stakeholder consultations. Finally in 2016 EHR standards were notified for integration in IT systems of healthcare providers across the country.

² The Policy (2020) was revised post-consultation and a new draft was released in 2022.

National Health Stack to create digital health records for all citizens. The eSanjeevani program is the latest government initiative that aims to create a national telemedicine-teleomatics infrastructure. These initiatives demonstrate India's commitment to leveraging digital technologies to improve the delivery of healthcare services to its citizens.

In contrast to India, Germany has made significant strides in the digitalisation of healthcare. The eHealth Law³, introduced in 2015, mandated that all medical practices and hospitals connect to the telematic infrastructure by the end of 2018. This led to the introduction of the E-Health Card, which has since been expanded to gather, process and use medical data. The German Digital Healthcare Act, introduced in 2019, further expanded digital health benefits by allowing doctors to prescribe and be reimbursed for digital health apps. On the whole, both countries exhibit a general tendency to utilise digital technologies in order to enhance the delivery of healthcare services to their citizens, as well as to demonstrate a strong commitment to embracing the benefits of digitalization within the healthcare sector.

Methodology

This paper aims to explore the design of digital telehealth systems for outpatient and ambulatory care, with a specific focus on the institutional frameworks in India and Germany. The research will concentrate on government interventions and public policies, rather than market or private players. It will examine the legal frameworks and policy interventions that both nations have implemented to develop national telemedicine/telehealth structures. The methodology will involve a descriptive and qualitative review of relevant government policies and legal frameworks that have been introduced to facilitate telemedicine development. Additionally, a comparative analysis of telemedicine frameworks in India and Germany will be conducted to identify lessons that can be learned from each country's experiences. The research will utilise both qualitative and quantitative data, such as government reports, research findings, and expert opinions, to provide a comprehensive analysis of the telemedicine frameworks in India and Germany.

Dissecting Telemedicine as an element of Digital Health Systems

Across the world, digital health systems commonly integrate telemedicine as a key component to enhance patient outcomes, optimise healthcare delivery, and lower costs. It is a broader application of technologies to transmit information and other applications wherein electronic communications and information technologies are used to support health-care services. According to WHO telemedicine is, "the delivery of health-care services where distance is 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 disease and injuries all in the interests of advancing the health of individuals and their communities". Critical to

³ For a comprehensive understanding, check this article, "*E-Health Law in Germany*" by Dr. Wolfgang Rehm and Diana Heimhalt

the definition are certain intrinsic components that mark the functional domain of telemedicine.

A clear dissection of telemedicine operations for better componential analysis can be seen in Figure 1, but for the purpose of this paper the three key functional patterns of telemedicine are listed below:

- Remote patient monitoring: Also known as telemonitoring, involves the use of Internet of Medical Things (IoMT) to monitor a patient's condition digitally.
- Synchronous digital care: The process involves interaction between medical professionals, or between doctors and patients, with the aim of treating patients who may not have timely access to specialist care.
- Asynchronous digital care: Remote storage and transmission of health data and images are performed, usually for non-urgent cases, where a health specialist reviews the data at a later time. This type of telemedicine is frequently employed in specialties such as dermatology and radiology.

