Methodology

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Introduction

Telemedicine as a mode of doctor- patient interaction has been in existence for over twenty years in India but its adoption was very minimal and fraught with lack of clarity and governmental recognition [1,2]. The Covid19 pandemic has catapulted Telemedicine from obscurity to almost a mainstream process of consultation once the government has authorized and legalized it through **Telemedicine Practice Guidelines** [15] in March 2020. The announcement of the **National Digital Health Mission** [16] by the Honorable Prime Minister on the Independence Day has paved the way for transformation of the nation through building of a digital health ecosystem. In the new ecosystem, telemedicine is poised to become a major connecting link between the healthcare seeker and the provider right from the unitary level upwards to the most complex care settings.

Tele consultations have a major advantage of being location agnostic for both the doctor and the patient and can be further aided by the use of remote devices for augmenting the data collection that may be required for better diagnosis or further management. Although it is well realized now that telemedicine as a business entity in the hospitals cannot be ignored, the lack of knowledge of the proper and need based selection of a system, implementation of the solutions by the healthcare providers and the confidence building measure required by education of the healthcare workers and the patients is deficient.

In order to bridge this knowledge gap in the healthcare industry regarding available telemedicine solutions in the market; four Organizations viz. Consortium of Accredited Healthcare Organisation (CAHO), Healthcare Information and Management System Society (HIMSS) (India), College of Healthcare Information Management Executives (CHIME), National Resource Centre for EHR Standards (NRCeS) and Digital Health India Association (DHIndia) Association forged an alliance to address this need and arrived at a decision to come up with a registry of Telemedicine solutions available in India.

This project examines telemedicine solutions that aim to meet healthcare needs in India after a thorough technological and suitability demonstration of the solutions]. In the Pre-COVID-19

era, patients were comfortable visiting a doctor for consultation in case of any health related problem; while adoption was tele consultation was limited in India [3]. Post (and with ongoing) COVID-19, it is inadvisable for the patients and doctors to share common physical space for the purpose of consultation, unless it is absolutely essential. Telemedicine platforms attempt to bridge the new and relatively urgent demand in healthcare access and healthcare services resulting from this unique situation [4]. The core purpose of Telemedicine platforms is to enable doctor-patient interactions remotely with the help of digital technologies, facilitated via smart / feature phone, computer and with the help of the Internet [5]. To give a simple example, telemedicine solutions fulfils the need of a patient to consult with a doctor in a virtual environment through a Text/Audio/Video facility. Such consultations can be further aided by the use of remote devices for augmenting the data collection that may be required for better diagnosis or further management. These consultations are location agnostic for both the doctor and the patient. In this registry, we intend to list all products that are available to facilitate telemedicine services, in different care settings and also enable the healthcare provider to choose an appropriate solution suited to their needs. The registry will also be helpful for the technology solution providers in planning and designing their roadmap to fulfil the requirements of the healthcare provider.

1. How we look at the Telemedicine Platform

We examine the features and maturity levels of the different telemedicine solutions and map them for an easy understanding of the provider by adopting a socio-technical systemic view of Telemedicine Platform. Telemedicine Platform is not just a standalone solution, but a component of the larger healthcare ecosystem, i.e. an amalgamation of informational, technical, and infrastructural components, which exhibits a desired behavior [7, 8] and are detailed below.

1.1 Technical Interface

The different aspects that are evaluated are listed below:

- **Scope of Telemedicine services[9]**
    - **Tele Consultation (for patients / caregivers / remote healthcare workers/ Virtual outpatient departments / online Clinics)[10]**

        This includes functionalities to provide support for immediate interaction and communication between the doctor and patient in geographically

separate locations to facilitate diagnosis and treatment. Solution should provide inclusive interaction for the circle of patient care including one-time, follow-up and continuous care. The solutions may provide for **Remote Patient Monitoring** at home by interfacing with devices that may be proprietary or third-party ones (blood sugar monitor, vital signs monitor, Tele ECG, etc.). The remote monitoring features are very helpful for wellness solutions and Healthcare at home for chronic conditions to augment remote diagnostic/therapeutic support and interventions to improve the clinical outcomes.

- **Tele ICU**

   Solutions providing Intensive care support from a command centre to remotely located intensive care units through remote monitoring and real-time audio/video interactions. Design must also support local / bedside caregivers of patients to capture and transmit information with or without device integration.

- **Specialized Teleservices [11]**

   These solutions provide telemedicine services useful for a specific type of health condition or discipline. Services such as Teleradiology, Telecardiology, Telepathology, Telepsychiatry, Health & Wellness etc. are considered in this category.

- **User Interface and Platform**

   Mobile application, web Application, IVR application, website, separate solution /software for recording the consultation or an integrated module of the existing HMIS, etc.

- **Integration**

   Interfaces that allow integration with Proprietary/ Third Party health technologies such as EMR/ EHR / PHR, diagnostic devices, IoT devices, etc.

