Legal, Ethical and Administrative Issues in Telemedicine and Electronic Consultations

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Rationale of Telemedicine


It's from my Telemedicine Man!

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
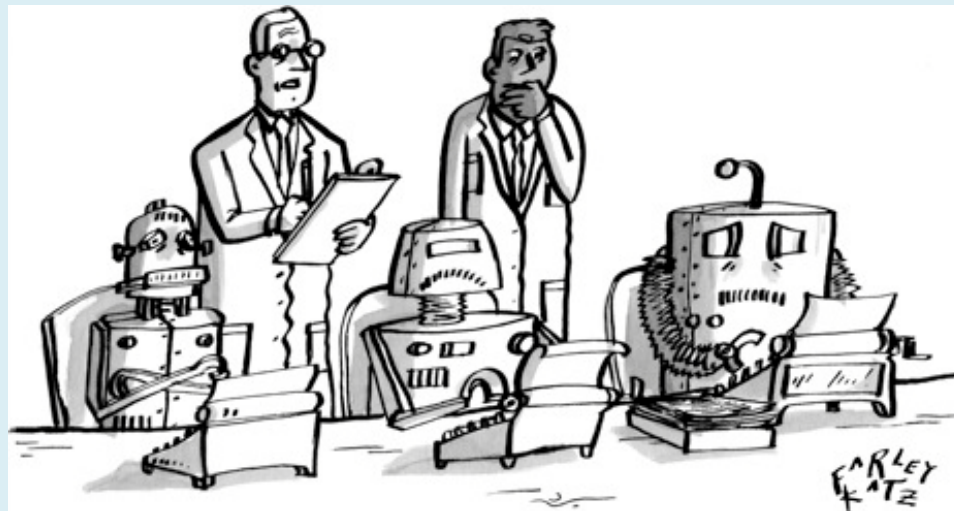
Stakeholders

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. Liasoning agencies
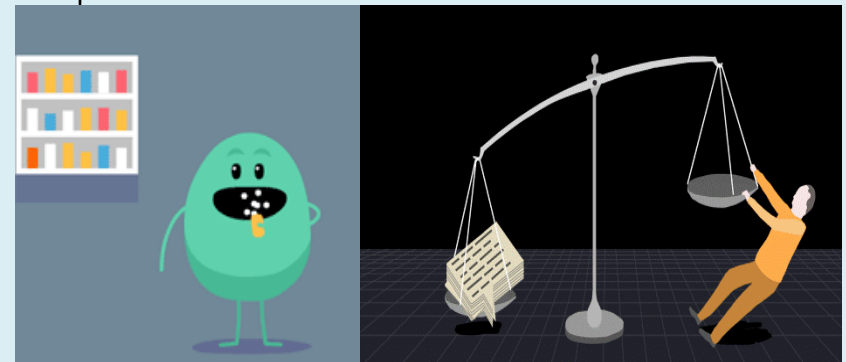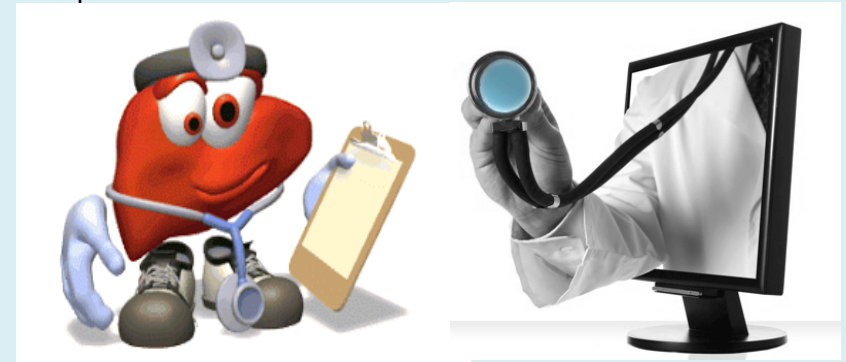
Separate entities , yet connected and inter-dependent