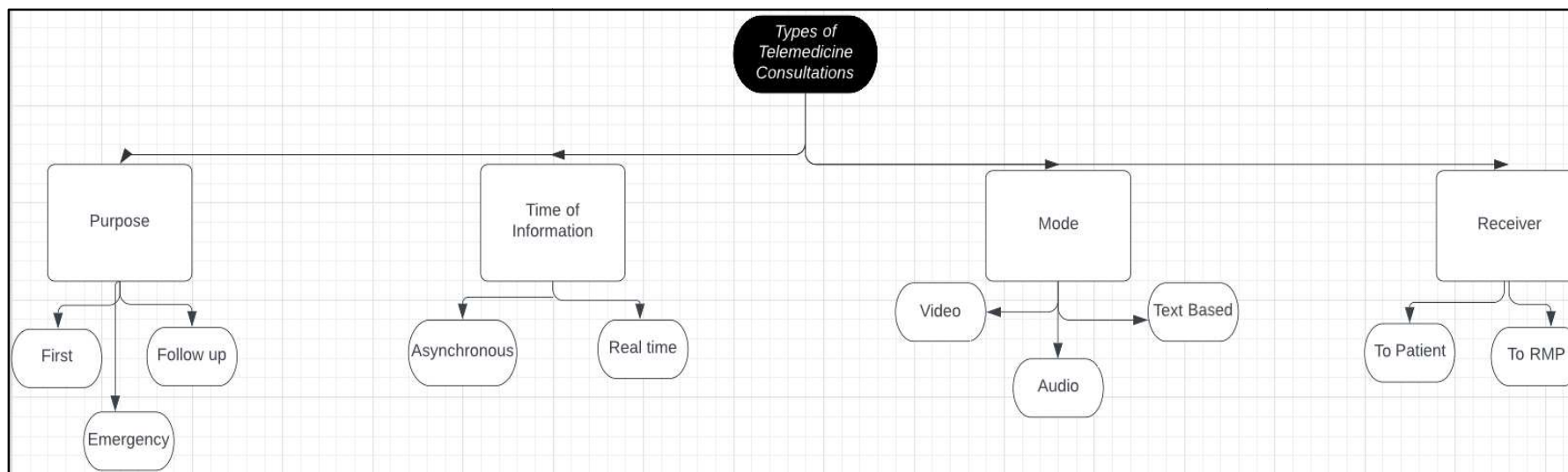


Figure 1: Components/Types of Telemedicine Consultations

Source: Author, Indian Telemedicine Practice Guidelines (2020)

While these components are essential for the effective functioning of the system, there are certain precursors that influence the development and advancement of this system. A careful analysis of WHO’s recent Consolidated Telemedicine Implementation Guidelines (2022) show six key system benchmarks every national telemedicine healthcare infrastructure must take into account in order to create an effective and well functioning telemedicine system. These are represented in Figure 2.

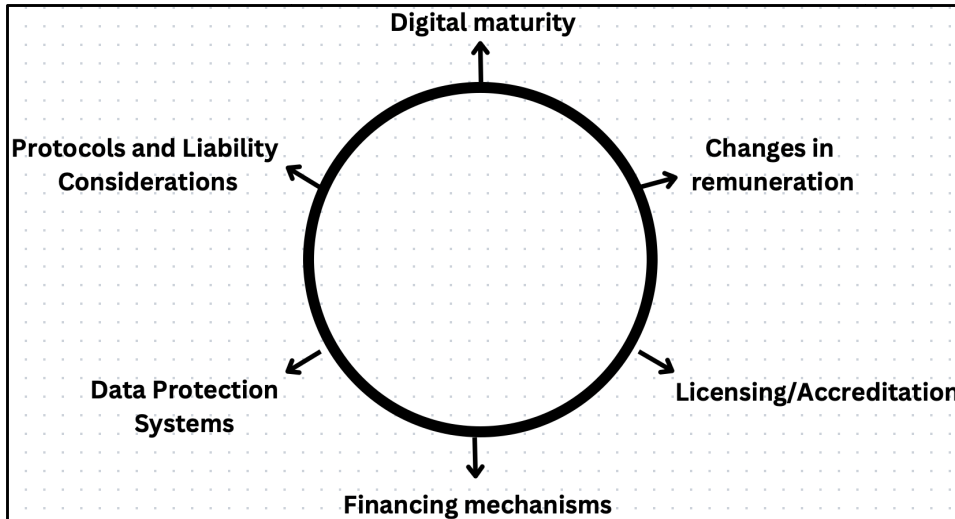


Figure 2: Six Key Telemedicine System Antecedents

Source: Author, WHO Consolidated Telemedicine Implementation Guide (2022)

These antecedents are situated at a crucial juncture, aiding in the evaluation of telehealth systems as a whole and enabling comparative analyses of systems and countries. During the discussion phase, they will be utilised to gain a better understanding.

Socio-economic Profile - Understanding the context

Telemedicine has emerged as a valuable tool for improving access to healthcare services, particularly in rural areas. The adoption of telemedicine, however, is influenced by several factors, including the rural-urban population, digital divide, age demographics, per capita income, and healthcare systems. Therefore, before delving into a comparative analysis of the telemedicine system in Germany and India, certain context specific metrics need to be understood for a better judgement.

