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REVIEW ARTICLE **OPEN ACCESS**

Telemedicine: A Regulatory Framework and Regulatory Impediments to Telehealth Prior to and After Covid-19

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ABSTRACT
The purpose of this study is to elucidate the importance of telemedicine, regulations in India and United States of America (USA) and as well as to compare the telehealth regulatory obstacles prior to and after COVID-19. Years ago, telemedicine was thought to be futuristic and experimental, but it is now a reality. With technological advancements, telemedicine solutions are now more easily accessible and more relatively inexpensive. Telemedicine was only in use in the USA starting in the 19th century, but the Indian Ministry of Health and Family Welfare and Indian Space Research Organisation (ISRO) Department of Information and Technologies made efforts to make it possible. The primary governing body for telemedicine is American Telemedicine Association, and each state has its own set of rules. Early in the COVID-19 Pandemic, the utilization of telemedicine increased as patients and healthcare professionals looked for secure means to receive and deliver care. Despite a variety of clinical and operational challenges, telehealth's mainstream adoption has been hampered by a number of legal and regulatory obstacles. The goal of telemedicine developments should not be the complete digitization of the healthcare system, but rather the technology usage to improve areas that may not be operating to reach their potential.
Keywords: *Telemedicine, Telehealth, COVID-19, Healthcare system, Regulatory barriers*

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INTRODUCTION

The term "telemedicine" was first used in the early 1970s [1]. Telemedicine is derived from Greek word "tele" and Latin word "mederi". "Tele" denotes distance, while "mederi" denotes healing. Its broad meaning is "Healing at a distance." Telemedicine is the delivery and support of healthcare services over long distances using electronic information and communication technology. People all throughout the world battle to get fast, excellent specialty healthcare because of where they live—rural and remote places in particular. The potential of telemedicine to bridge this gap and increase access to health services in the rural areas [2].

TYPES OF TELEMEDICINE

Store-and-forward telemedicine, Real-time interactive telemedicine and Remote patient monitoring are all services provided by telemedicine providers to address a variety of health conditions [3].

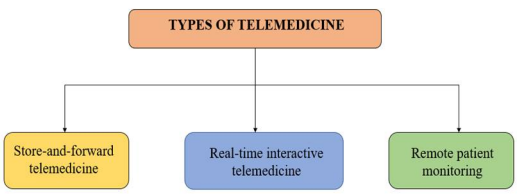

Figure 1: Types of Telemedicine

STORE-AND-FORWARD TELEMEDICINE

The requirement for a doctor and patient to interact face-to-face is eliminated with store-and-forward telemedicine. Instead, after being obtained from the patient, information about the patient, such as biosignals or medical images, can be provided to the professional as needed. Dermatology, radiography, and pathology are all medical specialties where this technique is widespread [4].

II. REAL-TIME INTERACTIVE TELEMEDICINE

Real-time telemedicine, often known as live telemedicine, makes it simple to conduct a doctor-patient visit whenever and wherever. Any two-way communication that enables doctors and patients to speak to one another in real time, such as video conferences and phone consultations, is referred to as live telemedicine [5].

III.REMOTE MONITORING

It is also referred to as self-testing or self-monitoring. Remote monitoring, which enables patients to self-monitor their health using a range of technology equipment that can measure and record vital signs, is another crucial and widely utilised form of telemedicine [6].

BENEFITS OF TELEMEDICINE

- Ease and efficiency
- Prevention and Control of infectious illnesses
- Enhanced Examination
- General medical care and treatment of long-term illnesses [7]

Although they have different definitions, telehealth and telemedicine are phrases that can be used interchangeably. The use of electronic communications to transmit medical data from one location to another with the goal of enhancing patient health is known as telehealth [8].

MATERIAL AND METHODS

This is study, where effort has been made to study, regulations of telemedicine in India and United states and the regulatory environment of telehealth before and after COVID-19. In this comparative study, primary and secondary sources of data have been referred to which include the following:

- Journal Articles published in peer-reviewed publications
- Websites of regulatory agencies and organizations
- Guidelines and guidance documents issued by the regulatory authorities of the countries included in the study.

RESULTS AND DISCUSSION

TELEMEDICINE IN INDIA

The introduction of Telemedicine was the result of collaboration between ISRO, the Department of Information and Technology, the Ministry of Foreign Affairs, and the Ministries of Health and Family Welfare. In 2001, ISRO connected the Apollo Chennai hospital to the Apollo rural hospital in Andhra Pradesh, enabling the use of telemedicine in India. Telemedicine flourished and helped millions of individuals across the nation during the Covid-19 outbreak. By 2025, the telemedicine market will be worth more than $5.4 billion [1].