- Legal
- Ethical
- Administrative

Legal aspects

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
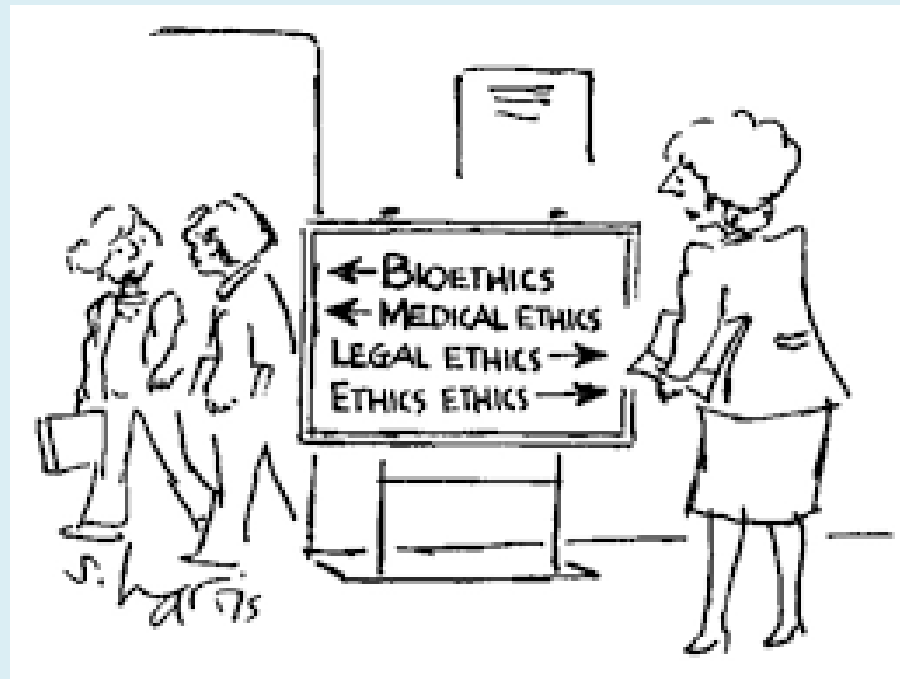
For Patient: Privacy,
Confidentiality,
Right to avail required treatment- expertise
Informed Consent

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
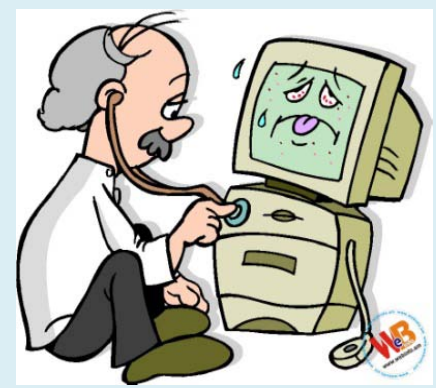
Information and Privacy Related Issues
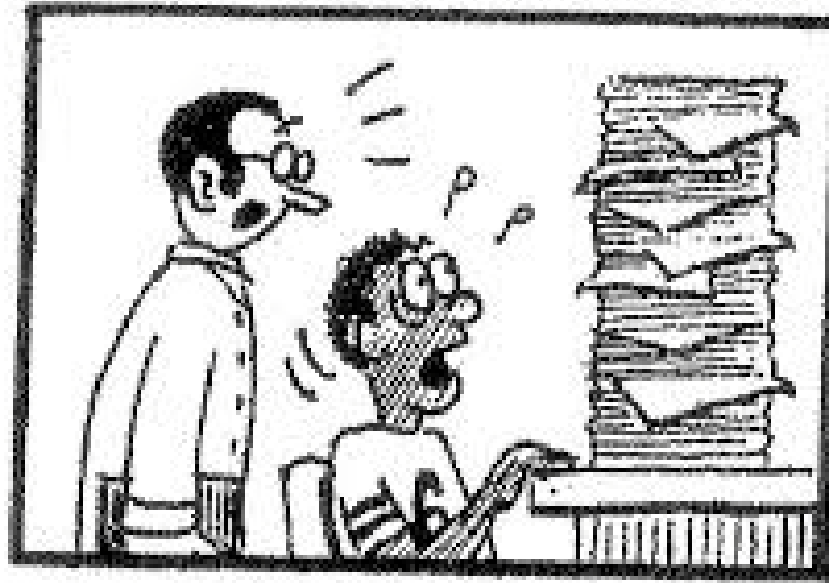
"The biggest risk in this study is just reading the consent form!"