Firstly, Germany has a predominantly urban population, with 75% of the population residing in urban areas. In contrast, India has a predominantly rural population, with 65% of the population residing in rural areas.⁴ This demographic difference has implications for the adoption and implementation of telemedicine, as rural areas are often underserved by traditional healthcare systems. This pools into another fact that Germany has a low digital divide, with 90.3% internet penetration, which facilitates the widespread adoption of telemedicine. In contrast, India has a high digital divide, with only 34.4% internet penetration in rural areas, hindering the adoption of telemedicine in remote and underserved areas.⁵

Additionally, Germany also has a significantly higher old age population, with 22% of the population aged 65 or above, compared to India, which has a lower old age

⁴ Data from World Bank projections

⁵ India’s data was taken from the Centre for Monitoring Indian Economy Pvt. Ltd, while Germany’s data was extracted from DataReportal’s Digital 2023 Report (both are private organisations using third party sources)

population of only 7%.⁶ This demographic difference has implications for the adoption of telemedicine, as the elderly are often the most in need of healthcare services and may require specialised telemedicine solutions.

In case of income, Germany has a higher per capita income, with an average of \$51,203.6 in 2021, while India has a lower per capita income of \$2,256.6 in 2021. This difference in income has implications for the affordability and accessibility of telemedicine services, as lower-income individuals may be less likely to have access to healthcare services, including telemedicine.

Both Germany and India have a high share of private outpatient care, which has implications for the adoption of telemedicine. Private outpatient care providers may be more likely to adopt telemedicine solutions, given the potential cost savings and efficiencies associated with remote care delivery.

Most importantly, the telemedicine market size in Germany is currently estimated at US \$6.87 billion, while in India, the market size is significantly smaller at US \$830 million.⁷ This difference in market size reflects the difference in the adoption and implementation of telemedicine in the two countries.

Understanding the frameworks

India

The Indian government has put in place several acts, policies, and guidelines to regulate the practice of telemedicine. The National Medical Commission Act, 2019, and the Telemedicine Practice Guidelines issued under the Medical Council of India code provide a legal framework for the practice of telemedicine in India. While The Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 regulate the prescribing and dispensing of drugs, the Information Technology Act, 2000, the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011, and the Information Technology (Intermediaries Guidelines) Rules 2011, provide a regulatory framework for data privacy and security in telemedicine. Other Service Provider Regulations under the New Telecom Policy 1999 and the Telecom Commercial Communication Customer Preference Regulations, 2018, regulate the use of telecommunication technology for telemedicine.

The Ayushman Bharat Digital Mission and National Health Stack are two key initiatives by the Indian government to boost digital healthcare infrastructure in India, thereby also influencing the telemedicine domain. The National Digital Health Mission aims to create a national digital health ecosystem, enabling access to health services anytime, anywhere, and on-demand. The National Health Stack provides a framework for the standardisation of health data, digital health infrastructure, and digital health services.

The National Telemedicine Service is a key initiative by the Indian government, comprising two variants of eSanjeevani. The eSanjeevani Ayushman Bharat-Health

⁶ Data from World Bank projections

⁷ Data extracted from Statista

and Wellness Centre is a doctor-to-doctor telemedicine platform based on the hub-and-spoke model. It is being implemented at Health & Wellness Centres under the Ayushman Bharat Scheme and is operational at 1,55,000 Health & Wellness Centres across India from December 2022. The second one, eSanjeevaniOPD is a patient-to-doctor telemedicine platform that provides outpatient services to citizens in the confines of their homes. It was rolled out on 13th April 2020 during the first lockdown in the country when all the OPDs were closed. With over 250 onlineOPDs set up on the platform, more than 220 of these online OPDs are specialist OPDs, and the rest are general OPDs.

Although the Medical Council of India (MCI) issued guidelines on telemedicine in 2003, recognizing the potential of telemedicine to provide healthcare services to remote areas, telemedicine did not witness much adoption till Covid-19. It remained primarily as an elite service being provided by the private sector. Through Ayushman Bharat, the government has instilled a goal-oriented, policy-led push to the domain that has boosted its uptake.