In India, there were no formal telemedicine regulations until 2019. The 2019 Coronavirus Disease (COVID-19) has significantly increased the use of telemedicine in India. The Indian government has also begun offering its telemedicine service, known as eSanjeevani (National TeleConsultation Service, Ministry of Health and Family Welfare, 2020). The national teleconsultation portal for the Indian government on the internet is called eSanjeevani. On April 13, 2020, the government launched eSanjeevaniOPD during the initial lockdown (Press Information Bureau, Government of India, 2021). The Board of Governors, which replaced the Medical Council of India, has developed guidelines in conjunction with National Institution for Transforming India (NITI) Aayog. In order to allow (Registered Medical Practitioner) RMPs to consult via telemedicine in accordance with the telemedicine practise 2020 standards in Appendix 5, clause 3.8 was added to the Indian Medical Council's code of conduct (Professional Conduct, Etiquette and Ethics Regulation, 2002). The 2002 regulations already include four appendices, therefore "Appendix 5" is added to include the "Telemedicine Practice Guidelines"[9].

GUIDELINES

All telemedicine consultations should follow the expertise of a licenced medical professional: If a digital consult is sufficient or a physical examination is necessary, an RMP is in a good position to make that decision. Practitioner must use good judgement and never cut corners with patient care.

Registered Medical Practitioner:

An individual who is listed in the State Medical Register or the Indian Medical Register in accordance with the Indian Medical Council Act 1956 is referred to as a Registered Medical Practitioner (RMP).

Prior to starting any telemedicine appointment, seven factors must be taken into account.

1.Telemedicine should be suitable and appropriate for the context

- In order to determine whether an in-person consultation or a telemedicine consultation is necessary in a particular circumstance for the benefit of the patient, Registered Medical Practitioners should use their professional judgement. Before deciding to continue with any type of health-related instruction, counselling, or medical care, they must take into account the modes/technologies available and their suitability for a diagnosis.
- **The Difficulty level of the condition of the patient:** The scenario and the health issue of all patients is unique; therefore, someone who is new to treatment can convey about the complaints like headache, vomiting etc. in contrast to a diabetic patient who has previously sought care might visit with an emergency like diabetic ketoacidosis. Under the inherent constraints of telemedicine, the RMP must maintain the same standard of care as face-to-face sessions.

2. The recognition of the patient and the licenced physician is necessary

- The client and the RMP must be able to identify one another during a telemedicine consultation.
- A RMP ought to authenticate the details of the patient. The RMP needs to make sure that a patient can examine the qualifications and information about how to reach.
- The State Medical Council's or MCI's assigned registration number must be shown by every RMP on all prescriptions, websites, electronic communications and the bills which are provided to those who are ill.

3.Telemedicine approach

- There are primarily 3 approaches: text, audio, and video (chat, images, messaging, email, fax etc.). The RMP needs to take into account their advantages, drawbacks, and suitability.

Table 1.Communication Models: Strengths and Limitations [10]

Mode	Strengths	Limitations
Video: Facetime, apps, video chat platforms, telemedicine facilities, etc.	• Closest to a real-time, in-person consultation • Easier to identify patients • RMP can observe the patient and speak with the carer	• Requires a high-quality internet connection on both sides, failing which will result in a less than ideal flow of information.
Audio from phones, VOIP, apps, etc.	• Appropriate and quick • Unrestricted reach • No additional infrastructure is needed • Privacy is guaranteed	• Nonverbal signs could be overlooked. • Not appropriate for circumstances that call for a visual check (such as a skin, eye, or tongue examination) or physical contact
Telemedicine based on text: Specialist chat-based telemedicine using smartphones, SMS, websites, and messaging apps like WhatsApp, Google Hangouts, and Facebook Messenger.	• Efficient and speedy • Documentation and identification could be a crucial component of the platform. • If RMP contains enough context from other sources, it can be used for urgent instances, follow-ups, or second opinions.	• Beyond the visual and tactile clues, vocal cues are also lost in text-based encounters. • Establishing rapport with the patient is challenging.
ASYNCHRONOUS: Email Fax, recordings etc	• Convenient and simple to record • No specific download or app is needed. • Pictures, data, and reports can be easily shared	• Non-real-time interaction means that only one-way context is available, relying solely on the patient's articulation

4.Consent of Patient

Any telemedicine consultation must have the patient's agreement. In the following circumstances, the consent may be implied or express:

- The permission is assumed if the patient requests a telemedicine consultation.
- If a healthcare professional, RMP, or carer requests a consultation through telemedicine, an explicit patient agreement is required.

