Legal, Ethical and Administrative Issues in Telemedicine and Electronic Consultations

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Rationale of Telemedicine
**Purpose of Telemedicine:**

- Outreach of quality health services to all parts of the country
- Faster, cheaper and more communicative medium for:
  - medical consultation,
  - follow-ups,
  - record keeping and
  - sharing of required information.
- Better healthcare by the consultations with experts of various fields

**Demarcation between tele-medicine and non-telemedicine—Not yet clear**

- **Telemedicine**: secure videoconferencing or store and forward technology to provide or support health care delivery

- **Non-Telemedicine**: telephone calls, emails, images transmitted via fax, and text messages without visualization of the patient. (In USA many states, such as California)

- ATA and a few states, such as Montana, include all of above in Telemedicine
Stakeholders

1. Patient
2. Doctors
3. Telemedicine Technicians
4. Paramedics
5. Administrators
6. Tele-service providers
7. Pharma industry
8. Insurance sector
9. Policy makers
10. Law implementing agencies
11. Law agencies
12. Liaisoning agencies
Separate entities, yet connected and inter-dependent

- Legal
- Ethical
- Administrative
Harnessing the Telemedicine and E-Health Media
For Patient: Privilege to expertise availability
Reimbursement

For Doctors: Credential for telemedicine treatment
Access to patient data
Standard protocols
Remuneration

For service providers and administrators:
Cross-border licensing
Instrument maintenance regulations
Remuneration
Ethical aspects
For Patient:  Privacy,  
Confidentiality,  
Right to avail required treatment - expertise  
Informed Consent

For Doctors:  Responsibility of treatment  
Data use for treatment and research  
Privacy, Confidentiality maintenance  
Commitment to meet the patient directly if needed  
Local condition adaptation

For service providers and administrator:  
Cross -border cultural, language differences consideration  
Responsibility for right transmission of conferencing,  
of data  
and storage

Consideration of Doctor’s: Expertise,  
Availability  
Willingness
Administrative aspects
• Clear terms and conditions pertaining to transmission, recording and storage of sessions and patient data
• Regular maintenance, up-gradation of instruments and soft wares
• Providing infrastructure and manpower to both ends of telemedicine network
• Capacity building
• Creating awareness among the masses and the health providers
• Conducting classes/training programmes for health-workers and technicians
• Standard protocols
• Charges and remunerations
• Cross-border licensing
The biggest risk in this study is just reading the consent form!
Knowledge to patient
Acceptance of virtual consultancy by patient
Written consent- i) for immediate use
  ii) future uncategorized use of information

Enlisting practitioners for Telemedicine - let the patient also choose his doctor

Privacy during tele-consultation of patient at both ends

Patient data confidentiality: during consultation, transfer and storage

Health Information in India is not integrated with technology as is in western countries.

Language, time-zone and cultural variation consideration while consulting.
Responsibility and Guidelines Related Issues

Accountability
Responsibility
Credentialing and Privileging
Professional negligence

Responsibility: Who holds the baby?: the patient, the referring doctor, the treating doctor, or all of them? Time to stop passing on the baton!!

Reliability and accuracy of digital images/data by telemedicine: Finally who is the decision maker?

Infrastructure building and maintenance

Standards and interoperability: no universal standard guidelines in India

Safety and privacy of the equipments, network and cloud storage

Cross border practice issues.
Law and regulations, administrative issues
- No clear, separate Telemedicine and electronic media-related health laws
- Lack of legalization of tele-consultation
- No enlistments of requirement of tele-consultant.
- Lack of provision for tele-consulting in Insurance sector.
- Infrastructure development
- Remuneration issues
- Reimbursement issues
- Area of jurisdiction is not clear.
Current Indian scenario of laws governing IT and information

Health related laws
- Drugs and Cosmetics Act, 1940
- Indian Medical Council Act 1956 and Indian Medical Degree Act 1916

But no separate Telemedicine laws
- National e-health Authority (NeHA)

Technology related laws
- Information Technology Act, 2000
- Article 21 of Indian Constitution
- The Privacy (Protection) Bill, 2013: section 3
- New Telecom Policy 1999 ("OSP Regulations")
International laws and regulations

• United Kingdom: Data Protection Act 1984;
  • Computer Misuse Act 1990
  • Data Protection Act 1998
  • British Medical Association (2005): guidelines for telemedicine

• European Union: Medical devices safety regulation by European Union Directive (93/42/EEC) and other rules

• USA: Health Insurance Portability and Accountability Act (HIPAA) of 1996
  Teleradiology is reimbursed nationally
  Medicare reimbursement in rural areas
  In some states non-telemed services reimbursement

• South Africa: “Telemedicine Code of Ethics and Professional Conduct”, Lists twelve, single-statement moral imperatives

• Australia: “Medico legal aspects for telehealth services for Victorian Public Health Services” written by Michael Regos, Partner, DLA Piper

• World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine adopted in 1999
...Future directives
Future directives...

• **Standardized Format:** Information to patients and consent form
  Option to opt out in future

• **Telemedicine courses:** Mandatory for all new medical students
  Refresher courses for medical practitioners

• **Responsibility of privacy, confidentiality and security of patient information, treatment:**
  By both the referring and consulting physicians

• **Qualifications and skills:** Expertise & eligibility of the doctor

• **Accreditation:** To the practicing telemedicine practicing doctors

• **Building confidence:** Of both the patient and distant doctor create bonding of mutual trust

• **Provision for remuneration:** For each player should be decided clearly
• Medical insurance:
  Clear outlines for tele-consulting insurance

• Cross-border issues:
  Should be governed by an international body

• Standards, Interoperability:
  Standards of the equipments and tele-services
  periodic checks and submission to regulatory authority

• Instrument and services: Liability, maintenance, safety

• Licensing: The authorization and capability of the service provider

• Telemedicine laws: IT laws for information storage and access

• E-health portal for regulations and grievances
  For social media such as apps, SMS, telephonic consultations
References


➤ Regos M. **Telehealth -Medico-legal aspects of telehealth services for Victorian public health services.** 2015. Partner DLA Piper Australia.


Thank you