Germany

In Germany, the institutional setup of telemedicine involves several key stakeholders, including government bodies, professional associations, and private companies. The Federal Ministry of Health is responsible for health policy in Germany and sets the legal and regulatory framework for telemedicine and other digital health services. The National Association of Statutory Health Insurance Physicians and the German Medical Association develop guidelines and quality standards for telemedicine services provided by doctors, while the National Association of Statutory Health Insurance Funds negotiates with healthcare providers on behalf of the insurance funds and sets reimbursement rates for telemedicine services.

The Digital Health Innovation Platform (DIP) is a government-funded initiative that aims to promote the development and implementation of digital health solutions in Germany. It provides funding, technical support, and networking opportunities for startups and other innovators working in the digital health space. Private telemedicine providers are also available in Germany, and they offer various telemedicine services subject to the same legal and regulatory framework as traditional healthcare providers.

The legal framework for telemedicine in Germany is based on several laws and regulations that govern the provision of healthcare services and the use of digital technologies. The German Medical Association has established guidelines for telemedicine that cover issues such as data protection, informed consent, and quality assurance. These guidelines are widely respected by healthcare providers and insurers. The Digital Healthcare Act that came into effect in 2020 and introduced important changes to the legal framework for telemedicine in Germany is a legal framework for the reimbursement of telemedicine services by the statutory health insurance system and allowed doctors to provide certain telemedicine services across state lines.

The German Social Code V is the main legal framework for healthcare in Germany. It sets out the rules and regulations for the provision of healthcare services, including telemedicine services. It also establishes the legal framework for reimbursement of healthcare services by the statutory health insurance system. Telemedicine providers

in Germany are subject to strict data protection regulations, including the General Data Protection Regulation (GDPR) and the Federal Data Protection Act. These regulations require healthcare providers to protect patient data and ensure that patients give informed consent to the collection and use of their data.

The telemedicine system in Germany has undergone significant evolution. After getting the first statutory regulation in 2015 to later being generally prohibited, in 2018⁸, telemedicine in Germany does not have an explicit legislative enactment but rather draws its functionary capacity from other legal-policy instruments mentioned above.

Model Analysis

By conducting a model-based analysis of the current system-mechanisms in the telemedicine infrastructures of both countries, it becomes clear that the policy approaches and outlook tangents of the two nations differ.

The Indian telemedicine system (Figure 3) is designed with multiple layers of policy interventions. The top-down planning approach is adopted for policy formation, while the implementation process is a combination of both top-down and bottom-up flow. The system's layered structure flows from the Central government led initiative, the National Digital Health Mission (NDHM) now known as the Ayushman Bharat Digital Mission, at the top of the hierarchy, consisting of two crucial components at the two (provider-patient) ends, namely, the Health Service Registry (delivery end) and the Health Information Exchange (user end). The Ayushman Bharat Digital Mission (ABDM) is primarily aimed at integrating the healthcare ecosystem in India and aligning it towards a more patient-centric focus. The ABDM's primary components concerning telemedicine are the National Health Stack (NHS) (health registries, electronic health records, personal health records) and eSanjeevani (a telemedicine platform).