Information Exchange for Patient rating

Before making any professional decisions, RMPs must make every attempt to compile adequate medical data about the patient's condition.

Details pertaining to the patient

- In order to be able to make an informed clinical decision, an RMP must have access

to the specific and necessary medical information pertaining to the patients.

- Any information supported by technology-based tools and conversations with healthcare professionals/providers can be used to complement this knowledge.
- The RMP has the right to ask the patient for more information if they feel that the information provided is insufficient. Depending on the nature of the material, it may be communicated immediately or later via email or text. For instance, an RMP can suggest to the patient undergoing various laboratory or radiographic testing. In such cases, the consultation may be deemed paused and continued at the new time. At any moment, an RMP may offer appropriate health education.

5.Consultation types: Original consultation/Follow-up consultation

The first and the follow-up are the two different kinds of patient consultations. When a patient requests a teleconsultation for the first time without having previously had an in-person consultation, an RMP might only have a basic understanding of the patient.

First Consult denotes that

- The patient is seeing the RMP for the initial time, or
- The patient has previously seen the RMP but it has been more than six months since that appointment, or
- The patient has seen the RMP in the past yet, for a separate health concern.

Follow-Up Consult(s) indicates

•Within six months of their prior in-person meeting, the patient has another consultation with the same RMP regarding the same health issue.

But it won't be regarded if: There are significant signs that aren't related to the same medical problem; and/or RMP can't remember the details of prior treatment and counsel.

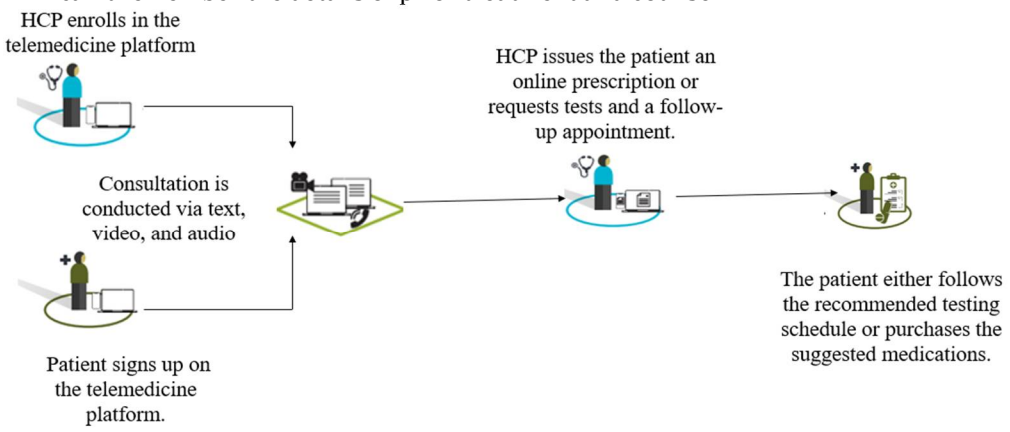

Figure 2: Consultation over Telemedicine Platform

6.Managing patients: Health information, Counseling, and Medication

- Based on the type of consultation, if disease being effectively handled by means of telemedicine, the RMP may exercise their expert judgement in order to:
  - Give Health instructions as applicable in instance;
  - Offer Counseling linked to particular clinical issue; and/or
  - Recommend Medications.
- **Health Education:** An RMP may convey lessons about disease prevention and health promotion. They might be connected to a person's nutrition, level of exercise, decision to stop smoking, infectious diseases, and other factors.
- **Counseling:** This is detailed guidance offered to the patients, such as dietary limitations, instructions for a patient taking chemotherapy for cancer, correct hearing aid use, at-home physical therapy, etc. to lessen the underlying ailment.
- **Prescription of Drugs:** The RMP has the authority to prescribe drugs via telemedicine consultation. The typical in-person consult still requires the same level of professional accountability. The same general idea will apply to a telemedicine consult in cases where a medical

issue calls for a specific procedure for diagnosis and prescription, similar to a face-to-face consultation.

Specific limitations

Depending on the type of consultation and the form of consultation, there are several restrictions on the prescribing of medications on consultation via telemedicine. The types of medications which can be given through teleconsultation shall be announced after periodic interaction with the Central Government.