➢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
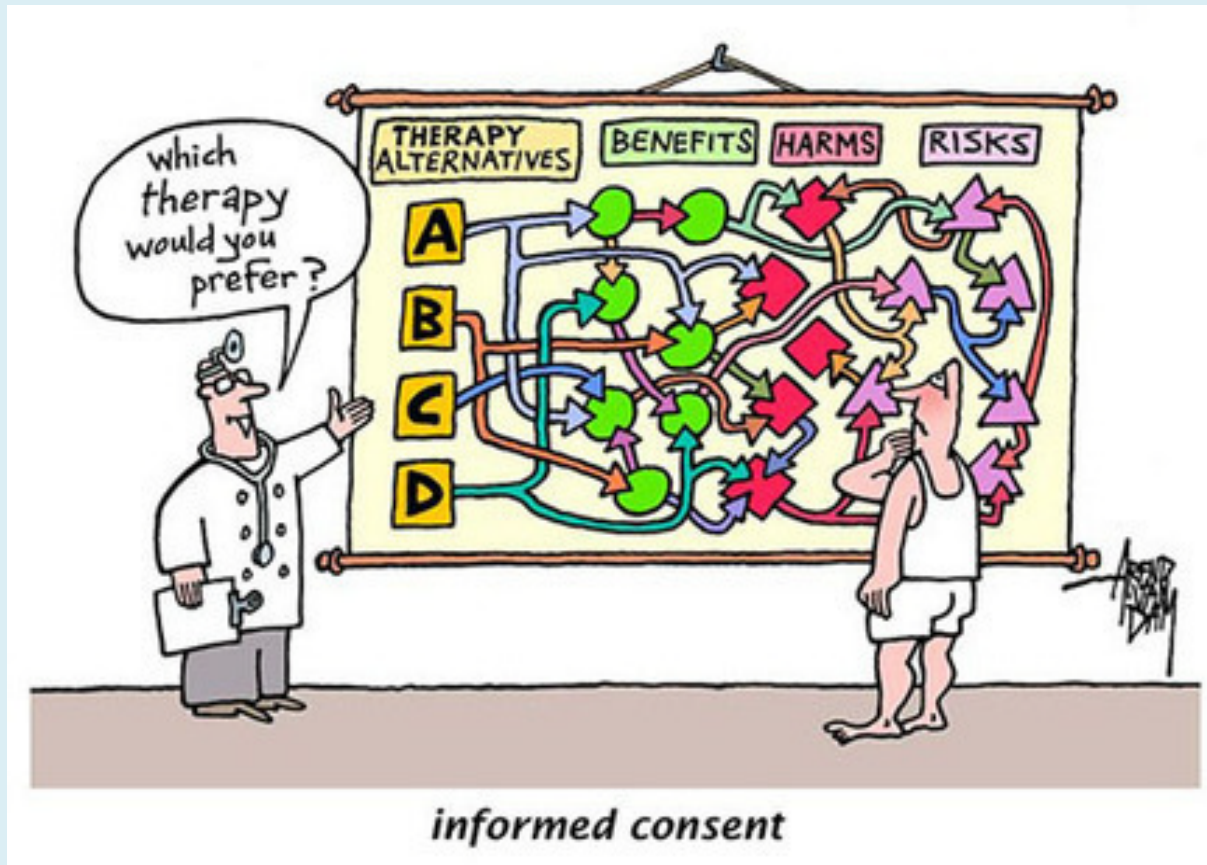
Accountability
Responsibility
Credentialing and Privileging