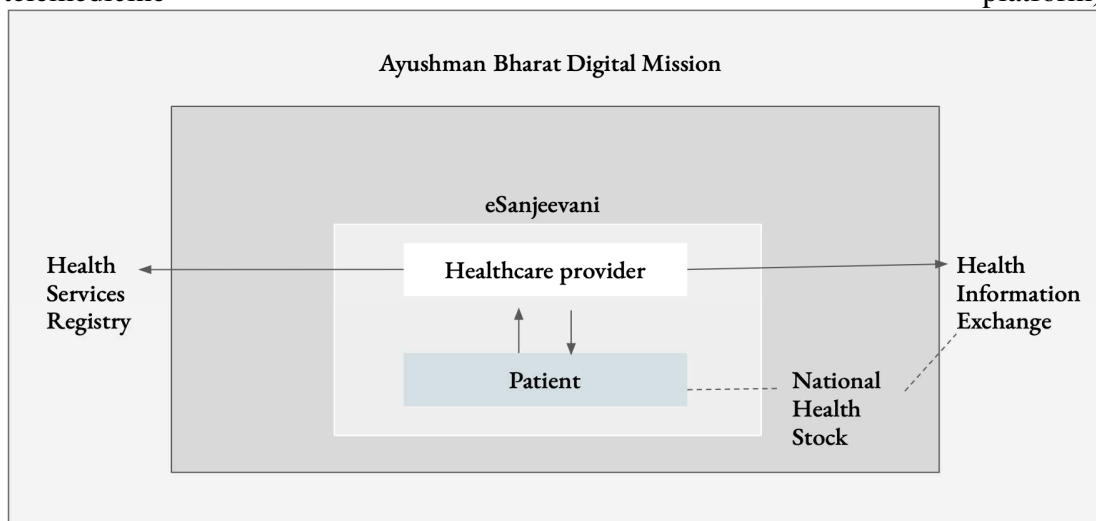


Figure 3: Indian Outpatient Telemedicine System

Source: Author

⁸ The ban was later withdrawn in 2019.

It is noteworthy that the NHS serves as a lever and connector to the foundational building blocks already established and concentrates on research and development of specific applications and services required to enhance healthcare delivery in India. It also merges with the Health Information Exchange framework propagated under the ABDM. The innermost juncture consists of the eSanjeevani policy initiative by the Government of India, based on the hub-and-spoke model and mainly comprising patient-doctor interaction through digital means. Although the Ministry of Health and Family Welfare, Government of India, has implemented it as a centralised system, eSanjeevani is intended to operate in a decentralised manner and can be used by healthcare providers in both the public and private sectors throughout the country.

The Indian telemedicine healthcare system's design is predominantly driven by government funding and policies. The government provides financial assistance to health workers and telemedicine service providers, although private telemedicine healthcare services also exist⁹. The telemedicine public policy design in the Indian setup is somewhat centralised and driven by the Central government's propositions and legislations.

The German telemedicine system (Figure 4) on the other hand is characterised by a unique Public Private Partnership (PPP) model that fosters decentralisation, which is initiated at the legislative level, and adopts liberal market regulations. The government plays a role by establishing a national telematics infrastructure that improves interoperability by mandating E-health cards and digital health registries. However, government's welfare-oriented policy interventions are limited. This decentralisation has led to a system where patients choose telemedicine services, both public and private, based on their preferences.

⁹ Some examples are Tata health, Practo, Apollo telehealth, among many others.

