

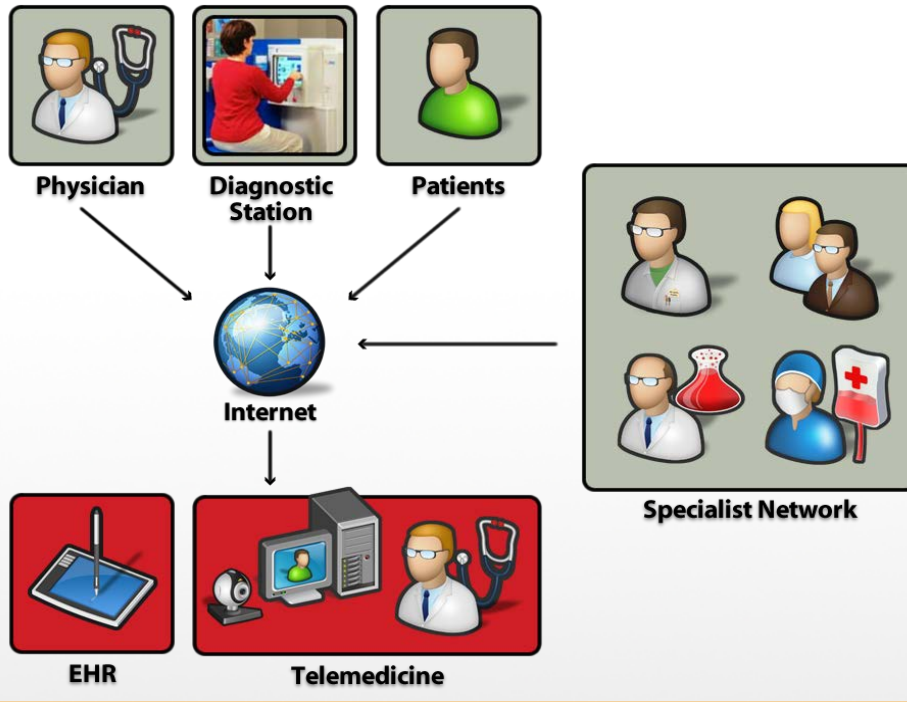
Medico-Legal Risks in Practicing Telehealth: Opportunities and Limitations



By Kar-wai Tong
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What is telehealth?

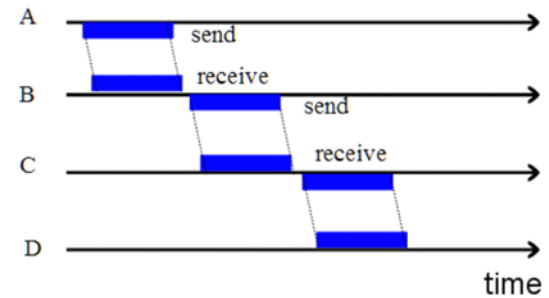
A Simplified Conceptual Framework



Examples



Store and forward



Impact of telehealth



- A means to improving inequitable access to health services in developing and developed countries, e.g. cities vs. rural areas
- Believed in general to reduce medical costs



Impact of telehealth

- For instance, in a systematic economic review (up to June 2009), the following results were found:
 - Cost-effective: Telehealth by real time video communication for home care and access to on-call hospital specialists
 - Mixed results: Telehealth in rural areas
 - Not cost-effective: local telehealth services between hospitals and primary care

Wade, V. A., Karnon, J., Elshaug, A. G., & Hiller, J. E. (2010). A systematic review of economic analyses of telehealth services using real time video communication. *BMC Health Services Research*, 10: 233. doi: 10.1186/1472-6963-10-233



Government Responses

- Positive responses in the use of telehealth from a number of jurisdictions, e.g. South Africa, Nigeria, Pakistan, England, Wales, the US, Russia, Australia, Japan, India, Taiwan, Hong Kong, and China, etc.



Government Responses

- For instance, England treated telemedicine as a national strategy to modernize the National Health Services in 1998.

NHS Executive. (1998). Information for Health: An Information Strategy for the Modern NHS 1998-2005. Retrieved January 12, 2017 from http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4014469.pdf



Government Responses

- For example, China also planned to actively develop telehealth (遠程醫療) in rural areas.