➢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

But no separateTelemedicine laws
National e-health Authority (NeHA)

Health related laws

Technology related laws

Drugs and Cosmetics Act, 1940

Information Technology Act, 2000

Indian Medical Council Act
1956 and Indian Medical Degree Act 1916

**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) of1996
  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
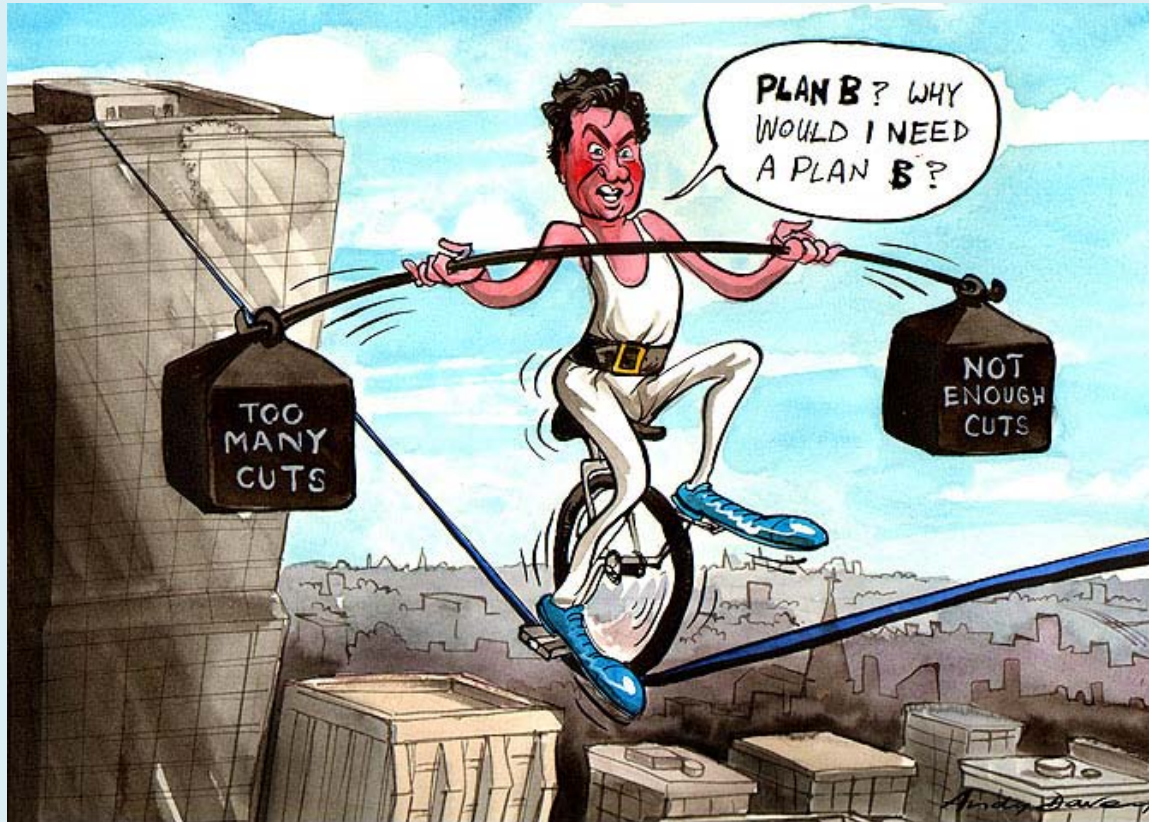
Future directives...

- **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

Future directives...

- **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- heath portal for regulations and grievances**
  For social media such as apps, SMS, telephonic consultations

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Thank you

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