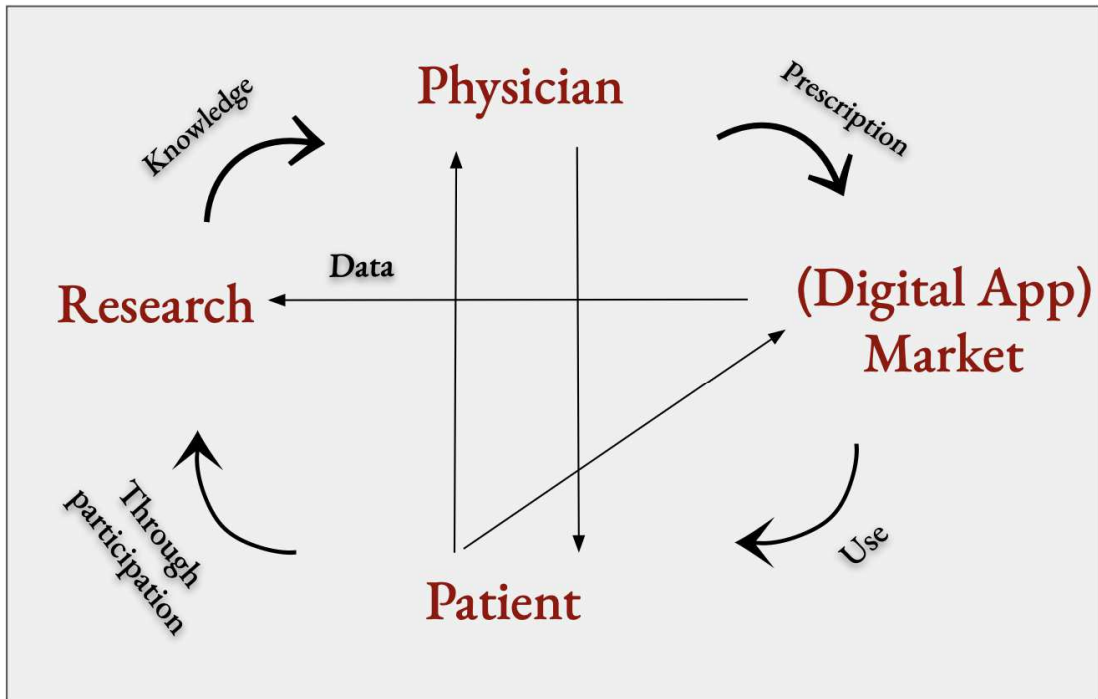


Figure 4: German Outpatient Telemedicine System

Figure 4: German Outpatient Telemedicine System

Source: Author

An interesting aspect of the German telemedicine system is the incorporation of digital apps, which are absent in the Indian telemedicine system. In addition to prescribing medication, healthcare providers may recommend telemedicine digital apps, which patients may then utilise. This creates an opening for patient-centric information to reach the market players, who are then incentivized to perform better through the availability of information¹⁰. This information flows back into the healthcare system, improving knowledge and creating a self-correcting and circular telemedicine system, making the system intrinsically self-sufficient. Furthermore, the public-private partnership model in the German telemedicine system ensures that both the government and private sector contribute to the funding of the system. The government establishes the national telematics infrastructure, while the private sector provides telemedicine services to the patients while getting reimbursed through the statutory health insurance. This combination of funding ensures that the telemedicine system is financially sustainable in the long run.

Discussion

Both India and Germany have implemented telemedicine in their healthcare systems, but each country faces its own challenges and has achieved its own successes. To

¹⁰ Since 2016-2017, doctors have been receiving extra compensation for exchanging electronic medical records with other healthcare providers and for overseeing and evaluating simple insurance claims data via the internet. Going forward, medical practitioners who choose not to partake in the online review of such basic insurance claims information will experience a decrease in their payment.

make a meaningful comparison, it is important to evaluate each country's approach in the context of the six key antecedents established by the World Health Organization mentioned above.

To begin with, India's Telemedicine Practice Guidelines (TPG) only cover registered medical practitioners (RMPs), excluding other healthcare professionals like nurses, dentists, and community health professionals who provide medical advice through telemedicine. Additionally, the TPG does not apply to telemedicine platforms that connect RMPs with patients and hospitals unless the hospital maintains the platform for its RMPs and patients. In contrast, Germany, on similar lines, has implemented recent reforms to fill this caveat and expand the delivery mechanism. For instance, the Patients Data Protection Act, which took effect in October 2020, made ePrescriptions mandatory for physicians, dentists, and clinics. The Digital Supply and Care Modernization Act, passed in 2021, aimed to digitise nursing care. These developments in Germany demonstrate a comprehensive approach to digital healthcare that extends to a wider range of healthcare professionals and entities involved in delivering telemedicine services.

In India, telemedicine services are commonly financed through a variety of government-funded initiatives, private health insurance, and out-of-pocket payments made by patients. On the other hand, Germany's telemedicine system is primarily financed through statutory health insurance contributions, supplemented by incentivized private-market players. Both countries exhibit distinct approaches, with India favouring state-led interventions while Germany focuses on insurance and incentivizing the adoption of healthcare systems. Additionally, both countries are pressing for critical research and development (R&D) of new healthcare technologies, with Germany showing a stronger preference through funding institutionalised research facilities.

India is yet to establish a comprehensive and up-to-date data protection regulation, despite efforts made through the introduction of the Personal Data Protection Bill and the Health Data Management Policy¹¹, which aim to provide legal frameworks for safeguarding personal and health-related data, a fully integrated and comprehensive data protection framework is still lacking in India. In contrast, Germany has implemented strict data protection regulations, such as the General Data Protection Regulation, supported by a well-established infrastructure for data protection and security measures like robust encryption and security protocols.