中共中央、國務院關於加大統籌城鄉發展力度進一步夯實農業農村發展基礎的若干意見 (2009年12月31日，中發 [2010] 1號), 第 14 段. 請參見：
<http://theory.people.com.cn/BIG5/41038/10898892.html>

(English translation: Central Committee of the Chinese Communist Party and State Council, Opinions of the CPC Central Committee and the State Council on Exerting Greater Efforts in the Overall Planning of Urban and Rural Development and Further Solidifying the Foundation for Agricultural and Rural Development (No. [2010] 1, 31 December 2009), para 14. Retrieved January 12, 2017 from
<http://theory.people.com.cn/BIG5/41038/10898892.html>)



Definitions

- Sood and colleagues reviewed a total of 104 ‘unique, legitimate and explanatory’ definitions of telemedicine
- They revealed that each of these definitions had highlighted one or more of the following four elements:
 - medical (e.g. health care delivery),
 - technological (e.g. communications technologies),
 - spatial (e.g. geographical separation of patients and doctors),
and
 - benefits (e.g. improved access of healthcare services).

Sood, S. et al. (2007). What is telemedicine?

A collection of 104 peer-reviewed perspectives and theoretical underpinnings.

Telemedicine and e-Health, 13(5), p. 574.



Definitions

- No universal definitions
 - Professional bodies, e.g. the American Telemedicine Association
 - Governmental, e.g. the Food & Drug Administration in the US
 - Statutory (national level), e.g. the Telemedicine Act 1997 in Malaysia
 - Statutory (federal level), e.g. the Oklahoma Telemedicine Act 1997 in the US
 - Regional political/economic entity, e.g. the European Union
 - International (WHO)



Definitions

- The American Telemedicine Association
 - Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status. Closely associated with telemedicine is the term “telehealth,” which is often used to encompass a broader definition of remote healthcare that does not always involve clinical services. ...

American Telemedicine Association. (n.d.). Telemedicine Glossary.

Retrieved January 12, 2017 from

<http://thesource.americantelemed.org/resources/telemedicine-glossary>



Definitions

- The Food and Drug Administration (US)
 - Telemedicine: The delivery and provision of health care and consultative services to individual patients and the transmission of information related to care, over distance, using telecommunications technologies. Telemedicine incorporates direct clinical, preventive, diagnostic, and therapeutic services and treatment; consultative and follow-up services; remote monitoring of patients; rehabilitative services; and patient education.

Reichertz, P. S., & Halpern, N. Y. L. (1997). FDA Regulation of telemedicine devices. Food and Drug Law Journal, 52, p. 517.



Definitions

- Telemedicine Act 1997 (Malaysia)
 - Telemedicine: the practice of medicine using audio, visual and data communications (section 2)
- Oklahoma Telemedicine Act 1997 (US)
 - Telemedicine: the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data, or exchange of medical education information by means of audio, video, or data communications (section 36-6802)
 - But a consultation through telephone or facsimile machine is expressly excluded from this statutory definition



Definitions

- World Health Organization
 - Telemedicine: the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interest of advancing the health of individuals and their communities.

World Health Organization, WHO Group Consultation on Health Telematics. (1998). A health telematics policy in support of WHO's Health-for-All Strategy for Global Health Development (WHO/DGO/98.1, 1998), p. 10.



Different Terminologies

- Also, contemporary semantic debates on the confused but overlapping terminologies:
 - telehealth
 - Cybermedicine
 - ehealth
 - mhealth (i.e. mobile health)



Applications

- Contemporary applications of telemedicine include but are not limited to
 - Tele-surgery and robotics
 - Tele-radiology
 - Tele-pathology
 - Tele-psychiatry
 - Tele-dermatology
 - Tele-ambulance service
 - Transmission and remote monitoring of patient data
 - Video conferencing, and
 - Tele-health education



Applications

- Mobile telemedicine
- An example: the Mobile Health for Development programme set up by the United Nations Foundation in collaboration with a mobile device company to collect health data in Africa through the use of mobile devices.

United Nations, 'United Nations Office for Partnerships - Report of the Secretary-General' Document A/65/347 [16] (The Sixty-fifth General Assembly, New York, United States, 14 September – 30 December 2010)



Legal Barriers to Its Development

- Legal uncertainty
- Medical malpractice insurance
- Health data privacy
- Protectionism → Regulatory framework and technical standards, e.g. licensure & credentialing requirements
- Reimbursement and taxation
- Jurisdiction & choice of law



Legal Issues in Telehealth

Categories

a) Traditional
medico-legal
issues not
exclusive to the
digital
environment

Examples

- (i) Clinical negligence
- (ii) Licensure and credentialing
- (iii) Medical records and privacy data protection
- (iv) Fraud and abuse
- (v) Intellectual property
- (vi) Antitrust
- (vii) Sales of drugs, medical device, and dietary supplements