- **Mode of User Interaction and Communication**

SMS, email, Voice on feature phone, Video chat, remote monitoring through connected medical devices, Chatbot, Multilingual support, Call Centre with trained paramedics

- **UI and UX**

    Workflow of the solution from the end-users perspective (Patient, Doctor, Admin).

1.2 Infrastructure and Policy

- **Type of Business Model**
    - Business to customer
    - Business to Business
    - Business to Business to Customer
    - Business to Government
    - Any Other (combinations of these)

- **Type of consultation & Mode of interaction**
    - Type of Consultation - First Time Visit, Follow-up, Second Opinion, Counselling, Cross Consultation, Multiparty Consultation, Training and Education, etc.
    - Mode - Synchronous and asynchronous

- **Socio-demographic and Socio-cultural factors[12,13]**
    - Affordability, Variable literacy levels, Inclusivity for Specially abled, Multilingual
    - Services for Urban, Semi-Urban, Rural or Remote regions
    - Privacy control in case of consultation use for stigmatized conditions

- **Technical infrastructure requirement[3]**
    - Type of IT Infrastructure required in terms of Hardware and bandwidth for the solution at patient and provider end
- **Mapping of access and privileges [14]**

- Role-based access like administrator, doctor, patient, caregivers, nurse, support staff and dynamic relations between them at the organizational level

1. 3. Informational Processing

- Privacy & Security related policies for Data Storage, Data access Privacy and Data transmission
- Consent management - Consent is expected to be taken for using the platform, for the actual consultative interaction and for use of patient's data for research or any other purposes by the solution provider or the third party.
- Clinical taxonomies, drug database and protocols catering to health specialities
- Health IT Standards and Compliances designed for Telemedicine Solution
    - Telemedicine Practice Guidelines (TPG)[15]
    - National Digital Health Blueprint(NDHB)[16]
- Interoperability Standards for health information exchange
    - HL7 FHIR, LOINC, SNOMED CT, ICD 10 etc.
- IT Security standards to avoid man in middle attack, encryption and secure APIs

2. STAGES OF STUDY

Pilot Phase

Since the need for providing information to stakeholders is urgent (as per the pandemic situation and the quarantine scenario), the first phase of evaluation (pilot phase) was designed using a rapid methodology and quick deployment on the field.

After the learning from the pilot phase and preliminary report, the entire process of collection of data and evaluation has been divided into three stages and each stage contains a number of steps, as shown in figure 1 & figure 2
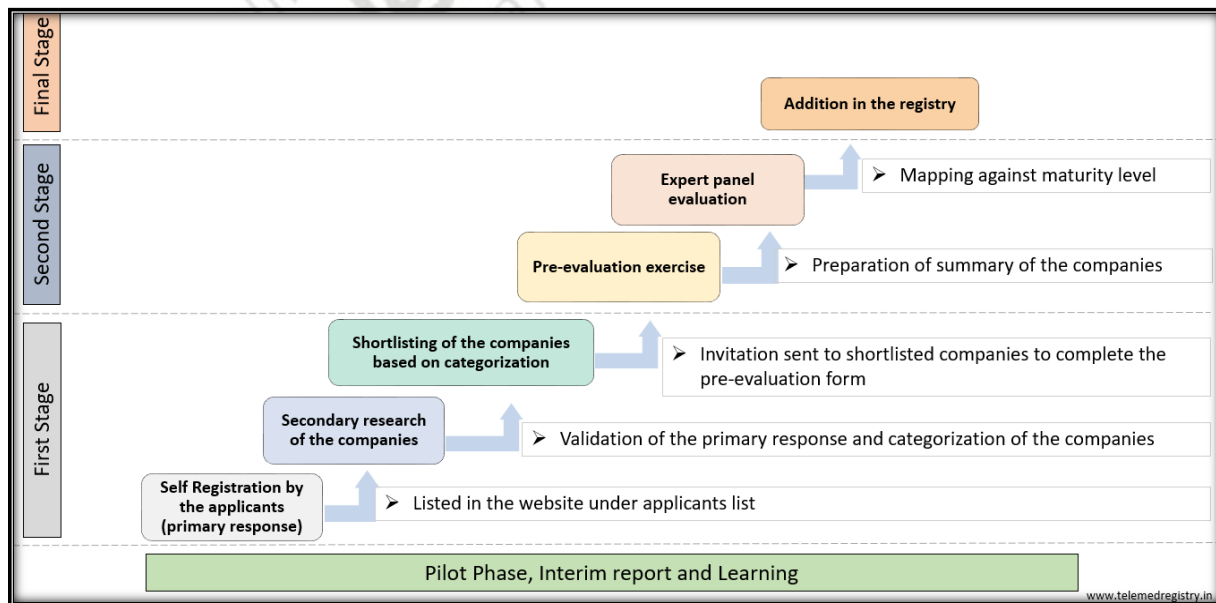
<u>Figure 1</u>

Process for Pilot study

<u>Figure 2</u>

Final Study Design

2.1 Method of Data Collection and Validation

2.1.1 First Stage

2.1.1.1 Application for Registry

A self-reported survey or self-registration form (*primary response form*) is filled by the applicants (telemedicine solution providers). The form is made available on the telemedicine registry website and also on other social media platforms (LinkedIn, Twitter, and Facebook). It is a simple questionnaire that contains questions covering aspects of socio-technological view. The total number of responses collected are displayed under the *'Applicant'* tab on the website.