Listing Group	Approach to consultation [Video/Audio/Text]	Type of Consultation [First-consultation/ Follow-up]	List of Medications
O	Any	Any	List O
A	Video	First Consultation Follow-up, for continuation of medications	List A
B	Any	Follow-up	List B
Prohibited	Not to be prescribed	Not to be prescribed	Any drug or substance listed under Drug and Cosmetic Act's Schedule X, as well as the Narcotic Drugs and Psychotropic Substances Act of 1985

Table 2: Drug lists that are permitted based on the nature and method of consultation[10]

7.RMP Duties and Responsibilities

Medical morals, data confidentiality, and privacy

- Standards of medical ethics, such as expert standards for preserving patient confidentiality and privacy in accordance with the Indian Medical Council (IMC) Act, will be obligatory and must be followed.
- Registered Medical Practitioners must fully abide by the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, as well as for handling and transferring the private data about the individual's health. This must be done and is mandatory.
- If there is reasonable evidence to infer that a technology security breach or someone other than an RMP was the cause of the patient's privacy and confidentiality being violated, then Registered Medical Practitioners won't be held accountable for the confidentiality violation. The RMPs ought to guarantee that an appropriate level of care is used when engaging such services.
- Misconduct: In addition to the broad obligations according to the MCI Act's provisions for morality, ethics, etc., it is particularly stated that while utilizing telemedicine, all actions that willfully jeopardize patient care, privacy and confidentiality, or break any applicable laws are expressly prohibited.
- Penalties: In accordance with IMC Act, ethics, and other applicable laws [10].

TELEMEDICINE IN THE UNITED STATES

Telemedicine had a long history in the US. One of the earliest telemedicine applications in the United States was created in the year 1960 by National Aeronautics and Space Association (NASA). In the course of Project Mercury, healthcare professionals kept an eye on the astronauts. [11].

American Telemedicine Association is responsible for overseeing telemedicine in the USA. The ATA is in charge of creating the rules for telemedicine in the USA. The ATA takes telemedicine and telehealth into account simultaneously. State and federal laws must be followed by the practitioner. In America, only a few states restrict the utilization of telemedicine to issue prescriptions for restricted drugs, and only a smaller number of states permit telemedicine under specific conditions. The United States has advanced due to the fact that medical boards in numerous states now offer standards for both practitioners and patients inside the state. The American Telemedicine Association and the Federation of State Medical Boards are the two main organizations involved in telemedicine.

The RMP is allowed to offer the advice and assistance in other jurisdictions where he is not authorized through the program known as cross-state licensing. The licensing authorities also concur to formally recognize the laws and procedures of a licensee's home state under a system known as mutual recognition. Recently, numerous state boards have been attempting to standardize the requirements. Online In accordance with state legislation in the state where the practitioner is registered, prescriptions for controlled medications, chronic pain, and specific diseases are permitted. In certain cases, the beginning of telemedicine involved an on-site medical examination proceeded by a distant communication because the doctor-client relationship is crucial to a successful therapy. In the USA, obtaining the patient's consent before counselling is absolutely necessary, and the process for obtaining consent differs between states.

Almost all states obtain authorization in writing, with the use of audiovisual techniques permitted under specific circumstances [1].

In USFDA Telemedicine and Telehealth services comes under 42 CFR § 410.78. Title 42 represents the public health. It consists of 5 chapters. Part 410(Supplementary Medical Insurance Benefits) comes under the Subchapter B (Medicare Program) of Chapter IV (Centers for Medicare and Medicaid Services, Department of Health and Human Services) [12].

Health Insurance Portability and Accountability Act

A US legislation known as the Health Insurance Portability and Accountability Act,1996 (HIPAA) provides the protection and confidentiality with regard to health information. With the establishment of industry-wide standards for healthcare data on electronic billing and other processes, it seeks to end healthcare fraud and abuse. Also, critical patient health information must be protected and processed securely. This is handled by the privacy rule and the security rule, and it is crucial in telemedicine.

Medicare Program

The Medicare Program covers some people with qualifying limitations as well as US seniors 65 and older. The current restrictions hinder the widespread adoption and use of e-health and set a precedent for other large commercial insurers, despite exceptions to Medicare's Telemedicine Payment Policy. In 2017, the United States Senate considered the Creating Opportunities Now for Required and Effective Care Technology (CONNECT) for Health Act, but nothing came of it [13].