The licensing and accreditation of healthcare providers in both countries is another critical node affecting quality healthcare delivery. In both India and Germany, this process is overseen by a complex network of regulatory bodies and organisations. In India, the Ministry of Health and Family Welfare is supported by the National Medical Commission and the National Accreditation Board for Hospitals and Healthcare Providers (NABH)¹² to ensure that medical practitioners and healthcare organisations meet rigorous standards of quality. The NABH plays a vital role in accrediting hospitals and healthcare facilities, ensuring that they adhere to strict quality standards. In Germany, the Federal Ministry of Health is supported by the

¹¹The implementation of the policy is a gradual process that involves several stakeholders and requires the development of supporting infrastructure and technologies. As such, it is an ongoing effort, and the full extent of its implementation and impact is yet to be realised.

¹² For more information, see National Patient Safety Implementation Framework (2018-2025)

German Medical Association and the German Institute for Standardization in regulating medical professionals and accrediting healthcare facilities. The German Medical Association oversees the registration and regulation of medical professionals, while the German Institute for Standardization evaluates healthcare facilities against established standards to ensure that they provide safe and effective patient care. Here, India has observed a slight push with the introduction of the National Health Stack that provides another database of healthcare providers, providing a counter-system for checking.

Moreover, the eSanjeevani initiative has been a crucial step towards a more uniform framework for telemedicine services. However, the development of a legal framework for telemedicine in India is still in its early stages, and liability concerns remain a critical issue. In the event of medical negligence, the National Consumer Disputes Redressal Commission has ruled that telemedicine services fall under the purview of the Consumer Protection Act and the Indian Medical Council Regulations. These regulations set out guidelines and standards for telemedicine practice in India.

On the other hand, Germany has an established system of clinical protocols, and its telemedicine services are subject to the same standards of care as traditional healthcare services. Liability concerns are also taken seriously, with healthcare providers required to have professional liability insurance. This requirement ensures that healthcare providers are held accountable for any negligence or malpractice that may occur during the delivery of healthcare services.

Lastly, in India, the Telemedicine Practice Guidelines released by the Ministry of Health and Family Welfare in March 2020 state that health workers providing teleconsultations should be remunerated according to the guidelines issued by the Indian Medical Association or the respective State Medical Councils. In Germany, the remuneration for health workers providing telemedicine services is at the same level as those providing traditional healthcare services, and the German government has passed the Digital Healthcare Act, which provides for the reimbursement of telemedicine services by health insurance companies.

Conclusion

Telemedicine is an innovative solution for delivering healthcare services to people who face difficulties accessing healthcare facilities due to distance or mobility issues. Both India and Germany have adopted policies and regulations to ensure the safety, security, and privacy of telemedicine services. The Indian government has taken several initiatives, including the Ayushman Bharat Digital Mission and the National Health Stack, to develop a national digital health ecosystem. The government-funded National Telemedicine Service, comprising two variants of eSanjeevani, has made significant progress in providing telemedicine services to people in India.

The institutional setup of telemedicine in Germany involves various stakeholders, including the government, professional associations, and private companies. The Federal Ministry of Health, the National Association of Statutory Health Insurance Physicians, and the German Medical Association develop guidelines and quality standards for telemedicine services. The Digital Health Innovation Platform provides funding, technical support, and networking opportunities for startups and innovators

in the digital health space. The legal framework for telemedicine in Germany is based on several laws and regulations that govern the provision of healthcare services and the use of digital technologies, including the German Social Code V, the Digital Healthcare Act, and data protection regulations.

In conclusion, both India and Germany have recognised the potential of telemedicine and have established legal and regulatory frameworks to promote its growth. The Indian government has taken significant initiatives to develop a national digital health ecosystem, while Germany has a robust institutional setup for telemedicine, involving various stakeholders. The success of telemedicine in both countries depends on the effectiveness of these policies and regulations, the quality of services provided, and the ability to ensure the safety, security, and privacy of patients' data. As technology continues to advance, telemedicine is expected to become an essential tool for delivering healthcare services globally, and policymakers will need to continue to develop and refine policies and regulations to ensure its effective implementation.

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