2.1.1.2 Secondary Research

The primary response of each company is validated by the telemedicine registry team. Secondary research is performed by gathering from the company's website, third party databases like Crunchbase and Google Play Store (for the mobile application)[17].

2.1.1.3 Shortlisting based on categorization

Once the company's responses are validated, they are categorized based on the type of services they provide. The shortlisted companies are then invited for the next stage of evaluation. All the companies that are found unsuitable are not included in the registry but a mail is sent to them for additional clarity before removing them from the list.

Reasons for non-inclusion in the registry

- The product is in the development or pilot phase (these products will be considered in future once they are deployable).
- Incomplete information provided on the website and the initial information on the application form
- Does not fit under the three defined categories *(refer 1.1)*

2.2 Evaluation Process

2.2.1 Second Stage

2.2.1.1 Pre-evaluation Exercise

A pre-evaluation form is sent to the shortlisted companies by email (address provided in the primary response). This form is meant to gather additional details about the company and the product. It is a guided form filling exercise (applicants could also fill it on their own with the help of glossary available on the website), a member from the telemedicine registry team gets in touch with the applicant and provides telephonic guidance to complete the form [18]. Once the form is filled, an online demonstration slot is allotted to the companies depending on the availability of the telemedicine provider and the Expert Panel team.

The pre-evaluation form is a multilayered/branched form and contains a complete list of questions for each category. The form has been prepared after review of the available literature, multiple articles, discussion with experts and our learning from the pilot phase study.

A summary is prepared using the pre-evaluation form and the Secondary research done in the first stage and made available to the expert panels well before the evaluation process

2.2.1.2 Expert Evaluation

The main focus of this step is to examine and evaluate the telemedicine product. A demonstration of the entire product is done by the telemedicine provider. The evaluation process is scheduled for *45 mins* out of which *25-30 mins* is given to the telemedicine provider to demonstrate the product. During the demo, the members of the expert panel can raise any query related to the features of the product. Once the evaluation is completed, the final assessment form is filled by the expert panel.

2.2.2 Method used for the Evaluation process

- **Walkthrough Method**

"A walkthrough method starts with a task analysis that specifies the sequence of steps or actions required by a user to accomplish a task, and the system responses to those actions."[19] The entire expert evaluation process is designed and performed by this method. The walkthrough method uncovers the associations between various components of teleconsultation platforms and makes them available for analysis and also for quantification, but with subjective descriptions [17]. The expert panel evaluates the product on all the three aspects *(Technical Interface, Infrastructure and Policy, Information processing)*. [20]

Things that must be covered during the demonstration by the solution provider include but are not restricted to:

o **Application workflow** from doctor's as well as patient's perspective and also from the administrative point of view focusing on the Technological Interface and Infrastructure with compliance to relevant policies

Workflow at the Patient side involves - Consent, Registration, Doctor Search, Payment, Scheduling, Interaction and Communication.

Workflow at Doctor's side involves - Log In, Interaction and Communication, Recording of Interaction, Diagnosis, ePrescription, Review of the visit, Digital signature/E-signature

Admin Module (if applicable) – Mailing, ePrescription, Booking appointments, Dashboard and Analysis.

o **Data Management**: Data capturing and storing method, compliance to various Healthcare IT standards, protection of patient's privacy and confidentiality and aspects of data security focusing on Information/ data processing.

2.2.3 How do we create an effective and Bias-free expert review?

- Our evaluation team is a multidisciplinary team with domain experts (with no vested interest) from technical and functional fields required to provide an unbiased and effective assessment to all features and complexities of telemedicine solutions. The entire evaluation process and results are discussed with experts from all our alliance partners.

- A complete and anonymized summary of the applicant company is prepared and sent well before to the expert panels. The name of the company is revealed only at the time of evaluation

- After completing the process of evaluation for a particular product, an evaluation form is filled which includes descriptive comments and rating the products on different parameters by using Brainwriting, Consultative process and a Round-Robin brainstorming.

- The experts panel remains constant across the applicants for a given category, in order to reduce observer bias

- There is a panel of experts available for evaluation and the profile of the experts is kept anonymous from the applicants until immediately before the start of the evaluation process.

2.2.4 Mapping against Maturity Level (DCHCN model)

The final report will contain the complete profiles of teleconsultation platforms (solutions) including review summary by the expert panel and their position on the DCHCN maturity level model.

2.3 Final Stage

2.3.1 Publication of Registry on the website (telemedregistry.in)

On complete evaluation of all applicants in a specific category, the registry will be populated on this website.

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