The Coronavirus Aid, Relief, and Economic Security Act (CARES ACT)

The Coronavirus Aid, Relief, and Economic Security Act (CARES), stimulus of $2 trillion package, was approved by a US Congress in the month of March 2020 in an effort to mitigate the economic harm caused by the global coronavirus pandemic [14].

States each have their own laws regarding:

1.Acceptable telehealth modalities
2.Who is qualified to offer telehealth services in the medical field and under what conditions
3.Establishing new patient-provider connections
4.Whether and how prescriptions for medicines can be made
5.Whether medical professionals from another state can treat patients without having a complete in-state licensure
6.How non-federal insurance companies pay for telehealth [15].

Prior to March 20	Following the CARES Act and the CMS 1135 Waiver
Who is qualified to provide and receive telehealth?	
Only a few authorised providers	For Medicare services, any sort of clinician may submit a claim.
Patients and providers that are already acquainted	There won't need to be any prior connections.
Where is telehealth possible?	
Exclusively at specific locations (i.e., designated rural areas, certain medical facilities)	Any location, including a patient's home, can be the starting point and location of telehealth.
Telehealth services must be provided by doctors from their offices.	Doctors can practise telehealth from home.
Cross-state telehealth may not be possible.	Patients in other states can now receive telehealth services (state-specific restrictions may still apply)
What is required for telehealth consultations	
Audio-visual is required (i.e., video technology)	There are two options: audio-visual AND audio-only.
Licensed technology platforms only	Platforms that are more widely accepted, such as FaceTime, Skype, and Zoom
How telehealth services are paid for	
Visits for telehealth are subject to Medicare coinsurance and deductibles.	For telehealth programmes funded by federal programmes, providers may not be required to share any expenses.
Payments for telehealth services are less than those for in-person services.	All telehealth appointments, even audio-only ones, will be paid for just like in-person appointments.

Table 3: Comparison of telehealth regulations from the Centres for Medicare & Medicaid Services before and after March 2020[16]

BARRIERS GENERAL TO TELEHEALTH ADOPTION PRIOR TO COVID-19

Prior to the coronavirus pandemic, there were substantial barriers in the path of people who wanted to employ telehealth services. Health disparities between urban and rural areas outlined a number of obstacles, including cost and payment rules, licencing requirements, equipment problems, incompatibility with electronic health records, and limitations in rural connectivity [17].

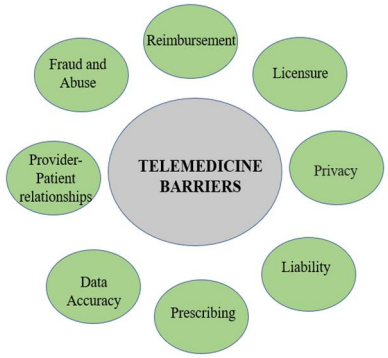

Figure 3: Barriers to Telehealth

TELEHEALTH AFTER COVID 19

1.Reimbursement

(i)Rates and Conditions for Medicare Reimbursement

Before the pandemic, there were a number of important restrictions on Medicare's ability to pay for telehealth services, including restrictions on the services that could be provided, how they could be delivered (including through technology platforms) and who could provide them.

Post-Pandemic Prognostications: Providers need to make sure they adhere to their compliance plans and meticulously record the services they offer.

(ii)Rates and Conditions for Medicaid Reimbursement

States have a lot of freedom when it comes to deciding whether to fund telehealth under Medicaid, how it will be delivered, what platforms can be utilised for technology, what kinds of telehealth facilities are permitted, and what kinds of professionals can provide those services.

Post-Pandemic Prognostications:

Similar to Medicare, short-term Medicaid adjustments could provide an unexpected exploratory function that eventually results in changes being implemented permanently in some capacity once the pandemic is over. States may have different laws governing such developments, so telehealth providers should keep an eye on any potential modifications to Medicaid rules to guarantee continued compliance.

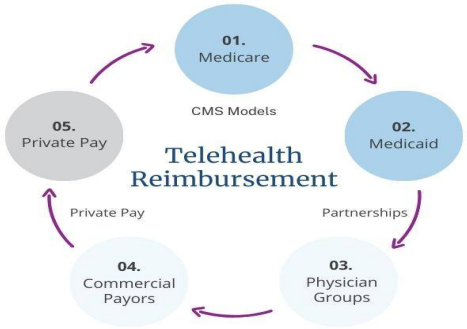

Figure 4: Reimbursement Proposals

2.Licenses for practitioners

The guidelines set forth by the relevant licensing board(s) for professionals offering telehealth services, must be followed by telemedicine service providers to confirm the legality of their telehealth procedures.