Legal Issues in Telehealth

Categories

Examples

b) Conflict of laws in cross-border telemedicine

Jurisdiction of alleged medical events involved in cross-border practices of telehealth



Legal Issues in Telehealth

Categories

c) Issues unique to the practice of telemedicine

Examples

- (i) Electronic signature
- (ii) Taxation and reimbursement of telehealth services
- (iii) Self-regulation for telecommunication network service providers



Legal Issues in Telehealth

- Some jurisdictions have taken a more proactive approach:
 - Germany passed the Data Protection Act in 1997 and other relevant law in subsequent years.
 - Malaysia enacted law to regulate the practices of telehealth in 1997.



Legal Issues in Telehealth

- Some jurisdictions have taken a more proactive approach:
 - In the United States, the federal government developed nation-wide telehealth strategies and introduced more than 20 legislations in the period of 1997-1999.
 - In Oregon, for example, it made enactment in the late 1990s to provide new licences for out-of-state doctors treating patients through telehealth practices in that state.
 - In California, the Telemedicine Development Act of 1996 was updated and replaced with a new Telehealth Advancement Act in 2011.



Legal Issues in Telehealth

- Other societies may not have paid sufficient legal attention to this sophisticated development.
 - Hong Kong is no exception.



Opportunities in Hong Kong

- Capability of Hong Kong
 - “In places where teleradiology has been tried, the evidence to date has been largely qualitative, but the first formal prospective research trial in the world is now underway in Hong Kong – another example of Hong Kong telemedicine **leading the world.**”

Wootton, R. (1998). Telemedicine in Hong Kong.
Hong Kong Medical Journal, 4(3), p. 260



Opportunities in Hong Kong

- Established centres at tertiary educational institutes, for instance,
 - The Centre for Telehealth and Telecare, Hong Kong Polytechnic University
 - The Telemedicine Centre, Faculty of Medicine, the Chinese University of Hong Kong



Opportunities in Hong Kong

- Basic infrastructure in place by the Hospital Authority to facilitate telehealth
 - A PPP initiative, namely the Public Private Interface – Electronic Patient Record sharing Pilot Project (PPI-ePR), since 2006.
 - Launch of the Electronic Health Record Sharing System (eHRSS) since March 2016 to provide a platform for public and private healthcare providers to share electronic health records.



Opportunities in Hong Kong

- Policy support by the Hong Kong Government
 - “**Innovation and technology** can improve our everyday life in a wide range of aspects, including communication, transportation, **healthcare**, education, the environment, public order, consumer spending and food safety. The Government will set aside \$500 million to set up an Innovation and Technology Fund for Better Living to finance projects that make use of innovation and technology to improve our daily life.” (Policy Address 2016, Hong Kong, para 87)



Limitations in Hong Kong

- Legal considerations not openly and/or sufficiently addressed
 - Legal barriers
 - Legal risks
 - Lack of public education in this aspect
 - Cross-border telemedicine practices in-between Hong Kong and China, for example,
 - <http://www.scmp.com/comment/letters/article/1822762/telemedicine-would-help-hong-kong-elderly-mainland-get-diagnosis>

Cross-border Telemedicine Practice in-between Hong Kong and China

- Some legal issues
 - Different legal approaches in “clinical negligence” cases or “medical accidents” in common-law and civil-law systems respectively in Hong Kong and China
 - Licensure and credentialing recognition of healthcare professionals in Hong Kong and China
 - Choice of law – Hong Kong law? PRC law?
 - Increased risks of clinical negligence, e.g.
 - Use of languages – misunderstanding arising from dialects
 - International drug name confusion, e.g. “Flomax”
 - In the US, a drug to treat enlarged prostates
 - In Italy, an anti-inflammatory drug
 - Value of damages



A Recent Incident

- The death incident of Wei Zexi (魏則西) in 2016 (retrieved January 12, 2017)
 - See, for example,
 - <https://mitpress.mit.edu/blog/cancer-and-internet-strange-sad-case-wei-zexi>
 - <https://www.theguardian.com/world/2016/may/03/baidu-investigated-in-china-after-death-of-student-who-sought-cancer-cure-on-internet>
 - In Chinese:
http://www.bbc.com/zhongwen/trad/china/2016/05/160503_ana_weizexi_responsibility



A Concluding Remark

- To allow a sustainable development in practicing telehealth and in lack of relevant local law, it is important for practitioners and patients in Hong Kong to have basic understanding on its inherent potential medico-legal risks.

Thank You!



Q & A