Post-Pandemic Prognostications: Increased practitioner licence portability may occur temporarily in some jurisdictions during the pandemic, but it's also probable that it will happen gradually over time and permanently, especially if more states join different licencing compacts. Organisations engaged within the telehealth must undertake action to make sure they continue to comply with state licencing regulations that may change in the future.

3.Data Protection

Post-Pandemic Prognostications: Following the crisis, organisations and business partners engaged must make sure they have followed with all HIPAA requirements before engaging in telehealth engagements.

4.Malpractice

Cases involving telemedicine malpractice have little prior history. Because of this, some malpractice insurance policies may not cover telemedicine services. Hawaii is one state that mandates that malpractice insurers provide coverage for telemedicine services, but the majority of states do not. Also, not all malpractice insurance policies will pay for services rendered in another state.

Post-Pandemic Prognostications: Similar to in-person services, the exposure to malpractice for telemedicine is going to differ depending on the assistance given and the methods that suppliers employ to manage risk. Despite the fact that there is currently little precedence for misconduct in telehealth claims, which is anticipated to progressively alter as telehealth adoption spreads, both in terms of total use and the range of service types offered.

5.Prescription

Federal and state law frequently place additional restrictions on prescribing in a telemedicine context, in addition to the broad prescribing guidelines provided by practitioner licensure laws. The location of the patient, the degree to which a doctor-patient relationship has been sufficiently developed, the existence of an emergency are among the factors.

Post-Pandemic Prognostications: It is anticipated that the reasonable limitations on the prescription of controlled medications in a telemedicine context will remain largely in place. To expand on and foster telemedicine as a means to tackle opioid crisis comprehensively, limitations that prevent the telehealth's application in treatment for an opiate use disorder are anticipated to gradually resolve in the upcoming years.

6.Interchange of electronic data and data security

The specific guidelines (ONC Regulations) governing interchangeability, censoring of information and improved data accessibility for patients were issued by the Office of the National Coordinator (ONC) for Health Information Technology (ONC) on May 1, 2020.

Post-Pandemic Prognostications: Providers of telehealth services should be ready to communicate information in a secure way that meets with information blocking restrictions. The need for telehealth platforms is expected to endure even after the crisis has passed as doctors and patients grow accustomed enhance the comfort and further advantages of some types of distant activities.

7.Patients' Informed Consent

Connecticut is one of the states that has legal patient approval rules which are specific to remote health care. However, several states, like Florida, have legal patient approval regulations which are applicable to all medical accommodations in general.

Post-Pandemic Prognostications: When getting patient consent for telehealth services as opposed to in-person treatments, there are particular factors to take into account. After the epidemic, providers should review the forms and procedures they had temporarily implemented.

8.Credentialing:

In order to employ specialists working part-time, accreditation telehealth is a practical solution for healthcare practitioners with constrained resources. The governmental actions enable some categories of service providers to accredit by referral according to specific circumstances since the process of obtaining credentials can be economically intensive.

Post-Pandemic Prognostications: As a way to deliver specialised treatment with constrained resources, watch for qualified physicians to continue using credentialing by proxy [18].

CONCLUSION

A modernised version of the healthcare system is telemedicine. The prospects for telemedicine are very positive. It can speed up processes in clinics and hospitals due to its beneficial and efficient characteristics. With advancing technology, telemedicine would become easier to use and more widely accepted in the years to come. While telemedicine originally emerged in India in the early 2000s, it first acquired prominence in USA in the nineteenth century. The USA has advanced its standards significantly, while India recently received its own regulations. Whereas India adheres to a single regulation, the USA has different rules for each state. Telemedicine utilisation changed dramatically during the pandemic period, and it is now a permanent fixture of the healthcare industry.

Despite the fact that the COVID-19 epidemic has increased barriers to providing healthcare, it has also opened up new possibilities. The COVID-19 epidemic presented telemedicine with a number of challenges with regards to medical confidentiality, the standard of care, doctor credentials and informed consent,

fraud, licences, compensation, clinical incompetence etc., but following COVID-19, the majority of these issues were resolved. The majority of medical treatments may be delivered via telehealth, and the pharmaceutical and information technology industries should work together to make this a huge success by advancing technology for people.

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